BRUNEI DARUSSALAM MEDICINES CONTROL AUTHORITY
MINISTRY OF HEALTH, BRUNEI DARUSSALAM

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

Product Registration Number	Product Name	Indication
BRU08010005P	Pharmaniaga Ciprofloxacin Tablet 500mg	Consideration should be given to official guidance on the appropriate use of antibacterial agents. Uncomplicated and complicated infections caused by ciprofloxacin-sensitive pathogens: Infections of the - respiratory tract. Ciprofloxacin can be regarded as an advisable treatment for pneumonias caused by *Klebsiella, Enterobacter, Proteus, Pseudomonas, Haemophilus, Branhamella, Legionella* , and *Staphylococcus* . - Middle ear (otitis media), of the paranasal sinuses (sinusitis), especially if these are caused by Gram-negative organisms including *Pseudomonas* or by *Staphylococcus* . - Eyes - Kidneys and / or urinary tract. - Genital organs, including adnexitis, gonorrhoea and prostatitis. - Abdominal cavity (e.g. bacterial infections of the gastrointestinal tract, biliary tract, peritonitis). - Skin and soft tissue - Bones and joints - Septicaemia* - Ciprofloxacin is also indicated for prophylaxis against infection in elective upper gastro-intestinal surgery and endoscopic procedures where there is an increased risk of infection. - Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or in state of neutropenia) - Selective intestinal decontamination in immunosuppressed patients * Pharmaniaga Ciprofloxacin should be only used: • When *Pseudomonas* is considered and the patient is allergic to antipseudomonal penicillins/cephalosporins. • For resistant organisms with no other alternative antibiotics available.
BRU08030023P	Augmentin Tablet 625mg	*AUGMENTIN* is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other beta-lactam antibiotics. *AUGMENTIN* should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data. *AUGMENTIN* oral presentations for twice daily dosing, are indicated for short-term treatment of bacterial infections at the following sites: *Upper respiratory tract infections (including ENT)* e.g. recurrent tonsillitis, sinusitis, otitis media. *Lower respiratory tract infections* e.g. acute exacerbation of chronic obstructive pulmonary disease (AECOPD)/acute exacerbation of chronic bronchitis (AECB), lobar and bronchopneumonia. *Genito-urinary tract infections* e.g. cystitis, urethritis, pyelonephritis. *Skin and soft tissue infections* , e.g. boils, abscesses, cellulitis, wound infections. *Bone and joint infections* e.g. osteomyelitis. *Dental infections* e.g. dentoalveolar abscess *Other infections* e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis. Susceptibility to *AUGMENTIN* will vary with geography and time (see *Pharmacological Properties, Pharmacodynamics* for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.

BRU08030024P	Augmentin Suspension 228mg/5ml	AUGMENTIN should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data. AUGMENTIN suspension (228mg/5ml and 457mg/5ml), for twice daily oral dosing, is indicated for short term treatment of bacterial infections at the following sites when amoxicillin resistant beta-lactamase producing strains are suspected as the cause. In other situations, amoxicillin alone should be considered. Upper respiratory tract infections (including ENT) e.g. recurrent tonsillitis, sinusitis, otitis media. Lower respiratory tract infections e.g. acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. Urinary tract infections e.g. cystitis, urethritis, pyelonephritis Skin and soft tissue infections e.g. cellulitis, animal bites. Dental infections e.g. severe dental abscess with spreading cellulitis. Susceptibility to AUGMENTIN will vary with geography and time (see Pharmacological Properties, Pharmacodynamics for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary. Mixed infections caused by amoxicillin-susceptible organisms in conjunction with AUGMENTIN susceptible beta-lactamase-producing organisms may be treated with AUGMENTIN suspension 228mg/5ml and 457mg/5ml. These infections should not require the addition of another antibiotic resistant to beta-lactamases.
BRU08030025P	Augmentin Suspension 457mg/5ml	AUGMENTIN should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data. AUGMENTIN suspension (228mg/5ml and 457mg/5ml), for twice daily oral dosing, is indicated for short term treatment of bacterial infections at the following sites when amoxicillin resistant beta-lactamase producing strains are suspected as the cause. In other situations, amoxicillin alone should be considered. Upper respiratory tract infections (including ENT) e.g. recurrent tonsillitis, sinusitis, otitis media. Lower respiratory tract infections e.g. acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. Urinary tract infections e.g. cystitis, urethritis, pyelonephritis Skin and soft tissue infections e.g. cellulitis, animal bites. Dental infections e.g. severe dental abscess with spreading cellulitis. Susceptibility to AUGMENTIN will vary with geography and time (see Pharmacological Properties, Pharmacodynamics for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary. Mixed infections caused by amoxicillin-susceptible organisms in conjunction with AUGMENTIN susceptible beta-lactamase-producing organisms may be treated with AUGMENTIN suspension 228mg/5ml and 457mg/5ml. These infections should not require the addition of another antibiotic resistant to beta-lactamases.

BRU08030034P	Zinacef Injection 750mg	*ZINACEF* is a bactericidal cephalosporin antibiotic which is resistant to most beta-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for the treatment of infections before the infecting organism has been identified or when caused by sensitive bacteria. Susceptibility to *ZINACEF* will vary with geography and time and local susceptibility data should be consulted where available (*see Pharmacological properties, Pharmacodynamics*). Indications include: – respiratory tract infections for example, acute exacerbation of chronic bronchitis, infected bronchiectasis, bacterial pneumonia, lung abscess and post-operative chest infections – ear, nose and throat infections for example, sinusitis, tonsillitis, pharyngitis and otitis media – urinary tract infections for example, acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria – soft-tissue infections for example, cellulitis, erysipelas and wound infections – bone and joint infections for example, osteomyelitis and septic arthritis – obstetric and gynaecological infections, pelvic inflammatory diseases – gonorrhoea particularly when penicillin is unsuitable – other infections including septicaemia, meningitis and peritonitis – prophylaxis against infection in abdominal, pelvic, orthopaedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk frominfection. Usually *ZINACEF* will be effective alone, but when appropriate it may be used in combination with an aminoglycoside antibiotic, or in conjunction with metronidazole (orally or by suppository or injection), especially for prophylaxis in colonic or gynaecological surgery. Where appropriate *ZINACEF* is effective when used prior to oral therapy with *ZINNAT* (cefuroxime axetil) in the treatment of pneumonia and acute exacerbations of chronic bronchitis.
BRU08030037P	Zinnat Tablet 250mg	*ZINNAT* is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to most β (beta)-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for the treatment of infections caused by susceptible bacteria. Susceptibility to *ZINNAT* will vary with geography and time, and it should be used in accordance with local official antibiotic prescribing guidelines and local susceptibility data. **Indications include**: – upper respiratory tract infections for example, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis – lower respiratory tract infections for example, pneumonia, acute exacerbations of chronic obstructive pulmonary disease – genito-urinary tract infections for example, pyelonephritis, cystitis and urethritis – skin and soft tissue infections for example, furunculosis, pyoderma and impetigo – gonorrhoea, acute uncomplicated gonococcal urethritis, and cervicitis Cefuroxime is also available as the sodium salt (*ZINACEF*) for parenteral administration. This permits the use of sequential therapy with the same antibiotic, when a change from parenteral to oral therapy is clinically indicated. Where appropriate *ZINNAT* is effective when used following initial parenteral *ZINACEF* (cefuroxime sodium) in the treatment of pneumonia and acute exacerbations of chronic obstructive pulmonary disease.

BRU08040052P	Becarin Cream 2%	Treatment of fungal infections of skin and nails including cutaneous candidiasis, tinea corporis, tinea cruris, tinea pedis and tinea versicolor (pityriasis versicolor).
BRU08050060P	Unocef Injection 500mg (Vial)	Ceftriaxone is indicated for the treatment of the following infections when caused by pathogens sensitive to Ceftriaxone, e.g.: **Sepsis;** **Meningitis;** **Disseminated Lyme borreliosis** (early and late stages of the disease); **Abdominal infections** (peritonitis, infections of the biliary and gastrointestinal tracts); **Infections of the bones, joints, soft tissue, skin and of wounds;** **Infections in patients with impaired defence mechanisms;** **Renal and urinary tract infections;** **Respiratory tract infections**, particularly pneumonia, and ear, nose and throat infections; **Genital infections**, including gonorrhoea; And **perioperative prophylaxis** of infections.
BRU08050061P	Unocef Injection 1000mg (Vial)	Ceftriaxone is indicated for the treatment of the following infections when caused by pathogens sensitive to Ceftriaxone, e.g.: **Sepsis;** **Meningitis;** **Disseminated Lyme borreliosis** (early and late stages of the disease); **Abdominal infections** (peritonitis, infections of the biliary and gastrointestinal tracts); **Infections of the bones, joints, soft tissue, skin and of wounds;** **Infections in patients with impaired defence mechanisms;** **Renal and urinary tract infections;** **Respiratory tract infections**, particularly pneumonia, and ear, nose and throat infections; **Genital infections**, including gonorrhoea; And **perioperative prophylaxis** of infections.
BRU08050068P	Krisovin Tablet 500	Griseofulvin is administered by mouth in the treatment of infections caused by various species of Epidermophyton, Microsporum, and Trichophyton. It is generally given for such infections that involve the scalp, hair, nails and skin and which do not respond to topical treatment such as Tinea barbae, Tinea capitis, Tinea corporis, Tinea cruris, Tinea Pedis and Tinea unguium. Infections of the soles of the feet, the palms of the hands and toenails respond slowly.
BRU08050070P	Betacin Eye Ear Drop	Betacin eye/ear drops are indicated in the treatment of the following conditions: - **Eye**: Corticosteroid-responsive allergic and inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, corneal injuries, superficial punctuate keratitis, vernal keratoconjuctivitis and as an adjunct in the treatment of superficial ocular infections caused by susceptible organisms. Betacin eye/ear drops are indicated in the tropical treatment of bacterial blepharitis, blepharoconjunctivitis, bacterial conjunctivitis, bacterial keratitis and bacterial keratoconjunctivitis. **Ear**: Allergic otitis externa, infective otitis and other corticosteroid-responsive disorders of the external auditory meatus. Betacin eye/ear drops are indicated in the treatment of external ear canal infections caused by susceptible organisms.

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BRU08060075P	Genta-Dex Eye Drops	Genta-Dex eye drops is indicated for the treatment of allergic and inflammatory conditions of the eye where there is superficial bacterial infection of the conjunctiva, cornea (without epithelial defect) and margin of eye lid. This includes conjunctivitis, keratitis and keratoconjunctivitis, corneal ulcers, blepharitis and blepharoconjunctivitis, acute meibomianitis and dacryocystitis. **N/B:** "To ensure that fungal infection has been eliminated before use of preparation."
BRU08060077P	Aecoras Ointment	For topical application in the treatment of fungal eczema, tinea pedis (Athlete's foot), tinea barbae, tinea cruris, tinea capitis, tinea imbricate, tinea corporis, pityriasis versicolor, fungal nappy rash and intertrigo caused by Trichophyton rubrum, Trichophyton mentagrophytes and Epidermophyton floccosum, in the treatment of cutaneous canidiasis and tinea versicolor.
BRU08060083P	Eryson Granules 200	Bronchitis, enteritis, venereal diseases, diphtheria, Legionella infections, pertussis, pneumonia, sinusitis. Prophylaxis of surgical infections, endocarditis, pharyngitis, perinatal streptococcal infections, rheumatic fever. Alternative to tetracyclines in Lyme disease, chlamydial & rickettsial infections, severe acne.
BRU08060084P	Eryson Granules 400	Bronchitis, enteritis, venereal diseases, diphtheria, Legionella infections, pertussis, pneumonia, sinusitis. Prophylaxis of surgical infections, endocarditis, pharyngitis, perinatal streptococcal infections, rheumatic fever. Alternative to tetracyclines in Lyme disease, chlamydial & rickettsial infections, severe acne.
BRU08060085P	Neo Cream 0.5% (w/w)	For skin infections, infected wounds and burns due to susceptible organisms. It is also used in surgical prophylaxis.
BRU08070090P	Zinnat Suspension 125mg/5ml	ZINNAT is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to most β (beta)-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for the treatment of infections caused by susceptible bacteria. Susceptibility to ZINNAT will vary with geography and time, and it should be used in accordance with local official antibiotic prescribing guidelines and local susceptibility data. Indications include: – upper respiratory tract infections for example, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis – lower respiratory tract infections for example, pneumonia, acute exacerbations of chronic pulmonary disease – genito-urinary tract infections for example, pyelonephritis, cystitis and urethritis – skin and soft tissue infections for example, furunculosis, pyoderma and impetigo – gonorrhoea, acute uncomplicated gonococcal urethritis, and cervicitis
BRU08070094P	Ecocort Cream	Ecocort cream in all its dosages as indicated for the treatment of dermatomycoses complicated by inflammatory and/or pruritic manifestations of skin disorders.
BRU08120169P	Oxacil Capsule 250	Cloxacillin is used in the treatment of infections due to staphylococci-resistant to benzylpenicillin; it is also used for mixed streptococcal and staphylococcal infections when the staphylococcal are penicillin resistant. The following infections are indicated: Respiratory tract infection, Ear, Nose and Throat infection, Infected wounds, Septicaemia, Endocarditis, Staphylococcal enterocolitis. Osteomylitis. CLOXACILLIN is sometimes given with ampicillin for infection due to Beta-lactamase producing Gram-negative organisms since it may inhibit the destruction of ampicillin.

BRU08120180P	Zithromax Film-Coated Tablet 250mg	Azithromycin Oral Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx; however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, azithromycin is indicated for the treatment of uncomplicated genital infections due to Chlamydia trachomatis. It is also indicated for the treatment of chancroid due to Haemophilus ducreyi and uncomplicated genital infections due to non-multiresistant Neisseria gonorrhoeae; concurrent infection with Treponema pallidum should be excluded.
BRU09010186P	Plavix Tablet 75mg	***Secondary prevention of atherothrombotic events*** Clopidogrel is indicated in: • Adult patients suffering from myocardial infarction (from a few days until less than 35 days), ischemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease. • Adult patients suffering from acute coronary syndrome: − Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA). − ST segment elevation acute myocardial infarction, in combination with ASA in medically treated patients eligible for thrombolytic therapy. ***In patients with moderate to high-risk Transient Ischemic Attack (TIA) or minor Ischemic Stroke (IS)*** Clopidogrel in combination with ASA is indicated in: - Adult patients with moderate to high-risk TIA (ABCD2[1] score ≥4) or minor IS (NIHSS[2] ≤3) within 24 hours of either the TIA or IS event. ***Prevention of atherothrombotic and thromboembolic events in atrial fibrillation*** In adult patients with atrial fibrillation who have at least one risk factor for vascular events, are not suitable for treatment with Vitamin K antagonists (VKA) and who have a low bleeding risk, clopidogrel is indicated in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke.
BRU09010187P	Symbicort Turbuhaler 160/4.5mcg Dose	Asthma Symbicort Turbuhaler is indicated for the treatment of asthma, to achieve overall asthma control, including the relief of symptoms and the reduction of the risk of exacerbations. Note: Symbicort (80/4.5 micrograms/inhalation) is not appropriate in patients with severe asthma. Chronic Obstructive Pulmonary Disease (COPD) Symbicort Turbuhaler is indicated in adults, aged 18 years and older, for the symptomatic treatment of patients with COPD with (FEV1 < 70% predicted normal) (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy.

BRU09020207P	Beprosalic Ointment	For the relief of the inflammatory manifestation of hyperkeratotic and dry corticosteroid-responsive dermatoses such as: psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.
BRU09020209P	Cloderm Scalp Application	Psoriasis and recalcitrant eczemas of the scalp. Clobetasol is a highly-active topical corticosteroid which is indicated for use in short courses for conditions which do not respond satisfactorily to less active steroids.
BRU09040232P0.5gV; BRU09040232P0.5gS	Stamaril Vaccine	STAMARIL is indicated for active immunization against yellow fever in persons: • travelling to, passing through or living in an area where there is a persisting or periodical risk of yellow fever transmission • travelling to any country that requires an International Certificate of Vaccination for entry (which may or may not depend on the previous itinerary), • handling potentially infectious materials (e.g. laboratory personnel). See sections 4.2, 4.3 and 4.4 regarding the minimum age for vaccination of children under special circumstances and guidance for vaccination of other specific patient populations. See the regular updates related to obligations and recommendations for yellow fever vaccination on the dedicated site of the World Health Organisation (WHO) or on the official sites of local health authorities. In order to comply with vaccine regulations and to be officially recognised, yellow fever vaccines must be administered by a qualified and trained health professional in an approved WHO vaccination centre and registered on an International Certificate of Vaccination. The validity period of this Certificate is established according to International Health Regulations (IHR) recommendations, and starts 10 days after primary vaccination and immediately after revaccination.

		A. FOR INTRAMUSCULAR ADMINISTRATION When oral therapy is not feasible and the strength, dosage form, and route of administration of the drug reasonably lend the preparation to the treatment of the condition, the intramuscular use of DEPO-MEDROL is indicated as follows: 1. ENDOCRINE DISORDERS Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance). Acute adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice, mineralocorticoid supplementation may be necessary, particularly when synthetic analogs are used). •Congenital adrenal hyperplasia •Hypercalcemia associated with cancer •Nonsuppurative thyroiditis 2. RHEUMATIC DISORDERS As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: •Post-traumatic osteoarthritis •Epicondylitis •Synovitis of osteoarthritis •Acute nonspecific tenosynovitis •Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy) •Psoriatic arthritis •Acute gouty arthritis •Ankylosing spondylitis •Acute and subacute bursitis

BRU09040237P	Depo-Medrol Sterile Aqueous Suspension 40mg/ml	3. COLLAGEN DISEASES During an exacerbation or as maintenance therapy in selected cases of: •Systemic lupus erythematosus •Systemic dermatomyositis (polymyositis) •Acute rheumatic carditis 4. DERMATOLOGIC DISEASES •Pemphigus •Bullous dermatitis herpetiformis •Severe erythema multiforme (Stevens-Johnson syndrome) •Exfoliative dermatitis •Mycosis fungoides 5. ALLERGIC STATES Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in: •Chronic asthmatic respiratory disorders •Drug hypersensitivity reactions •Contact dermatitis •Urticarial transfusion reactions •Atopic dermatitis •Acute non-infectious laryngeal edema (epinephrine is the drug of first choice) •Serum sickness 6. OPHTHALMIC DISEASES Severe acute and chronic allergic and inflammatory processes involving the eye, such as: •Herpes zoster ophthalmicus •Iritis, iridocyclitis •Chorioretinitis •Diffuse posterior uveitis •Optic neuritis

		7. GASTROINTESTINAL DISEASES To tide the patient over a critical period of the disease in: •Ulcerative colitis (systemic therapy) •Crohn's disease (systemic therapy) 8. RESPIRATORY DISEASES •Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate anti-tuberculous chemotherapy •Symptomatic sarcoidosis •Berylliosis •Loeffler's syndrome not manageable by other means •Aspiration pneumonitis 9. HEMATOLOGICAL DISORDERS •Acquired (autoimmune) hemolytic anemia •Erythroblastopenia (RBC anemia) •Secondary thrombocytopenia in adults •Congenital (erythroid) hypoplastic anemia 10. NEOPLASTIC DISEASES For palliative management of: •Leukemias and lymphomas in adults •Acute leukemia in children 11. EDEMATOUS STATES To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus. 12. MISCELLANEOUS •Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate anti-tuberculous chemotherapy •Trichinosis with neurologic or myocardial involvement

		B. FOR INTRA-SYNOVIAL OR SOFT TISSUE ADMINISTRATION (including peri-articular and intrabursal) (see section 4.4 Special warnings and precautions for use) DEPO-MEDROL is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: •Synovitis of osteoarthritis •Epicondylitis •Rheumatoid arthritis •Acute and subacute bursitis •Post-traumatic osteoarthritis •Acute gouty arthritis C. FOR INTRALESIONAL ADMINISTRATION DEPO-MEDROL is indicated for intralesional use in the following conditions: •Keloids •Localized hypertrophic, infiltrated, inflammatory lesions of: Lichen planus, psoriatic plaques, granuloma annulare and lichen simplex chronicus (circumscribed neurodermatitis) •Discoid lupus erythematosus •Alopecia areata DEPO-MEDROL may also be useful in cystic tumors or an aponeurosis or tendon (ganglia). D. FOR INTRARECTAL INSTILLATION •Ulcerative colitis
BRU09040245NP	YSP Bisacodyl Suppositories	i) Constipation. ii) Bowel preparation for radiological procedures and surgery.

BRU09070280P	Zyloric® 100mg Tablet	Allopurinol is indicated for reducing urate/uric acid formation in conditions where urate/uric acid deposition has already occurred (e.g. gouty arthritis, skin tophi, nephrolithiasis) or is a predictable clinical risk (e.g. treatment of malignancy potentially leading to acute uric acid nephropathy). The main clinical conditions where urate/uric acid deposition may occur are: • idiopathic gout; • uric acid lithiasis; • acute uric acid nephropathy; • neoplastic disease and myeloproliferative disease with high cell turnover rates, in which high urate levels occur either spontaneously, or after cytotoxic therapy; • certain enzyme disorders which lead to overproduction of urate, for example; − Hypoxanthine guanine phosphoribosyltransferase including Lesch-Nyhan syndrome; − glucose-6-phosphatase including glycogen storage disease; − phosphoribosylpyrophosphate synthetase; − phosphoribosylpyrophosphate amidotransferase; − adenine phosphoribosyltransferase; Allopurinol is indicated for the management of 2, 8-dihydroxyadenine (2, 8-DHA) renal stones related to deficient activity of adenine phosphoribosyltransferase. Allopurinol is indicated for the management of recurrent mixed calcium oxalate renal stones in the presence of hyperuricosuria, when fluid, dietary and similar measures have failed.
BRU09090327P	Metalyse Injection 10,000 Units	METALYSE® is indicated for the thrombolytic treatment of acute myocardial infarction (AMI).
BRU09100337P	Zoloft Tablet 50mg	Sertraline is indicated for the treatment of symptoms of depression, including depression accompanied by symptoms of anxiety, in patients with or without a history of mania. Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of depression or recurrence of further depressive episodes. Sertraline is indicated for the treatment of obsessive-compulsive disorder (OCD). Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of OCD. Sertraline is indicated for the treatment of panic disorder, with or without agoraphobia. Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of panic disorder. Sertraline is indicated for the treatment of post-traumatic stress disorder (PTSD). Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of PTSD. Sertraline is indicated for the treatment of social phobia (social anxiety disorder). Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of social phobia.

BRU09100345P	Lipitor™ 40mg Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum TG levels (Fredrickson Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. Prevention of Cardiovascular Disease In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD) such as age, smoking, hypertension, low HDL-C, or a family history of early CHD, LIPITOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, LIPITOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina *Pediatric Patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: - LDL-C remains ≥190 mg/dL or - LDL-C remains ≥160 mg/dL and • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient

BRU09110354P	Lipitor™ 10mg Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum TG levels (Fredrickson Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD) such as age, smoking, hypertension, low HDL-C, or a family history of early CHD, LIPITOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, LIPITOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina *Pediatric Patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: - LDL-C remains ≥190 mg/dL or - LDL-C remains ≥160 mg/dL and • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient

BRU09120367P	Dilantin 100mg Capsule	Clinical evidence indicates phenytoin is effective in controlling epilepsy, particularly of the generalised tonic-clonic type (grand mal) and psychomotor seizures. It will prevent or greatly decrease the incidence and severity of convulsive seizures in a substantial percentage of cases, and patients exhibit little tendency to become resistant to treatment.
BRU09120378P	Chloramine Tablet 4mg	Chlorpheniramine is used for the prophylactic and symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods and sneezing and rhinorrhoea associated with the common cold. It is also indicated for the symptomatic relief of pruritus associated with allergic reactions and of mild, uncomplicated allergic skin manifestations of urticarial and angioedema, in dermatographism, and in urticaria associated with transfusions. It is used as adjunctive therapy to epinephrine and other standard measures for anaphylactic reactions after the acute manifestations have been controlled, and to ameliorate the allergic reactions to blood or plasma.
BRU10010384P	Zyloric 300mg Tablet	Allopurinol is indicated for reducing urate/uric acid formation in conditions where urate/uric acid deposition has already occurred (e.g. gouty arthritis, skin tophi, nephrolithiasis) or is a predictable clinical risk (e.g. treatment of malignancy potentially leading to acute uric acid nephropathy). The main clinical conditions where urate/uric acid deposition may occur are: • idiopathic gout; • uric acid lithiasis; • acute uric acid nephropathy; • neoplastic disease and myeloproliferative disease with high cell turnover rates, in which high urate levels occur either spontaneously, or after cytotoxic therapy; • certain enzyme disorders which lead to overproduction of urate, for example; − Hypoxanthine guanine phosphoribosyltransferase including Lesch-Nyhan syndrome; − glucose-6-phosphatase including glycogen storage disease; − phosphoribosylpyrophosphate synthetase; − phosphoribosylpyrophosphate amidotransferase; − adenine phosphoribosyltransferase; Allopurinol is indicated for the management of 2, 8-dihydroxyadenine (2, 8-DHA) renal stones related to deficient activity of adenine phosphoribosyltransferase. Allopurinol is indicated for the management of recurrent mixed calcium oxalate renal stones in the presence of hyperuricosuria, when fluid, dietary and similar measures have failed.

BRU10010393P	Chloramine 4 Syrup	Chlorpheniramine is used for the prophylactic and symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods and sneezing and rhinorrhoea associated with the common cold. It is also indicated for the symptomatic relief of pruritus associated with allergic reactions and of mild, uncomplicated allergic skin manifestations of urticarial and angioedema, in dermatographism, and in urticaria associated with transfusions. It is used as adjunctive therapy to epinephrine and other standard measures for anaphylactic reactions after the acute manifestations have been controlled, and to ameliorate the allergic reactions to blood or plasma.
BRU10010399P	Seretide Accuhaler 50/500	**Asthma** *SERETIDE* is indicated in the regular treatment of asthma, including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** SERETIDE is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

		Glucocorticoids should only be considered as a purely symptomatic treatment, unless in case of some endocrine disorders, where they are used as substitution treatment. ANTI-INFLAMMATORY TREATMENT Rheumatic Disorders (as adjunctive therapy for short-term administration in the management of an acute episode or exacerbation) • post-traumatic osteoarthritis; • synovitis of osteoarthritis; • rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); • acute and subacute bursitis; • epicondylitis; • acute non-specific tenosynovitis; • acute gouty arthritis; • psoriatic arthritis; • ankylosing spondylitis. Collagen Diseases (during an exacerbation or as maintenance therapy in selected cases) • systemic lupus erythematosus; • acute rheumatic carditis; • systemic dermatomyositis (polymyositis); • polyarteritis nodosa; • Goodpasture's syndrome.

		Dermatologic Diseases • pemphigus; • severe erythema multiforme (Stevens-Johnson syndrome); • exfoliative dermatitis; • bullous dermatitis herpetiformis; • severe seborrheic dermatitis; • severe psoriasis; • mycosis fungoides; • urticaria. Allergic States (to control severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment) • bronchial asthma; • contact dermatitis; • atopic dermatitis; • serum sickness; • drug hypersensitivity reactions; • urticarial transfusion reactions; • acute non-infectious laryngeal edema (epinephrine is the drug of first choice). Ophthalmic Diseases (severe acute and chronic allergic and inflammatory processes involving the eye) • herpes zoster ophthalmicus; • iritis, iridocyclitis; • chorioretinitis; • diffuse posterior uveitis and choroiditis; • optic neuritis; • sympathetic ophthalmia.

BRU10020402P	Solu-Medrol Sterile Powder 500mg	Gastrointestinal Diseases (to manage critical periods of the disease) • ulcerative colitis (systemic therapy); • Crohn's disease (systemic therapy). Respiratory Diseases • symptomatic pulmonary sarcoidosis; • berylliosis; • fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate anti-tuberculous chemotherapy; • Loeffler's syndrome not manageable by other means; • aspiration pneumonitis. Edematous States • To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uremia of the idiopathic type or that due to lupus erythematosus. IMMUNOSUPPRESSSIVE TREATMENT Organ Transplantation TREATMENT OF HEMATOLOGICAL AND ONCOLOGICAL DISORDERS Hematologic Disorders • acquired (autoimmune) hemolytic anemia; • idiopathic thrombocytopenia purpura in adults (IV only; IM Administration is contraindicated); • secondary thrombocytopenia in adults; • erythroblastopenia (RBC anemia); • congenital (erythroid) hypoplastic anemia. Oncological Diseases For palliative management of: • leukemias and lymphomas in adults; • acute leukemia of childhood.

		TREATMENT OF SHOCK STATES Shock secondary to adrenocortical insufficiency or shock unresponsive to conventional therapy when adrenal cortical insufficiency may be present. (Hydrocortisone is generally the drug of choice. When mineralocorticoid activity is undesirable, methylprednisolone may be preferred.) Hemorrhagic, traumatic and surgical shock unresponsive to standard therapy. Although there are no well controlled (double-blind placebo) clinical trials, data from experimental animal models indicate that SOLU-MEDROL may be useful in shock states in which standard therapy e.g., fluid replacement has not been effective. OTHERS Nervous system • cerebral edema from tumour – primary or metastatic and/or associated with surgical or radiation therapy or head trauma; • acute exacerbations of multiple sclerosis; • acute spinal cord injury. The treatment should begin within 8 hours of injury. Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate anti-tuberculosis chemotherapy. Trichinosis with neurologic or myocardial involvement. Prevention of nausea and vomiting associated with cancer chemotherapy. ENDOCRINE DISORDERS • primary or secondary adrenocortical insufficiency; • acute adrenocortical insufficiency; • for these indications, the drugs of choice are hydrocortisone or cortisone. Synthetic analogues can be used in certain circumstances if they are combined with mineralocorticoids; • preoperatively and in the event of serious trauma or illness, in patients with known adrenal insufficiency or when adrenocortical reserve is doubtful; • congenital adrenal hyperplasia; • non-suppurative thyroiditis; • hypercalcemia associated with cancer.
BRU10020404P	Imdex 60mg CR Tablet	Prophylactic treatment of angina pectoris.
BRU10020412P	Seretide Accuhaler 50/100	**Asthma** *SERETIDE* is indicated in the regular treatment of asthma, including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** SERETIDE is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

BRU10020416P	Lipitor 20mg Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum TG levels (Fredrickson Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. Prevention of Cardiovascular Disease In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD) such as age, smoking, hypertension, low HDL-C, or a family history of early CHD, LIPITOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, LIPITOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina *Pediatric Patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: - LDL-C remains ≥190 mg/dL or - LDL-C remains ≥160 mg/dL and • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient

BRU10030426P	Aromasin 25mg Tablet	Exemestane is indicated for the adjuvant treatment of post-menopausal women with estrogen receptor positive early breast cancer who have received two to three years of tamoxifen and are switched to Exemestane for completion of a total of five consecutive years of adjuvant hormonal therapy. Exemestane is indicated for the second-line treatment of advanced breast cancer (ABC) in women with natural or induced post-menopausal status whose disease has progressed following anti-estrogen therapy alone. Exemestane is also indicated for the third-line treatment in post-menopausal woman with ABC whose disease has progressed following multiple hormonal therapies. Efficacy has not been demonstrated in patients with estrogen receptor negative status.
BRU10040445P	Seretide Accuhaler 50/250	**Asthma** *SERETIDE* is indicated in the regular treatment of asthma, including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** SERETIDE is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU10050466NP	Uphamol 250 Suspension 250mg/5ml (Orange)	Relieves fever, pain, discomforts of teething, headache, toothache, earache, common cold, influenza and post vaccination reactions.
BRU10050474P	Provinace Tablet 4mg	* Hypertension: Treatment of hypertension. * Heart Failure: Treatment of symptomatic heart failure. * Stable coronary artery disease: Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation.
BRU10050479P	Cozaar 100mg Film-Coated Tablet	**Hypertension** COZAAR is indicated for the treatment of hypertension. **Hypertensive Patients with Left Ventricular Hypertrophy** COZAAR is indicated for the reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy (see RACE). **Renal Protection in Type 2 Diabetic Patients with Proteinuria** COZAAR is indicated to delay the progression of renal disease as measured by a reduction in the incidence of doubling of serum creatinine and end stage renal disease (need for dialysis or renal transplantation), and to reduce proteinuria.

BRU10070512P	SW Metoclopramide Tablet 10mg	In adults, metoclopramide will be indicated for prevention of nausea and vomiting associated with chemotherapy and radiotherapy with low and minimal emetogenicity; the symptomatic treatment of acute migraine induced nausea and vomiting; the adjunct treatment of gastroparesis, the management of dyspepsia and gastroesophagel reflux disorder when other treatment options are unsuitable; and as adjuvant to surgical and radiological procedures.
BRU10070515P	Zaricort Cream	Zaricort Cream is used for the topical treatment of fungal infections where inflammation of the skin is also present such as those of tinea pedis (athlete's foot), tinea versicolor (white spot), tinea corporis (ringworm) and candidiasis.
BRU10070516P	Singulair® Tablet 10mg	SINGULAIR is indicated in adult and pediatric patients 1 year of age and older for the prophylaxis and chronic treatment of asthma, including the prevention of day- and nighttime symptoms, the treatment of aspirin-sensitive asthmatic patients, and the prevention of exercise-induced bronchoconstriction. SINGULAIR is indicated for the relief of daytime and nighttime symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older, and perennial allergic rhinitis in adults and pediatric patients 1 year of age and older). Because the benefits of SINGULAIR may not outweigh the risk of neuropsychiatric symptoms in patients with allergic rhinitis, reserve use for patients who have an inadequate response or intolerance to alternative therapies.
BRU10090540P	Cozaar Tablet 50mg	**Hypertension** COZAAR is indicated for the treatment of hypertension. **Hypertensive Patients with Left Ventricular Hypertrophy** COZAAR is indicated for the reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy (see RACE). **Renal Protection in Type 2 Diabetic Patients with Proteinuria** COZAAR is indicated to delay the progression of renal disease as measured by a reduction in the incidence of doubling of serum creatinine and end stage renal disease (need for dialysis or renal transplantation), and to reduce proteinuria.
BRU10090542PS2	Singulair Oral Granules 4mg	SINGULAIR is indicated in adult and pediatric patients 1 year of age and older for the prophylaxis and chronic treatment of asthma, including the prevention of day- and nighttime symptoms, the treatment of aspirin-sensitive asthmatic patients, and the prevention of exercise-induced bronchoconstriction. SINGULAIR is indicated for the relief of daytime and nighttime symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older, and perennial allergic rhinitis in adults and pediatric patients 1 year of age and older). Because the benefits of SINGULAIR may not outweigh the risk of neuropsychiatric symptoms in patients with allergic rhinitis, reserve use for patients who have an inadequate response or intolerance to alternative therapies.
BRU10090551P	Zoladex LA Depot Injection 10.8mg	Prostate cancer: Zoladex LA 10.8 mg is indicated in the management of prostate cancer suitable for hormonal manipulation. Breast cancer: Zoladex LA 10.8mg is indicated in the management of estrogen-receptor -positive breast cancer in premenopausal women.

BRU10100568P	Zithromax Powder For Oral Suspension 200mg/5ml	Azithromycin Oral Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx; however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, azithromycin is indicated for the treatment of uncomplicated genital infections due to Chlamydia trachomatis. It is also indicated for the treatment of chancroid due to Haemophilus ducreyi and uncomplicated genital infections due to non-multiresistant Neisseria gonorrhoeae; concurrent infection with Treponema pallidum should be excluded.
BRU10110587P; BRU10110587PS2	Metoclopramide Syrup 5mg/5ml	Adult population Metoclopramide is indicated in adults for: - Prevention of delayed chemotherapy induced nausea and vomiting (CINV). - Prevention of radiotherapy induced nausea and vomiting (RINV). - Symptomatic treatment of nausea and vomiting, including acute migraine induced nausea and vomiting. Paediatric population Metoclopramide is indicated in children (aged 1-18 years) for: - Prevention of delayed chemotherapy induced nausea and vomiting (CINV) as a second line option.
BRU10120604P	ClariClear Nasal Spray 0.05%	Clariclear® Nasal Spray is indicated for symptomatic relief of nasal and nasal pharyngeal congestion due to the common cold, sinusitis, hay fever or other upper respiratory allergies.
BRU11010624P	Elomet Ointment 0.1%	ELOMET Ointment 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses. The lotion formulation may be applied to scalp lesions.
BRU11010629P	Trandate™ Tablets 100mg	Tablet is indicated for: •Mild, moderate or severe hypertension. •Hypertension in pregnancy. •Angina pectoris with coexisting hypertension.
BRU11010636NP	YSP Bisacodyl Suppositories	i) Constipation. ii) Bowel preparation for radiological procedures and surgery.

BRU11010637P	Engerix-B 20 Adult Dose Suspension For Injection	***Engerix-B*** is indicated for active immunisation against HBV infection caused by all known subtypes in subjects of all ages considered at risk of exposure to HBV. It can be expected that hepatitis D will also be prevented by immunisation with ***Engerix-B*** as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection. Immunisation against hepatitis B is expected in the long term to reduce not only the incidence of this disease, but also its chronic complications such as chronic active hepatitis B and hepatitis B associated cirrhosis. In areas of **low prevalence** of hepatitis B, immunisation is particularly recommended for those belonging to groups identified at increased risk of infection (see below), however, universal immunisation of all infants and adolescents will contribute to the control of hepatitis B on a population basis. In areas of **intermediate and high prevalence** of hepatitis B, with most of the population at risk of acquiring the HBV, the best strategy is to provide universal immunisation of neonates, infants, children and adolescents, as well as adults belonging to groups at increased risk of infection. The WHO, the US Immunisation Practices Advisory Committee (ACIP) and the American Academy of Paediatrics advocate that the vaccination of new-borns and/or the vaccination of adolescents is the optimal strategy for the control of hepatitis B in all countries. Groups identified at increased risk of infection: health care personnel, patients frequently receiving blood products, personnel and residents of institutions, persons at increased risk due to their sexual behaviour, illicit users of addictive injectable drugs, travellers to areas with a high endemicity of HBV, infants born of mothers who are HBV carriers, persons originating from areas with a high endemicity of HBV, patients with sickle-cell anaemia, patients who are candidates for organ transplantation, household contacts of any of the above groups and of patients with acute or chronic HBV infection, subjects with chronic liver disease (CLD) or at risk of developing CLD (e.g. Hepatitis C virus carriers, persons who abuse alcohol), others (police personnel, fire brigade personnel, armed forces personnel and anybody who through their work or personal lifestyle may be exposed to HBV).

BRU11020643P	Dalacin C 300mg Capsule	Clindamycin is indicated in the treatment of serious infections caused by susceptible anerobic bacteria. Clindamycin is also indicated in the treatment of serious infections due to susceptible strains of streptococci, pneumococci, and staphylococci. Its use should be reserved for penicillin-allergic patients or other patients for whom, in the judgment of the physician, a penicillin is inappropriate. Because of the risk of colitis, before selecting clindamycin the physician should consider the nature of the infection and the suitability of less toxic alternatives (e.g., erythromycin). **Anaerobes**: Serious respiratory tract infections such as empyema, anerobic pneumonitis infections such as peritonitis and intra-abdominal abscess (typically resulting from anerobic organisms resident in the normal gastrointestinal tract); infections of the female pelvis and genital tract such as endometritis, non-gonococcal tubo-ovarian abscess, pelvic cellulitis and postsurgical vaginal cuff infection. **Streptococci**: Serious respiratory tract infections; serious skin and soft tissue infections. **Staphylococci**: Serious respiratory tract infections; serious skin and soft tissue infections. **Pneumococci**: Serious respiratory tract infections. Bacteriologic studies should be performed to determine the causative organisms and their susceptibility to clindamycin.
BRU11030669PS2; BRU11030669PS3	Caelyx 2mg/ml Concentrate For Infusion	**Breast Cancer** CAELYX®, as monotherapy, is indicated for the treatment of metastatic breast cancer. Ovarian Cancer CAELYX® is indicated for the treatment of advanced ovarian cancer in women who have failed a first-line platinum based chemotherapy regimen. **Multiple Myeloma** CAELYX® is indicated in combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and have not previously received bortezomib. Patients should have already undergone or are unsuitable for bone marrow transplant. **AIDS-related Kaposi's Sarcoma** CAELYX® is also indicated for AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (<200 CD4 lymphocytes/mm3) and extensive mucocutaneous or visceral disease. CAELYX® may be used as first-line systemic chemotherapy, or as second line chemotherapy in AIDS-KS patients with disease that has progressed with, or in patients intolerant to, prior combination systemic chemotherapy comprising at least two of the following agents: a vinca alkaloid, bleomycin and standard doxorubicin (or other anthracyclines).

BRU11030672P	Avodart Soft Capsules 0.5mg	**Monotherapy** *AVODART* is indicated for the treatment and control of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of the need for BPH-related surgery. **Combination With Alpha-Blocker** *AVODART* in combination with the alpha-blocker tamsulosin is indicated for the treatment of symptomatic BPH in men with an enlarged prostate.
BRU11040679P	Trandate™ Injection 5mg/ml x 5ml	Injection is indicated for: •Severe hypertension, including severe hypertension for pregnancy, when rapid control of blood pressure is essential. •May be used to achieve controlled hypotension during anaesthesia.
BRU11040690P	Engerix-B 10 Junior Dose Suspension For Injection	***Engerix-B*** is indicated for active immunisation against HBV infection caused by all known subtypes in subjects of all ages considered at risk of exposure to HBV. It can be expected that hepatitis D will also be prevented by immunisation with ***Engerix-B*** as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection. Immunisation against hepatitis B is expected in the long term to reduce not only the incidence of this disease, but also its chronic complications such as chronic active hepatitis B and hepatitis B associated cirrhosis. In areas of **low prevalence** of hepatitis B, immunisation is particularly recommended for those belonging to groups identified at increased risk of infection (see below), however, universal immunisation of all infants and adolescents will contribute to the control of hepatitis B on a population basis. In areas of **intermediate and high prevalence** of hepatitis B, with most of the population at risk of acquiring the HBV, the best strategy is to provide universal immunisation of neonates, infants, children and adolescents, as well as adults belonging to groups at increased risk of infection. The WHO, the US Immunisation Practices Advisory Committee (ACIP) and the American Academy of Paediatrics advocate that the vaccination of new-borns and/or the vaccination of adolescents is the optimal strategy for the control of hepatitis B in all countries. Groups identified at increased risk of infection: health care personnel, patients frequently receiving blood products, personnel and residents of institutions, persons at increased risk due to their sexual behaviour, illicit users of addictive injectable drugs, travellers to areas with a high endemicity of HBV, infants born of mothers who are HBV carriers, persons originating from areas with a high endemicity of HBV, patients with sickle-cell anaemia, patients who are candidates for organ transplantation, household contacts of any of the above groups and of patients with acute or chronic HBV infection, subjects with chronic liver disease (CLD) or at risk of developing CLD (e.g. Hepatitis C virus carriers, persons who abuse alcohol), others (police personnel, fire brigade personnel, armed forces personnel and anybody who through their work or personal lifestyle may be exposed to HBV).

BRU11040695P	Revolade™ Film-Coated Tablet 25mg	Revolade is indicated for the treatment of patients aged 6 years and above with primary thrombocytopenia (ITP) lasting 6 months or longer from diagnosis who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Revolade is indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy. Revolade is indicated in combination with standard immunosuppressive therapy for the first-line treatment of adult and adolescent patients 12 years and older with severe aplastic anemia. Revolade is indicated in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.
BRU11050700PS1; BRU11050700PS2	Tetraxim Vaccine	This vaccine is indicated in the joint prevention of diphtheria, tetanus, pertussis and poliomyelitis: • for primary vaccination in infants from the age of 2 months, • for booster vaccination, one year after primary vaccination during the second year of life, This vaccine may be associated or combined with the *Haemophilus influenzae* type b conjugated vaccine (Act-HIB). • for booster vaccination between 5 and 7 years of age, according to official recommendations.
BRU11050701P	Depo-Provera Vial 150mg/3ml	Depot-Medroxyprogesterone acetate (DMPA) injectable suspension is indicated for: Contraception Contraception (ovulation suppression) Gynecology Treatment of endometriosis Treatment of menopausal vasomotor symptoms Oncology Adjunctive and/or palliative treatment of recurrent and/or metastatic endometrial or renal carcinoma. Treatment of hormonally-dependent, recurrent breast cancer in post-menopausal women. Long-term Use: Since loss of bone mineral density (BMD) may occur in pre-menopausal women who use DMPA injection long-term (see Sections 4.4. Special Warnings and Precautions for Use - Additional Warnings and Precautions for Specific Use or Formulation, Contraception/Endometriosis - Injectable Formulations, Loss of Bone Mineral Density (BMD) and 5.1. Pharmacodynamic Properties - Clinical Studies, Bone Mineral Density Studies), a risk/benefit assessment, which also takes into consideration the decrease in BMD that occurs during pregnancy and/or lactation, should be considered.

BRU11060718P	Myleran™ Tablets 2mg	Busulfan is indicated for the palliative treatment of the chronic phase of chronic myeloid leukaemia. Busulfan is effective in producing prolonged remission in polycythaemia vera, particularly in cases with marked thrombocytosis. Busulfan may be useful in selected cases of essential thrombocythaemia and myelofibrosis.
BRU11070734P	Syntometrine® Injection 5IU/ml Ampoule	Active management of the third stage of labour (in order to facilitate separation of the placenta and thus reduce blood loss). Prevention and treatment for post-partum haemorrhage associated with uterine atony.
BRU11070737P	Zofran™ Tablets 8mg	**Adults** ZOFRAN oral formulations are indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. ZOFRAN is also indicated for the prevention of post-operative nausea and vomiting. **Paediatric Population** ***Oral formulation*** : ZOFRAN is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy. No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting.
BRU11080744P	Lanoxin PG Tablet 0.0625mg	**Cardiac Failure** Digoxin is indicated in the management of chronic cardiac failure where the dominant problem is systolic dysfunction. Its therapeutic benefit is greatest in those patients with ventricular dilatation. Digoxin is specifically indicated where cardiac failure is accompanied by atrial fibrillation. **Supraventricular Arrhythmias** Digoxin is indicated in the management of certain supraventricular arrhythmias, particularly atrial flutter and fibrillation.
BRU11080749P	Econazine Cream	Indicated for the topical treatment of inflammatory dermatoses where infected by susceptible organisms co-exist e.g. inflammatory fungal infections and infective eczema.
BRU11080751P	Urosin Film Coated Tablet 100mg	Hypertension, angina pectoris.
BRU11080753P	Fukole Capsule 150mg	Treatment and prevention of cryptococcal meningitis and other cryptococcal infections; treatment of vaginal, oropharyngeal and other forms of candidiasis; prevention of fungal infections in immunocompromised patients.
BRU11080758P	Loramide Capsule 2mg	Indicated for the control and symptomatic relief of acute non-specific diarrhea and of chronic diarrhea associated with inflammatory bowel disease.

BRU11090763P	Infanrix Hexa™	Infanrix hexa is indicated for primary immunisation against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and *Haemophilus influenzae* type B in infants from the age of 6 weeks and may be given to infants who received a first dose of Hepatitis vaccine at birth.
BRU11090767P	Sandimmun Neoral® Oral Solution 100mg/ml	**Transplantation indications** **Solid organ transplantation** Prevention of graft rejection following kidney, liver, heart, combined heart-lung, lung or pancreas allogeneic transplantations. Treatment of transplant rejection in patients previously receiving other immunosuppressive agents. **Bone marrow transplantation** Prevention of graft rejection following bone marrow transplantation. Prevention or treatment of graft-versus-host disease (GVHD). **Non-transplantation indications** **Endogenous uveitis** Active sight-threatening intermediate or posterior uveitis of non-infectious aetiology in patients where conventional therapy fails, or causes unacceptable side effects. Behçet uveitis with repeated inflammatory attacks involving the retina. **Nephrotic syndrome** Steroid-dependent and steroid-resistant nephrotic syndrome in adults and children, due to glomerular diseases such as minimal change nephropathy, focal and segmental glomerulosclerosis, or membranous glomerulonephritis. Sandimmun Neoral can be used to induce remissions and to maintain them. It can also be used to maintain steroid-induced remission, allowing withdrawal of steroids. **Rheumatoid arthritis** Treatment of severe, active rheumatoid arthritis. **Psoriasis** Treatment of severe psoriasis in patients in whom conventional therapy is ineffective or inappropriate.
BRU11090769P	Hyzaar® Plus Tablet 100/12.5mg	**Hypertension** HYZAAR® / HYZAAR® PLUS / HYZAAR® FORTE is indicated for the treatment of hypertension, for patients in whom combination therapy is appropriate. **Hypertensive Patients with Left Ventricular Hypertrophy** HYZAAR® / HYZAAR® PLUS / HYZAAR® FORTE is a combination of losartan (COZAAR) and hydrochlorothiazide. In patients with hypertension and left ventricular hypertrophy, losartan, often in combination with hydrochlorothiazide, reduces the risk of stroke in hypertensive patients with left ventricular hypertrophy (see RACE).

BRU11110814P	YSP Prednisolone 5mg Tablet	For the treatment of bronchial asthma, allergic disease, rheumatoid arthritis, rheumatosis, Still's disease, rheumatoid myocarditis, psoriasis, osteoarthritis, rheumatic myelitis, gouty arthritis, acute and chronic gout and other inflammatory skin disease.
BRU11120818P	Clarityn Syrup	Clarityne* products are indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhoea) and itching, as well as ocular itching and burning. Nasal and ocular signs and symptoms are relieved rapidly after oral administration. Clarityne* products are also indicated for relief of symptoms and signs of chronic and other allergic dermatologic disorders.
BRU11120820P	Ventolin™ Evohaler™	*VENTOLIN* Evohaler provides short-acting (4 to 6 hours) bronchodilation with fast onset (within 5 minutes) in reversible airway obstruction. It is particularly suitable for the relief and prevention of asthma symptoms. *VENTOLIN* Evohaler should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognised by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure). *VENTOLIN* Evohaler is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction and use of regular inhaled corticosteroid therapy.
BRU11120822P	Revolade™ Film-Coated Tablets 50mg	Revolade is indicated for the treatment of patients aged 6 years and above with primary thrombocytopenia (ITP) lasting 6 months or longer from diagnosis who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Revolade is indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy. Revolade is indicated in combination with standard immunosuppressive therapy for the first-line treatment of adult and adolescent patients 12 years and older with severe aplastic anemia. Revolade is indicated in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.
BRU11120823P	Coversyl® Plus 5mg	Treatment of essential hypertension in adults, Coversyl Plus 5mg/1.25mg film-coated tablet is indicated in patients whose blood pressure is not adequately controlled on perindopril alone.
BRU11120827PS2	Methycobal Injection 500mcg/ml	Peripheral neuropathies. Megaloblastic anemia caused by Vitamin B12 deficiency.

BRU11120835P	Indomen Capsule 25mg	Arthritis, rheumatism, arthritis deformans, and other inflammatory conditions.
BRU11120838NP	Champs D-Worms 6 Chewable Tablet (Chocolate)	Treatment of single or mixed infestation of intestinal parasites including Roundworm, Whipworm, Pinworm, Threadworm, Hookworm and Tapeworm.
BRU12010842P	Valdoxan® 25mg Film-Coated Tablet	Valdoxan is indicated for the treatment of major depressive episodes in adults.
BRU12010843P	Zofran Tablet 4mg	**Adults** ZOFRAN oral formulations are indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. ZOFRAN is also indicated for the prevention of post-operative nausea and vomiting. **Paediatric Population** ***Oral formulation*** : ZOFRAN is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy. No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting.
BRU12010856NP	Panadol Suspension 250mg/5ml	Panadol Suspension 120mg/5ml adalah diguna untuk melegakan demam, kesakitan akibat selesema, sakit tumbuh gigi, sakit gigi dan demam selepas vaksinasi. Panadol Suspension 250mg/5ml adalah diguna untuk melegakan demam, kesakitan akibat selesema, sakit tumbuh gigi dan sakit gigi dan demam selepas vaksinasi.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU12010857P	Targocid® Injection 200mg	Targocid is indicated in adults and in children from birth for the parenteral treatment of the following infections (see sections Posology and method of administration, Special warnings and precautions for use and Pharmacodynamic properties): •Complicated skin and soft tissue infections, •Bone and joint infections, •Hospital acquired pneumonia, •Community acquired pneumonia, •Complicated urinary tract infections, •Infective endocarditis, •Peritonitis associated with continuous ambulatory peritoneal dialysis (CAPD), •Bacteraemia that occurs in association with any of the indications listed above. Where appropriate, teicoplanin should be administered in combination with other antibacterial agents. Consideration should be given to official guidance on the appropriate use of antibacterial agents.
BRU12020860P	Yucomy Tablet 200mg	1. Ketoconazole Tablets should be used only when other effective antifungal therapy is not available or tolerated and the potential benefits are considered to outweigh the potential risks. 2. Ketoconazole Tablets are indicated for the treatment of the following systemic fungal infections in patients who have failed or who are intolerant to other therapies: blastomycosis, coccidioidomy cosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis 3. Ketoconazole Tablets should not be used for fungal meningitis because it penetrates poorly into the cerebrospinal fluid.
BRU12020864P	Zanidip® Tablet 10mg	ZANIDIP is indicated in adults for the treatment of mild to moderate essential hypertension.
BRU12020870P	Lyrica™ 150mg Capsules	<u>Neuropathic pain</u> Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. <u>Epilepsy</u> Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. <u>Generalised anxiety disorder</u> Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.

BRU12030874P	Brilinta™ 90mg F/C Tablet	**Acute Coronary Syndrome or a History of Myocardial Infarction** Brilinta, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with Acute Coronary Syndromes (unstable angina, non ST elevation Myocardial Infarction [NSTEMI] or ST elevation Myocardial Infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG). **Acute Ischemic Stroke or Transient Ischemic Attack (TIA)** BRILINTA is indicated to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score ≤5) or high-risk transient ischemic attack (TIA). For further information, please refer to section 'Pharmacodynamic properties'.
BRU12030880NP	Aqua Cream	In irritant conditions of the skin, it acts as an emollient to soften or soothe skin.
BRU12030882P	Cancidas Powder For Injection 50mg/Vial	CANCIDAS is indicated in adult and pediatric patients (12 months and older) for: • Empirical therapy for presumed fungal infections (such as *Candida* or *Aspergillus*) in febrile, neutropenic patients, whose fever has failed to respond to broad-spectrum antibiotics. • Treatment of Candidemia and the following *Candida* infections: intra-abdominal abscesses, peritonitis and pleural space infections. CANCIDAS has not been studied in endocarditis, osteomyelitis, and meningitis due to *Candida* . • Treatment of Esophageal Candidiasis • Treatment of Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies.
BRU12040884P	Dilantin Steri Vials 250mg In 5ml	Phenytoin is indicated for the control of status epilepticus of the tonic-clonic (grand mal) type and prevention and treatment of seizures occurring during or following neurosurgery.
BRU12040885P	Jevtana® 60mg Concentrate And Solvent For Solution For Infusion	JEVTANA in combination with prednisone or prednisolone is indicated for the treatment of adult patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing regimen.
BRU12040895P	Axcel Lignocaine Sterile Gel 2% w/w	Lignocaine 2% Sterile Gel is indicated as a surface anaesthetic and lubricant for: - The male and female urethra during cystoscopy, catheterisation, exploration by sound and other endourethral procedures. - Nasal and pharyngeal cavities in endoscopic procedures such as gastroscopy and bronchoscopy. - During photoscopy and rectoscopy. - Tracheal intubation. - Symptomatic treatment of pain in connection with cystitis and urethrisis. - To relief pain after circumcision in children.

BRU12050898P	Lamictal Dispersible Tablet 5mg	**EPILEPSY** **• Adults and Adolescents** LAMICTAL is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. **• Children (2 to 12 years of age)** LAMICTAL is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalised seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome (above 3 years of age only). Initial monotherapy treatment in newly diagnosed paediatric patients is not recommended. After epileptic control has been achieved during adjunctive therapy, concomitant anti- epileptic drugs (AEDs) may be withdrawn and patients continued on LAMICTAL monotherapy. If LAMICTAL 2 mg Chewable Dispersible Tablet is not available and the calculated dose in children is less than 2.5 mg daily, then LAMICTAL cannot be used. DO NOT attempt to administer partial quantities of the dispersible tablets. **BIPOLAR DISORDER** **• Adults (18 years of age and over)** LAMICTAL is indicated for the prevention of mood episodes in patients with bipolar disorder, predominantly by preventing depressive episodes.
BRU12050903NP	Panadol® ActiFast Caplets	Untuk kelegaan demam dan kelegaan sakit daripada ringan hingga sederhana termasuk: sakit kepala, migrain, sakit belakang, sakit muskuloskeletal, sakit senggugut, sakit osteoarthritis, sakit gigi, sakit selepas prosedur pergigian/pencabutan gigi, sakit selepas vaksinasi dan ketidakselesaan akibat selesema dan sakit tekak.
BRU12060908P	Methycobal Tablets 500mcg	Peripheral neuropathies.
BRU12060909P	Lyrica™ 75mg Capsules	<u>Neuropathic pain</u> Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. <u>Epilepsy</u> Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. <u>Generalised anxiety disorder</u> Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU12060910NP	Panadol® Soluble Tablet 500mg	Panadol® Soluble is used to relieve headache, fever, pain, and discomfort due to cold and flu and pain following dental procedures.
BRU12060912P	Canesten GYN 1 Day Therapy Vaginal Tablet 0.5g	Vaginitis caused by fungi – mostly candida – and/or trichomonads. Super infections caused by Canesten-sensitive bacteria.
BRU12060915NP	Drapolene Cream	For the treatment and prevention of nappy rash redness. For the relief of nappy rash and for use as an adjunct to baby care hygiene for the prevention of nappy rash. For the aftercare of small areas of superficial burns (limited to the epidermis), limited sunburn and the effects of weather.
BRU12070918P	Beclomet Nasal Aqua 50mcg/Dose Nasal Spray	Seasonal and perennial allergic rhinitis. Vasomotor rhinitis. Prevention of recurrence of nasal polyps after surgical removal.
BRU12070921NP	ENO Ginger Fruit Salt	Indicated for the symptomatic relief of acid indigestion, flatulence and stomach discomfort.
BRU12070922NP	ENO Fruit Salt	Indicated for the symptomatic relief of acid indigestion, flatulence and stomach discomfort.
BRU12070923P	Coversyl Plus 10mg/2.5mg Tablet	Coversyl Plus 10mg/2.5mg is indicated as substitution therapy for treatment of essential hypertension, in patients already controlled with perindopril and indapamide given concurrently at the same dose level.
BRU12070926NP	Bepanthen® Ointment	Bepanthen® Ointment is used for: • Prevention & treatment of nappy (diaper) rash. • Caring & treatment of sore/cracked nipples, for breastfeeding mothers. • Dry, chapped and cracked skin. • Minor skin injuries such as minor burns and wounds.
BRU12090933P	Xarelto® Film-Coated Tablet 10mg	Prevention of venous thromboembolism (VTE) in patients undergoing total hip replacement or total knee replacement surgery. Xarelto is indicated for the treatment of Deep Vein Thrombosis (DVT) and pulmonary embolism (PE), and for the prevention of recurrent DVT, PE in adults. (See section 'Special warnings and precautions for use' for haemodynamically unstable PE patients.)

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU12090938P	Glucophage® XR 750mg Extended Release Tablet	o Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with IGT* and/or IFG* who are: ▪ at high risk for developing overt type 2 diabetes mellitus (see section 5.1) and ▪ not suitable for intensive lifestyle modifications. Treatment with Glucophage XR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk (see section 5.1). *IGT: Impaired Glucose Tolerance; IFG: Impaired Fasting Glucose o Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. Glucophage XR may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.
BRU12090939P	Glucophage® Tablet 500mg	Treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. • In adults, Glucophage film-coated tablets may be used as monotherapy or in combination with other oral anti-diabetic agents or with insulin. • In children from 10 years of age and adolescents, Glucophage film-coated tablets may be used as monotherapy or in combination with insulin. A reduction of diabetic complications has been shown in overweight type 2 diabetic adult patients treated with metformin as first-line therapy after diet failure (see section 5.1).
BRU12100940NP	Dermoplex Calamine Cream	Soothes and relives nappy rashes, pickly heat, minor skin irritations, insect bites and sunburn.
BRU12100941P; BRU12100941PS2	Fragmin™ Solution For Injection 5,000IU (Anti-Xa)/0.2ml	Thromboprophylaxis in conjunction with surgery.
BRU12100942P	Prostin E2™ Vaginal Tablet 3mg	Oxytocic agent. Dinoprostone are indicated for the induction of labour, especially in patients with favourable induction features, when there are no foetal or maternal contraindications.
BRU12100943NP	Dianeal Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution With 2.5% Dextrose	Dianeal Low Calcium peritoneal dialysis solutions are indicated for use in chronic renal failure patients being maintained on peritoneal dialysis.

BRU12100944NP	Potassium Chloride Tablet 600mg (Slow Release)	For prevention and treatment of potassium deficiency.
BRU12100945NP	Anucare Suppositories	Uncomplicated haemorrhoids, simple anorectal inflammatory and irritations caused by or associated with proctitis or cryptitis. May be used pro- and post-operation in haemorrhoidectomy and repair of anal fistula as well as after incision of thrombosed or sclerosed anorectal veins.
BRU12100947PS3	Illiadin Decongestant Nasal Drops	Acute cold, paranasal sinusitis, syringitis, otitis media.
BRU12100949P	Lyrica Capsules 50mg	Neuropathic pain Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised anxiety disorder Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. Fibromyalgia Pregabalin is indicated for the management of fibromyalgia.
BRU12100951P	Prograf Capsule 0.5mg	Primary immunosuppression in liver and kidney allograft recipients and liver and kidney allograft rejection resistant to conventional immunosuppressive agents.
BRU12110953P; BRU12110953PS2	Fragmin™ Solution For Injection 2,500IU (Anti-Xa)/0.2ml, Single Dose Syringe	Thromboprophylaxis in conjunction with surgery.
BRU12110956NP	Vitamin C 100mg Tablet	Vitamin C is used in the treatment and prevention of deficiency.
BRU12110957PS1; BRU12110957PS2	Actrapid® 100IU/ml Solution For Injection	Treatment of diabetes mellitus.
BRU12110958P	Tretinon Cream 0.05%	Topical treatment of acne vulgaris, in which comedones, papules and pustules predominate.

BRU12110960NP	Daflon 500mg Tablet	-Treatment of symptoms related to venolymphatic insufficiency (heavy legs, pain, early morning restless legs). -Treatment of functional symptoms related to acute hemorrhoidal attack.
BRU12110963NP	Polysilic III Suspension	As antacid in dyspepsia, peptic ulcer, gastritis; use in the relief of abdominal distension and treatment of flatulence and oesophageal reflux with heartburn.
BRU12120967P	Cervarix™ Vaccine (Prefilled Syringe)	CERVARIX is indicated from 10 to 45 years of age for the prevention of premalignant ano-genital lesions (cervical, vulvar, vaginal and anal) and cervical and anal cancers caused by oncogenic Human Papillomaviruses (HPV) types 16 and 18.
BRU12120968NP	Dianeal Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution With 4.25% Dextrose	Ambuflex Container: Dianeal Low Calcium Peritoneal Dialysis Solutions are indicated for use in chronic renal failure patients being maintained on peritoneal dialysis. Ultrabag Container: Dianeal Low Calcium Peritoneal Dialysis Solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.
BRU12120969NP	ENO Orange	To relieve symptoms of indigestion.

BRU12120970P	Clamentin Film Coated Tablet 625mg	Clamentin are indicated for short-term treatment of bacterial infections at the following sites: - Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media. - Lower respiratory tract infections e.g. acute and chronic bronchitis, lobar and bronchopneumonia. - Genito-urinary tract infection e.g. cystitis, urethritis, pyelonephritis. - Skin and soft tissue infections e.g. boils, abscesses, cellulitis, wound infections. - Bone and joint infections e.g. osteomyelitis. - Dental infections e.g. dentoalveolar abscess. - Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis. <u>Gram positive</u> **Aerobes**: *Enterococcus faecalis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus viridans, *Staphylococcus aureus, *Coagulase negative staphylococci (including Staphylococcus epidermidis), Corynebacterium species, Bacillus anthracis, Listeria monocytogenes.* **Anaerobes**: *Clostridium species, Peptococcus species, Peptostreptococcus.* <u>*Gram negative:*</u> ***Aerobes** : *Haemophilus influenzae, *Escherichia coli, *Proteus mirabilis, *Proteus vulgaris, *Klebsiella species, *Moraxella catarrhalis, *Salmonella species, *Shigella species, Bordetella pertussis, Brucella species, *Neisseria gonorrhoeae, Neisseria meningitidis, Vibrio cholerae, Pasteurella multocida.* ***Anaerobes** : *Bacteroides spp. Including B. fragilis.* **including beta-lactamase producing strains resistant to ampicillin and amoxycillin.*
BRU12120971P	Survanta® Beractant Intratracheal Suspension	SURVANTA is indicated for prevention and treatment ("rescue") of Respiratory Distress Syndrome (RDS) (hyaline membrane disease) in premature infants. SURVANTA significantly reduces the incidence of RDS, mortality due to RDS and air leak complications.
BRU12120974P	Sutent™ Hard Capsules 12.5mg	**Gastrointestinal Stromal Tumor (GIST)** **SUTENT** is indicated for the treatment of gastrointestinal stromal tumor after disease progression on or intolerance to imatinib mesylate. **Advanced Renal Cell Carcinoma (RCC)** **SUTENT** is indicated for the treatment of advanced renal cell carcinoma. **Pancreatic Neuroendocrine Tumour (pNET)** **SUTENT** is indicated for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults.

BRU12120975PS2	Stelara Solution For Injection In Pre-Filled Syringe 45mg/0.5ml	**Plaque Psoriasis** ***(via subcutaneous administration only)*** STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A). **Psoriatic Arthritis (PsA)** ***(via subcutaneous administration only)*** STELARA alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **Crohn's Disease** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies. **Ulcerative Colitis** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.
BRU12120976P	Viagra 50mg Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil to be effective, sexual stimulation is required.
BRU12120977P	Viagra 100mg Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil to be effective, sexual stimulation is required.
BRU12120978P	Aerrane (Isoflurane USP) Inhalation Liquid	Volatile halogenated anaesthetic for general inhalation anaesthesia.
BRU12120980NP	Potcit Mixture	This is used in the treatment of inflammatory conditions of the bladder and to prevent crystalluria during treatment with sulphonamides. It may also be used as a potassium supplement.

BRU12120981P	Garbose Tablet 100mg	Additional therapy in association with diet in patients with diabetes mellitus.
BRU13010985P	Zanidip® 20mg Tablet	ZANIDIP is indicated in adults for the treatment of mild to moderate essential hypertension.
BRU13010987P	Pontalon Tablet 500mg	For the symptomatic relief of degenerative arthralgia and for the relief of mild to moderate pain, including muscular, traumatic and dental pain, headache, postoperative and post-partum pain and dysmenorrhea.
BRU13010988P	Co-Trimexazole Suspension	The two components of Co-trimexazole interfere with the bacterial synthesis of tetrahydrofolic acid at different points. It is used to treat infections caused by susceptible gram positive and gram negative bacteria. Suitable indications include:- a) Respiratory tract infections, including pneumocystic carinii b) Acute otitis media c) Bacterial dysentery d) Genital tract infections It is also used in prophylaxis regimens, particularly in cases of hypersensitivity to penicillins and in dysentery.
BRU13010995P	Daivonex® Ointment	Psoriasis vulgaris.
BRU13010996P	Seretide Evohaler 25/125mcg	**Asthma (Reversible Obstructive Airways Disease)** SERETIDE is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** SERETIDE is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU13010997P	Glucophage® Tablet 850mg	Treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. • In adults, Glucophage film-coated tablets may be used as monotherapy or in combination with other oral anti-diabetic agents or with insulin. • In children from 10 years of age and adolescents, Glucophage film-coated tablets may be used as monotherapy or in combination with insulin. A reduction of diabetic complications has been shown in overweight type 2 diabetic adult patients treated with metformin as first-line therapy after diet failure.
BRU13010998PS1; BRU13010998PS2	Revlimid® Capsules 5mg	Revlimid® in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
BRU13010999NP	Infusol® NS	● Plasma isotonic fluid replacement ● Sodium and chloride depletion ● Hypochloremic alkalosis ● Vehicle solution for supplementary medication
BRU13021006P	Canesten GYN 6 Day 6-Day-Therapy	Infectious vaginal discharge. Vaginitis due by fungi – mostly Candida – and/or Trichomonas. Super infections with Canesten-sensitive bacteria.
BRU13021008P	Prevenar 13 Suspension For Injection	Active immunization for the prevention of pneumococcal disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F (including invasive disease, pneumonia and acute otitis media) in infants and children from 2 months to 17 years of age. Active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* in adults aged 18 – 49 years old. Active immunization for the prevention of pneumococcal disease caused by *Streptococcus pneumonia* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults aged 50 years and older. This indication is based on immune responses elicited by Prevenar 13 and there have been no controlled trials in adults demonstrating vaccine efficacy.

BRU13021009P	Hemabate Sterile Solution 250mcg/ml	Hemabate Sterile Solution is indicated for aborting pregnancy between the 13th and 20th weeks of gestation as calculated from the first day of the last normal menstrual period and in the following conditions related to second trimester abortion: -Failure of expulsion of the fetus during the course of treatment by another method. -Premature rupture of membranes in intrauterine methods with loss of drug and insufficient or absent uterine activity. -Requirement of a repeat intrauterine instillation of drug for expulsion of the fetus. -Inadvertent or spontaneous rupture of membranes in the presence of a previable fetus and absence of adequate activity for expulsion. -Hemabate is indicated for the treatment of postpartum hemorrhage due to uterine atony which has not responded to conventional methods of management. Prior treatment should include the use of intravenously administered oxytocin, manipulative techniques such as uterine massage and unless contraindicated, intramuscular ergot preparations. Studies have shown that in such cases, the use of Hemabate has resulted in satisfactory control of hemorrhage, although it is unclear whether or not ongoing or delayed effects of previously administered ecbolic agents have contributed to the outcome. In a high proportion of cases, Hemabate used in this manner has resulted in the cessation of life-threatening bleeding and the avoidance of emergency surgical intervention.
BRU13021011NP	Extraneal Peritoneal Dialysis Solution 75g/L	EXTRANEAL is recommended as a once daily replacement for a single Dextrose exchange as part of a CAPD or automated peritoneal dialysis (APD) regimen for the treatment of chronic renal failure, particularly for some categories of patients who have lost ultrafiltration on Dextrose solutions, because it can extend time on CAPD therapy in such patients.
BRU13021012P	Afinitor Tablet 10mg	AFINITOR tablets are indicated for the ♦treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole. ♦treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with VEGF-targeted therapy. ♦treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic disease. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors. ♦treatment of adult patients with progressive, well-differentiated (Grade 1 or Grade 2), non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin with unresectable, locally advanced or metastatic disease. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors. ♦treatment of adult and pediatric patients, 1 years of age and older, with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not candidates for curative surgical resection. The effectiveness of AFINITOR is based on an analysis of change in SEGA volume (see section CLINICAL STUDIES). Clinical benefit such as improvement in disease-related symptoms or increase in overall survival has not been demonstrated. ♦treatment of adult patients with renal angiomyolipoma (AML) and tuberous sclerosis complex (TSC), not requiring immediate surgery. The effectiveness of AFINITOR in the treatment of renal angiomylipoma is based on an analysis of durable objective responses in patients treated for a median of 8.3 months. Further follow-up of patients is required to determine long-term outcomes.
BRU13021013P	Ketovid Cream 2%	Treatment of dermatophyte infections of the skin-tinea corporis, tinea cruris, tinea manus and tinea pedis caused by *Trichophyton rubrum* , *Trichophyton mentagrophytes* , *Microsporum canis* and *Epidermophyton floccosum* as well as in the treatment of cutaneous candidiasis, pityriasis versicolor and seborrhoeic dermatitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU13021015P	Azopt Eye Drops, Suspension	AZOPT is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.
BRU13021016P	Rhewlin SR Tablet 100mg	Diclofenac sodium is an orally active non-steroidal anti-inflammatory agent (NSAID) which has analgesic, anti-inflammatory and antipyretic properties. It is used in the treatment of rheumatic arthritis and other rheumatic diseases.
BRU13021017P	Xepa Hydrogen Peroxide Solution 6%	As first aid for minor cuts, wounds and abrasions, to remove dressing from wounds and as mouthwash in the treatment of acute stomatitis and as deodorant gargle. It is also used to remove ear wax.
BRU13021019P; BRU13021019PS2	Stilamin 3000 For Injection 3mg/Ampoule	-Severe acute haemorrhage from oesophageal varices -Severe acute haemorrhage from gastric or duodenal ulcers, or accompanying acute erosive or hemorrhagic gastritis -Adjuvant treatment in pancreatic, biliary and intestinal fistulae -Prophylaxis and treatment of postoperative complications following pancreatic surgery -Adjuvant treatment in diabetic ketoacidosis
BRU13021020P	Loradine Syrup 1mg/ml	Relief of symptoms associated with allergic rhinitis e.g. sneezing, nasal discharge and itching, as well as ocular itching and burning. Chronic urticaria and other allergic dermatologic disorders.
BRU13021021P	Decozol Oral Gel 2% w/w	Therapeutic and prophylactic treatment of candidiasis of the oropharyngeal cavity and gastrointestinal tract.
BRU13021022P	Rasitol Injection 20mg/2ml	Oedema due to cardiac, hepatic cirrhosis and nephritic syndrome. Treatment of mild to moderate degree of hypertension.
BRU13021023P	Fusate-250 Tablet	Staphylococcal infections e.g. osteomyelitis, septicaemia, endocarditis, cystic fibrosis, pneumonia, cellulitis, surgical and traumatic wound infections.
BRU13021024P	Premarin Vaginal Cream	Premarin (conjugated oestrogens, CE) Vaginal Cream is indicated in the treatment of atrophic vaginitis, dyspareunia and kraurosis vulvas. Estrogens with or without pregestins should not be used for the prevention of cardiovascular disease or dementia.
BRU13021026P	Kaletra Film-Coated Tablet 200mg/50mg	Kaletra is indicated in combination with other antiretroviral agents for the treatment of HIV-infection. This indication is based on analyses of plasma HIV RNA levels and CD4 cell counts in a controlled study of Kaletra of 48 weeks duration, and in smaller uncontrolled dose-ranging studies of Kaletra of 72 weeks (for oral solution) and 144-360 weeks (for tablets) duration. At present, there are no results from controlled trials evaluating the effect of Kaletra on clinical progression of HIV. Once daily administration of Kaletra has not been studied in therapy experienced patients.

BRU13021028P	Holoxan For Injection 1g	Holoxan is to be administered exclusively by physicians with experience in oncology. It is indicated in inoperable malignant tumours that are sensitive to ifosfamide, e.g. bronchial carcinoma, ovarian carcinoma, testicular tumours, soft-tissue sarcoma, breast cancer, pancreatic carcinoma, hypernephroma, endometrial carcinoma, malignant lymphomas. Special remark: Should during treatment with Holoxan a cystitis in connection with macro- or microhaematuria appear, Holoxan therapy has to be interrupted until normalization.
BRU13031029NP	Panadol Extend Caplet 665mg	Panadol Extend is a sustained release formulation that provides relief of muscle and joint pain such as backache, pain of osteoarthritis, rheumatic pain and muscular ache and pains. It is also suitable for fever, headache, migraine, period pain, toothache, pain after dental procedures, neuralgia, pain after vaccination, sore throat and the discomfort from colds and influenza.
BRU13031030P	Canesten Clotrimazole Cream 1% w/w	The confirmed indications for Canesten include: 1) All dermatomycoses due to dermatophytes (e.g. Tricophyton species) 2) All dermatomycoses due to yeast (Candida species) 3) Dermatomycoses due to moulds and other fungi 4) Skin diseases showing secondary infection with these fungi Examples of dermatomycoses listed under 1-4: interdigital mycoses (eg. Athlete's foot), paronychias (associated with nail-mycoses), mycoses in skin folds, candida vulvitis, candida balanitis, pityriasis versicolor, erythrasma.
BRU13031035P	Hydralazine Tablets 50mg	Hydralazine is an antihypertensive agent which acts predominantly by causing direct peripheral vasodilatation. Hydralazine tends to improve renal, uterine and cerebral blood flow and its effect on diastolic pressure is greater than its effect on the systolic pressure. It has a more marked effect on the standing than on the supine pressure. It is used for the treatment of moderate to severe hypertension usually in conjunction with a beta-adrenoceptor blocking agent (Beta blocker) and a thiazide diuretic.
BRU13031037P	Tracidol Capsule 50mg	For the management of moderate to severe pain.
BRU13031039NP	Infusol® S3	● Low salt syndrome ● Hypochloraemic alkalosis
BRU13031040P	Intril SR 1.5mg Tablets	Indapamide is indicated for the treatment of Essential hypertension.

BRU13031042P	Inox Capsule 100mg	Treatment of the following conditions:- Systemic mycoses: Systemic aspergillosis and candidiasis, cryptococcosis (including cryptococcal meningitis), histoplasmosis, sporotrichosis, paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or typical mycoses. Dermatological/opthalmological: Onychomycosis, pityriasis versicolor, dermatomycosis and oral candidiasis. Gynaecological: Vulvovaginal candidiasis
BRU13031043P	Doxycap Capsule 100mg	• Rickettsial infections, including typhus, Rocky mountain spotted fever and Q fever • Chlamydial infections, including psittacosis, lymphogranuloma venerum, trachoma and inclusion conjunctivitis • Mycoplasmal infections, especially those caused by Mycoplasma pneumonia • Brucellosis and plague (use in association with streptomycin) • Tularaemia, chronic bronchitis, chancroid, granuloma inguinale, urinary tract infections, acne • Malabsorption syndromes such as tropical sprue and Wipple's disease • Cholera, relapsing fever, leptospirosis and early stage of Lyme disease • Balantidiasis, amoebic dysentery (use in association with an amoebicide) • Syphilis, yaws, gonorrhoea, actinomycosis, anthrax, rat bite fever and acute necrotising ulcerative gingivitis.
BRU13031045P	Recormon Pre-Filled Syringe 2000IU/0.3ml	Recormon is indicated for: - Treatment of anemia associated with chronic renal failure (renal anemia) in patients on dialysis. - Treatment of symptomatic renal anemia in patients not yet undergoing dialysis. - Treatment of symptomatic anemia in adult patients with non-myeloid malignancies receiving chemotherapy. - Increasing the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported increased risk of thromboembolic events. Treatment should only be given to patients with moderate anemia (Hb 10 to 13 g/dl [6.2 to 8.1 mmol/l], no iron deficiency) if blood conserving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females; 5 or more units for males). * Deficiency is defined as an inappropriately low serum erythropoietin level in relation to the degree of anemia.
BRU13031046P	Leukeran Tablet 2mg	Leukeran is indicated in the treatment of Hodgkin's disease; certain forms of non-Hodgkin's lymphoma; Chronic lymphocytic leukaemia; Waldenstrom's macroglobulinaemia.

BRU13031047P	Recormon Pre-Filled Syringe 4000IU/0.3ml	Recormon is indicated for: - Treatment of anemia associated with chronic renal failure (renal anemia) in patients on dialysis. - Treatment of symptomatic renal anemia in patients not yet undergoing dialysis. - Treatment of symptomatic anemia in adult patients with non-myeloid malignancies receiving chemotherapy. - Increasing the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported increased risk of thromboembolic events. Treatment should only be given to patients with moderate anemia (Hb 10 to 13 g/dl [6.2 to 8.1 mmol/l], no iron deficiency) if blood conserving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females; 5 or more units for males). * Deficiency is defined as an inappropriately low serum erythropoietin level in relation to the degree of anemia.
BRU13031050P; BRU13031050PS2; BRU13031050PS3	Isentress 400mg Tablet	**Adults** ISENTRESS is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients. This indication is based on analyses of plasma HIV-1 RNA levels in three double-blind controlled studies of ISENTRESS. Two of these studies were conducted in clinically advanced, 3-class antiretroviral (NNRTI, NRTI, PI) treatment-experienced adults through 96 weeks and one was conducted in treatment-naïve adults through 240 weeks. The use of other active agents with ISENTRESS is associated with a greater likelihood of treatment response. **Pediatrics** ISENTRESS is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in children and adoloscents 2 years of age and older. This indication is based on the evaluation of safety, tolerability, pharmacokinetic parameters and efficacy of ISENTRESS through at least 24-weeks in a multi-center, open-label, noncomparative study in HIV-1 infected, treatment-experienced children and adoloscents 2 to 18 years of age (see VIId. Clinical Studies) The safety and efficacy of ISENTRESS have not been established in children less than 2 years of age.

BRU13041051P	Taxotere 80mg/4ml Concentrate For Solution For Infusion	Breast Cancer: TAXOTERE (docetaxel) in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with: • operable node-positive breast cancer. • operable node-negative breast cancer. For patients with operable node-negative breast cancer, adjuvant treatment should be restricted to patients eligible to receive chemotherapy according to internationally established criteria for primary therapy of early breast cancer (see section *Pharmacodynamic Properties*). TAXOTERE (docetaxel) in combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition. TAXOTERE (docetaxel) in combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. TAXOTERE (docetaxel) monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer in whom previous therapy has failed. Prior therapy should have included an anthracycline unless clinically contraindicated. Non-Small Cell Lung Cancer: TAXOTERE (docetaxel) is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer even after failure of platinum-based chemotherapy. TAXOTERE (docetaxel) in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer, in patients who have not previously received chemotherapy for this condition. TAXOTERE in combination with carboplatin represents a treatment option to cisplatin-based therapy. Ovarian Cancer: TAXOTERE (docetaxel) is indicated for the treatment of metastatic carcinoma of the ovary after failure of first-line or subsequent chemotherapy. Squamous Cell Carcinoma of the Head and Neck: TAXOTERE (docetaxel) is indicated as monotherapy in the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck after failure of a previous chemotherapy regimen. Prostate Cancer: TAXOTERE (docetaxel) in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostatic cancer. Gastric Adenocarcinoma: TAXOTERE (docetaxel) in combination with cisplatin and 5-fluorouracil is indicated for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease. Head and Neck Cancer: TAXOTERE (docetaxel) in combination with cisplatin and 5-fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

BRU13041052P	Fosamax Plus Tablet 70mg/5600IU	Fosamax Plus is indicated for: • Treatment of osteoporosis in postmenopausal women where vitamin D supplementation is recommended. FOSAMAX plus reduces the incidence of fractures, including those of the hip and spine (vertebral compression fractures). • Treatment of osteoporosis in men where vitamin D supplementation is recommended. The optimal duration of use of biphosphonates for the treatment of osteoporosis has not been determined. All patients on biphosphonates therapy should have the need for continued therapy reevaluated on a periodic basis.
BRU13041055P	Alpranax Tablet 0.5mg	Anxiety States: Symptoms include anxiety, tension, agitation, insomnia, apprehension, irritability and/or autonomic hyperactivity resulting in a variety of somatic complaints. Mixed Anxiety-Depression: Symptoms of both anxiety and depression occur simultaneously. Neurotic or Reactive Depression: Patients show a depressed mood or a pervasive loss of interest or pleasure. Symptoms include anxiety, psychomotor agitation and insomnia. Other characteristics are appetite disturbances, changes in weight, somatic complaints, cognitive disturbances, decreased energy, feeling of worthlessness or guilt or thoughts of death or suicide. Alprazolam should not be used in patients whose primary symptom of depression is psychomotor retardation; with a diagnosis of bipolar depression; with psychotic symptoms. Anxiety states, mixed anxiety-depression or neurotic depression associated with other diseases, e.g. the chronic phase of alcohol withdrawal and functional or organic disease, particularly certain gastrointestinal, cardiovascular or dermatological disorders. Alprazolam is also indicated for the treatment of panic disorder, with or without agoraphobia. The effectiveness of Alprazolam for long-term use exceeding 6 months has not been established. The physician should reassess the usefulness of the drug for the individual patient from time to time.
BRU13041056NP	Liquid Paraffin	When used externally: For occlusive emollient purpose of the skin. Also used as a lubricant. When used orally: Used as an emollient laxative to soften stools.
BRU13041058P	Pegasys Pre-Filled Syringe 180mcg/0.5ml	1) Pegasys is indicated in combination with other medicinal products, for the treatment of chronic hepatitis C (CHC) in patients with compensated liver disease. This includes patients with compensated cirrhosis and patients with HIV disease that is clinically stable (e.g. antiretroviral therapy not required or receiving stable antiretroviral therapy). The optimal way to use Pegasys in patients with chronic hepatitis C is in combination with ribavirin. The combination of Pegasys and ribavirin is indicated in naïve patients and patients who have failed previous treatment with interferon alpha (pegylated or non-pegylated) alone or in combination therapy with ribavirin. Monotherapy is indicated mainly in case of tolerance or contraindication to ribavirin. 2) Chronic Hepatitis B: Pegasys is indicated for the treatment of both HBeAg-positive and HBeAg-negative chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication and liver inflammation.

BRU13041059P	Borymycin Capsule 50mg	Borymycin Capsule is indicated in the treatment of the following infection caused by susceptible strains: Respiratory infections caused by *Mycoplasma pneumonia* ; Psittacosis due to *Chlamydia psittaci* ; Trachoma caused by *Chlamydia trachomatis* , although the infections is not always eliminated, as judged by immunofluorescence; Inclusion conjunctivitis caused by *Chlamydia trachomitis* ; Nongonocccal urethritis in adults caused by *Ureaplasma urealyticum* or *Chlamydia trachomatis* ; Chancroid due to *Haemophilus ducreyi* ; Chlolera caused by *Vibrio chlorae* . Minocycline is indicated for treatment of infections caused by the following gram-negative microorganism, when bacteriologic testing indicates appropriate susceptibility to the drug: *Escherichia coli; Enterobacter aurogenes; Shigella species: Acinetobacter species;* Respiratory tract infections caused by *Haemophilus influenza* ; Respiratory tract and urinary tract infections caused by *Klebsiella species* . Minocycline is indicated for treatment of infection caused by the following gram-positive microorganism, when bacteriologic testing indicates appropriate susceptibility to the drug: Upper respiratory tract infections caused by *Streptococcus pneumoniae* ; Skin and skin structure infections caused by Minocycline-sensitive organism; Uncomplicated urethritis in men due to *Neisseria gonnorheae* and for the treatment of other gonococcal infections when penicillin is contraindicated. Minocycline is an alternative drug in the treatment of the following infections: infections in women caused by *Neisseria gonorrhoea* ; Syphilis caused by *Treponema pallidum* ; Listeriosis due to *Listeria monocytogenes* ; Anthrax caused by *Bacillus anthracis* ; Infections caused by Clostridium species; In severe acne, Minocycline may be used as an adjunct therapy. Oral Minocyline is indicated in the treatment of asymptomatic carriers of *Neisseria meningitidis* to eliminate meningococci from the nasopharynx. It is recommended that prophylactic use of Minocycline be reserved for situations in which the risk of meningococcal meningitis is high. Oral Minocycline also has been used in the treatment of infections caused by *Mycobacterium marinum* .
BRU13041060P	Kytril Tablet 1mg	Kytril is indicated for the prevention of nausea and vomiting induced by cytostatic therapy.
BRU13041061NP	Venofer® Solution For Injection 100mg/5ml	Venofer is indicated for the treatment of iron deficiency in the following indications: • Where there is a clinical need for a rapid iron supply • In patients who cannot tolerate oral iron therapy or who are non-compliant • Where oral iron preparations are ineffective (e.g. In active inflammatory bowel disease) Venofer should only be administered where the indication is confirmed by appropriate investigations.
BRU13041062NP	Calamine Cream	Calamine has mild astringent and antipruritic actions and is used as a dusting powder, cream lotion or ointment in a variety of skin conditions although its value is uncertain.

BRU13041063P	Apuzin Tablet 25mg	Hypertension: It may be used alone or in combination with other antihypertensive agents, especially thiazide type diuretics. There is an additive effect on lowering blood pressure when combined Captopril and thiazide are used. Congestive heart failure: For patients who have not responded adequately to treatment with diuretics and digitalis. Following myocardial infarction. Diabetic nephropathy.
BRU13041064P	Lezpain Film-Coated Tablet 135mg	For the symptomatic treatment of abdominal pain and cramps, bowel disturbances and intestinal discomfort related to irritable bowel syndrome.
BRU13041067NP	White Soft Paraffin BP	For treatment of dry skin conditions.
BRU13041068NP	Calamine Lotion 15% w/v	Calamine has mild astringent and antipruritic actions and is used as a dusting powder, cream lotion or ointment in a variety of skin conditions although its value is uncertain.
BRU13061069P	Votrient™ Film-Coated Tablets 200mg	**Renal cell carcinoma (RCC)** Votrient is indicated for the treatment of patients with advanced and/or metastatic renal cell carcinoma (RCC). **Soft tissue sarcoma (STS)** Votrient is indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. The Phase III trial population excluded patients with gastrointestinal stromal tumor (GIST) or adipocytic STS.
BRU13061070PS1; BRU13061070PS2; BRU13061070PS3	NovoMix® 30 FlexPen® Suspension For Injection 100 U/ml	Treatment of patients with diabetes mellitus requiring insulin.

BRU13061071P	Duphaston Tablet 10mg	**Progesterone deficiencies** • Treatment of dysmenorrhoea • Treatment of endometriosis • Treatment of secondary amenorrhoea • Treatment of irregular cycles • Treatment of dysfunctional uterine bleeding • Treatment of pre-menstrual syndrome • Treatment of threatened abortion, associated with proven progesterone deficiency • Treatment of habitual abortion, associated with proven progesterone deficiency • Treatment of infertility due to luteal insufficiency • Luteal support as part of an Assisted Reproductive Technology (ART) treatment **Hormone replacement therapy** To counteract the effects of unopposed estrogen on the endometrium in hormone replacement therapy for women with disorders due to the natural or surgical induced menopause with an intact uterus.
BRU13061073P	Prednisolone Tablet 20mg	Prednisolone is a synthetic corticosteroid with predominantly glucocorticoid activity. It allows for a greater margin of safety than more potent agents. It is used for its anti-inflammatory and immune-suppressant glucocorticoid activity. It is indicated for allergic disorders such as bronchial asthma and allergic skin conditions, blood disorders, including auto-immune haemolytic anaemia and idiopathic thrombocytopenic purpurea, selected collagen and rheumatic disorders, connective tissue disorders such as arthritic and systemic lupus erythematosus, gastrointestinal disorders, hepatic disorders, neuromuscular disorders, selected ocular disorders, renal disorders and severe skin disorders.
BRU13061074P	Kytril For Infusion 3mg/3ml	Kytril is indicated for the prevention or treatment of nausea and vomiting induced by cytostatic therapy and for the prevention and treatment of post-operative nausea and vomiting.
BRU13061075P	Minison Tablet 1mg	Prazosin is indicated for the treatment of hypertension.

BRU13061076PS3	Xeloda™ Tablets 500mg	*Breast Cancer:* Xeloda in combination with docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. Xeloda is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of a taxane and an anthracycline-containing chemotherapy regimen or for whom further anthracycline therapy is not indicated. *Colorectal cancer:* Xeloda is indicated for the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. Xeloda is indicated for the treatment of metastatic colorectal carcinoma. *Gastric Cancer* Xeloda is indicated for first-line treatment of advanced gastric cancer in combination with a platinum-based regimen.
BRU13061079NP	Maltofer® Syrup	Treatment of iron deficiency without anaemia and iron deficiency anaemia. Prophylactic therapy of iron deficiency during pregnancy.
BRU13061080P	Noriday® Tablet	Contraception.
BRU13061081P	Keppra 250mg Film-Coated Tablet	Keppra is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy. Keppra is indicated as adjunctive therapy: • in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy. • in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy. Keppra Concentrate is an alternative for patients (adults and children from 4 years of age) when oral administration is temporarily not feasible.
BRU13061082P	Keppra 500mg Film-Coated Tablet	Keppra is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy. Keppra is indicated as adjunctive therapy: • in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy. • in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy. Keppra Concentrate is an alternative for patients (adults and children from 4 years of age) when oral administration is temporarily not feasible.

BRU13061083PS3; BRU13061083PS4; BRU13061083PS5	Avastin Concentrate For Solution For Infusion 400mg/16ml	***Metastatic carcinoma of the colon or rectum(mCRC)*** Avastin in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum. ***Metastatic Breast Cancer (mBC)*** Avastin in combination with paclitaxel is indicated for the treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer. Avastin in combination with capecitabine is indicated for first-line treatment of patients with HER2-negative metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate. Patients who have received taxane and anthracycline-containing regimens in the adjuvant setting within the last 12 months should be excluded from treatment with Avastin in combination with capecitabine. The effectiveness of Avastin in metastatic breast cancer (mBC) is based on an improvement in progression-free survival. Currently, no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Avastin in breast cancer. ***Non-Small Cell Lung Cancer (NSCLC)*** Avastin, in combination with carboplatin and paclitaxel, is indicated for first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic nonsquamous, non-small cell lung cancer. Avastin, in combination with erlotinib, is indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations. ***Malignant Glioma (WHO Grade IV) - Glioblastoma*** Avastin, as a single agent is indicated for the treatment of patients with glioblastoma after relapse or disease progression following prior therapy. The effectiveness of Avastin in glioblastoma is based on an improvement in objective response rate. There are no data demonstrating an improvement in disease-related symptoms or increased survival with Avastin. ***Advanced and/or metastatic Renal Cell Cancer (mRCC)*** Avastin in combination with interferon alfa-2a is indicated for first-line treatment of patients with advance and/or metastatic renal cell cancer. ***Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer*** Avastin, in combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (FIGO stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. Avastin, in combination with carboplatin and gemcitabine or in combination with carboplatin and paclitaxel is indicated for the treatment of patients with recurrent, platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer who have not received prior bevacizumab or other VEGF-targeted angiogenesis inhibitors. Avastin in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin is indicated for the treatment of patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents. ***Cervical Cancer*** Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU13061084PS2	Xeloda Tablet 150mg	*Breast Cancer:* Xeloda in combination with docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. Xeloda is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of a taxane and an anthracycline-containing chemotherapy regimen or for whom further anthracycline therapy is not indicated. *Colorectal cancer:* Xeloda is indicated for the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. Xeloda is indicated for the treatment of metastatic colorectal carcinoma. *Gastric Cancer* Xeloda is indicated for first-line treatment of advanced gastric cancer in combination with a platinum-based regimen.
BRU13061085P	Uripax Film-Coated Tablet 200mg	Symptomatic relief of dysuria, vesical suprapubic pain, nocturia, frequency & incontinence associated with cystitis, prostatitis, urethritis & urethrotrigonitis. Relief of vesico-urethral spasm due to catheterisation, cytoscopy or indwelling catheters & sequelae or surgical intervention of the lower urinary tract.
BRU13061087P	Elonva Solution For Injection 150mcg/0.5ml	Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program.
BRU13061088P	Maxitrol Eye Ointment	MAXITROL® combines two antibiotics, neomycin sulfate and polymyxin B sulfate, offering broad spectrum antibacterial activity with the anti-inflammatory activity of a corticosteroid, dexamethasone, for combating certain microbial infections of the anterior segment of the eye(s). The suspension also contains hypromellose for maximum effectiveness and comfort. MAXITROL® is indicated for ocular inflammation when concurrent use of an antimicrobial is judged necessary.

BRU13061090P	Ciproxol Intravenous Infusion BP 0.2% w/v	Treatment of the following infections caused by organism strains: - **Lower Respiratory Tract Infections** caused by *Escherichia coli, Klebsiella pneumonia, Enterobacter cloacae, Proteus mirabilis* and *pseudomonas aeruginosa* . - **Urinary Tract Infections** caused by E*scherichia coli, Klebsiella pneumonia, Enterobacter cloacae, Proteus mirabilis, Providencia rettgeri, Morganella morganii, Citrobacter freundii, Citrobacter diversu* and *pseudomonas aeruginosa* . - **Skin and Soft Tissue Infections** caused by *Escherichia coli, Klebsiella pneumonia, Enterobacter cloacae, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Morganella morganii, Citrobacter freundii, pseudomonas aeruginosa, Staphylococcus aureus* and *Staphylococcus epidermidis* (methicillin-resistant strains). In the last case, concomitant treatment with another antibiotic is suggested, in order to prevent organism resistance to ciprofloxacin. - **Gastrointestinal Tract Infections** caused by multiresistant gram-negative organisms, in combination with an antibiotic against anaerobes. - **Bone and Joint Infections** caused by *Enterobacter aeruginosa, Serratia marcescens, Pseudomonas aeruginosa* , and *Enterobacter spp.* in general. Other severe / complicated infections, patients with sepsis or neutropenia, Ps. Aeruginosa infections.
BRU13061091NP	Infusol® W Intravenous Infusion BP	Sterilised water for injection is generally used as diluents for other drugs.
BRU13061092P	Isoket Ampoule 10mg/10ml	Indicated in the treatment of unresponsive left ventricular failure secondary to acute myocardial infarction, unresponsive left ventricular failure of various aetiology and severe or unstable angina pectoris.
BRU13061095NP	Vitamin B1 Tablet	Thiamine is used in the treatment and prevention of thiamine deficiency.
BRU13071099P	Champix 1mg Film-Coated Tablet	Varenicline is indicated for smoking cessation.
BRU13071100P	Iodosorb Ointment	Iodosorb ointment is indicated for the topical treatment of chronic exuding wounds.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU13071101P	Glucophage XR 500mg Extended Release Tablet	o Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with IGT* and/or IFG* who are: ▪ at high risk for developing overt type 2 diabetes mellitus (see section 5.1) and ▪ not suitable for intensive lifestyle modifications. Treatment with Glucophage XR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk (see section 5.1). *IGT: Impaired Glucose Tolerance; IFG: Impaired Fasting Glucose o Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. Glucophage XR may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.
BRU13071104P	Gonal-F Powder And Solvent For Solution For Injection 75IU (5.5mcg)/ Vial	In adult women • Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. • Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as *in vitro* fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer.
BRU13071108PS1; BRU13071108PS2	Revlimid® Capsules 25mg	Revlimid® (lenalidomide) in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
BRU13071109PS1; BRU13071109PS2	Revlimid® Capsules 15mg	Revlimid® (lenalidomide) in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
BRU13071111P	Micosten-H Cream	Infections of the skin by dermatophytes or *Candida sp* . in which inflammatory symptoms are prominent. Particularly indicated for the initial stages of treatment may be continued with Micosten-H Cream. May also be used for mycotic infections with bacterial superinfection.

BRU13071114P	Sandimmun Neoral Capsule 25mg	**Transplantation indications** **Solid organ transplantation** Prevention of graft rejection following kidney, liver, heart, combined heart-lung, lung or pancreas allogeneic transplantations. Treatment of transplant rejection in patients previously receiving other immunosuppressive agents. **Bone marrow transplantation** Prevention of graft rejection following bone marrow transplantation. Prevention or treatment of graft-versus-host disease (GVHD). **Non-transplantation indications** **Endogenous uveitis** Active sight-threatening intermediate or posterior uveitis of non-infectious aetiology in patients where conventional therapy fails, or causes unacceptable side effects. Behçet uveitis with repeated inflammatory attacks involving the retina. **Nephrotic syndrome** Steroid-dependent and steroid-resistant nephrotic syndrome in adults and children, due to glomerular diseases such as minimal change nephropathy, focal and segmental glomerulosclerosis, or membranous glomerulonephritis. Sandimmun Neoral can be used to induce remissions and to maintain them. It can also be used to maintain steroid-induced remission, allowing withdrawal of steroids. **Rheumatoid arthritis** Treatment of severe, active rheumatoid arthritis. **Psoriasis** Treatment of severe psoriasis in patients in whom conventional therapy is ineffective or inappropriate.
BRU13081115P	Champix 0.5mg & 1mg Tablet	Varenicline is indicated for smoking cessation.

BRU13081120P	Enbrel® 25mg Solution For Injection In Pre-Filled Syringe	*Rheumatoid arthritis* Treatment of signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis. Enbrel can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. *Polyarticular juvenile idiopathic arthritis* Treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Enbrel has not been studied in children aged less than 2 years. *Psoriatic arthritis* Enbrel is indicated for reducing signs and symptoms of active arthritis in patients with psoriatic arthritis. Enbrel can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. *Axial Spondyloarthritis* *Ankylosing spondylitis* Treatment of active ankylosing spondylitis in adults. *Non-radiographic axial spondyloarthritis* Treatment of adults with active* non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs NSAIDs). *Active disease is defined as a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of ≥4. *Plaque psoriasis* Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA. *Pediatric plaque psoriasis* Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.
BRU13081122P	Requip® Tablet 1mg	REQUIP® is indicated for the treatment of idiopathic Parkinsons's disease: • REQUIP may be used alone (without levodopa[L-Dopa]) in the treatment of idiopathic Parkinson's disease; • Addition of REQUIP to levodopa may be used to control "on-off" fluctuations and permit a reduction in the total daily dose of L-Dopa.
BRU13081124P	Heparinol 5000IU/ml	Heparin is indicated for prophylaxis and treatment of thrombo-embolic disorders such as thrombophlebitis, pulmonary embolism, myocardial infarction, arterial embolism and other occlusive vascular disease. It is also used to prevent thrombo-embolic complication from cardiac and vascular surgery, dialysis, frostbite and other perfusion procedures. Heparin is also used as anticoagulant in blood transfusions and for laboratory purposes.
BRU13081125P	Pharmaniaga Pyrazinamide Tablet 500mg	Indicated in combination with other antituberculars, in the treatment of tuberculosis after failure with the primary medications. It is effective only against mycobacteria.

BRU13081127P	Ketovid Shampoo 2% w/v	Treatment and prophylaxis of infections in which the yeast Malassezia (previously called Pityrosporum) is involved, such as pityriasis versicolor (localised), seborrhoeic dermatitis and pityriasis capitis (dandruff).
BRU13081128P	Maxitrol Eye Drops	MAXITROL® combines two antibiotics, neomycin sulfate and polymyxin B sulfate, offering broad spectrum antibacterial activity with the anti-inflammatory activity of a corticosteroid, dexamethasone, for combating certain microbial infections of the anterior segment of the eye(s). The suspension also contains hypromellose for maximum effectiveness and comfort. MAXITROL® is indicated for ocular inflammation when concurrent use of an antimicrobial is judged necessary.
BRU13091130P	Erbitux® 5mg/ml Solution For Infusion	Erbitux® is indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer • in combination with irinotecan-based chemotherapy or continuous infusional 5-fluorouracil/folinic acid plus oxiplatin; • as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. Erbitux® is indicated for the treatment of patients with squamous cell cancer of the head and neck • in combination with radiation therapy for locally advanced disease; • in combination with platinum-based chemotherapy for recurrent and/or metastatic disease.
BRU13091132NP	Beafort Syrup	It is a Vitamin B supplement.
BRU13091133P	Clexane 4000 IU (40mg)/0.4ml	Enoxaparin sodium is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prevention of thrombus formation in extracorporeal circulation during hemodialysis. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure , respiratory insufficiency, severe infection or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent Percutaneous Coronary Intervention (PCI).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU13091135P	Iodosorb Powder	For the topical treatment of chronic exuding wounds.
BRU13091136P	Anlodin Tablet 10mg	Amlodipine is indicated in the treatment of hypertension and, in most cases, can be used as monotherapy. Patients insufficiently controlled with a single antihypertensive e.g. thiazide diuretic, beta-blockers or angiotensin-converting enzyme inhibitors, may benefit from the addition of amlodipine. Amlodipine can also be used as first line treatment of myocardial treatment of myocardial ischemia, both in cases of fixed obstruction (stable angina), and/or in cases following vasoconstriction or vasospasm (Prinzmetal's angina or variant angina). Amlodipine can therefore be used in cases where the clinical picture suggests a possible vasospastic component even if there is no confirmation of this clinical situation. Amlodipine can used alone or in combination with other anti-angina drugs, in patients suffering from angina who do not respond to nitrates or adequate doses of beta-blockers.
BRU13091138P	Clexane 6000 IU (60 mg)/0.6ml	Enoxaparin sodium is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prevention of thrombus formation in extracorporeal circulation during hemodialysis. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure , respiratory insufficiency, severe infection or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent Percutaneous Coronary Intervention (PCI).
BRU13091140P	Camazol Tablet 5mg	It is used for the treatment of thyrotoxicosis, Grave's disease and in the preparation of subtotal thyroidectomy.
BRU13091142NP	Sulbumin 200 Capsule	Symptomatic treatment of all forms of function asthenia.
BRU13091143P	Velcade® 3.5 mg For Injection (Sterile Lyophilized Powder)	VELCADE is indicated for the treatment of patients with multiple myeloma. VELCADE is indicated for the treatment of patients with mantle cell lymphoma.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU13091144P	Bezamidin Tablet 200mg	Bezamidin Tablet is used with conjunction with dietary and lifestyle modification in the treatment of all types of hyperlipoproteinaemia responsive to drug therapy (types IIa, IIb, III, IV and V). It is also indicated in the treatment of secondary hyperlipidaemias associated with an underlying disorder (e.g. Diabetes mellitus), when treatment of the underlying disorder does not result in adequate control of the hyperlipidaemic state.
BRU13091145NP	A-Bite Cream	For the relief of itch due to mosquitoes and other insects bites.
BRU13101149P	Erycin Film Coated Tablet 250mg	Upper and lower respiratory tract infections, skin and soft tissues infections, ear and oral infections.
BRU13101151NP	ENO Fruit Salt Lemon	Indicated for the symptomatic relief of acid indigestion, flatulence and stomach discomfort.
BRU13101152P	Hycamtin™ Injection 1mg	Hycamtin is indicated for the treatment of: • metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy. • small cell lung cancer sensitive disease after failure of first-line chemotherapy. In clinical studies submitted to support approval, sensitive disease was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the Phase III study) or at least 90 days (in the Phase II studies) after chemotherapy. Hycamtin in combination with cisplatin is indicated for the treatment of patients with histologically confirmed Stage IV-B, recurrent, or persistent carcinoma of the cervix, which is not amenable to curative treatment with surgery and/or radiation therapy. For efficacy data see *Clinical Studies* .

BRU13101153P	Clexane 2000 IU (20mg)/0.2ml	Enoxaparin sodium is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prevention of thrombus formation in extracorporeal circulation during hemodialysis. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure , respiratory insufficiency, severe infection or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent Percutaneous Coronary Intervention (PCI).
BRU13101154P	Axcel Mefenamic Acid Suspension	Relief of mild to moderate pain including headache, dental pain, postoperative pain and dysmenorrhea; in musculoskeletal and joint disorders such as osteoarthritis and rheumatoid arthritis and in children with fever and juvenile rheumatoid arthritis.
BRU13101155P	Ovidrel Solution For Injection 250mcg/0.5ml In Pre-filled Pen	Ovidrel® is indicated in the treatment of • Women undergoing superovulation prior to assisted reproductive technologies (ART) such as in vitro fertilisation (IVF): Ovidrel® is administered to trigger final follicular maturation and luteinisation after stimulation of follicular growth, • Anovulatory or oligo-ovulatory women: Ovidrel® is administered to trigger ovulation and luteinisation in anovulatory or oligo-ovulatory patients after stimulation of follicular growth.

BRU13101156P	Sandimmun Neoral Capsule 100mg	**Transplantation indications** **Solid organ transplantation** Prevention of graft rejection following kidney, liver, heart, combined heart-lung, lung or pancreas allogeneic transplantations. Treatment of transplant rejection in patients previously receiving other immunosuppressive agents. **Bone marrow transplantation** Prevention of graft rejection following bone marrow transplantation. Prevention or treatment of graft-versus-host disease (GVHD). **Non-transplantation indications** **Endogenous uveitis** Active sight-threatening intermediate or posterior uveitis of non-infectious aetiology in patients where conventional therapy fails, or causes unacceptable side effects. Behçet uveitis with repeated inflammatory attacks involving the retina. **Nephrotic syndrome** Steroid-dependent and steroid-resistant nephrotic syndrome in adults and children, due to glomerular diseases such as minimal change nephropathy, focal and segmental glomerulosclerosis, or membranous glomerulonephritis. Sandimmun Neoral can be used to induce remissions and to maintain them. It can also be used to maintain steroid-induced remission, allowing withdrawal of steroids. **Rheumatoid arthritis** Treatment of severe, active rheumatoid arthritis. **Psoriasis** Treatment of severe psoriasis in patients in whom conventional therapy is ineffective or inappropriate.
BRU13101158P	Endoxan Tablet 50mg	Endoxan is used within a combination chemotherapy regimen or as monotherapy in • **Leukaemias**: acute or chronic lymphocytic and myelogenous leukaemias • **Malignant lymphomas**: Hodgkin's disease, non-Hodgkin's lymphomas, plasmacytoma • **Metastasizing and non-metastasizing malignant solid tumours**: ovarian cancer, testicular cancer, breast cancer, small cell lung cancer, neuroblastoma, Ewing's sarcoma • **Progressive 'autoimmune diseases**': eg. Rheumatoid arthritis, psoriatic arthropathy, systemic lupus erythematosus, scleroderma, systemic vasculitides (eg. With nephrotic syndrome), certain types of glomerulonephritis (eg. with nephrotic syndrome), myasthenia gravis, autoimmune haemolytic anaemia, cold agglutinin diseases. • **Immunosuppressive treatment in organ transplantations**.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU13101159P	CEF-4® Injection 500mg	CEF-4® is used in the treatment of susceptible infections including:- - Lower Respiratory Tract Infections - Urinary Tract Infections - Skin and Soft Tissue Structure Infections - Bacterial Septicemia - Bone and Joint infections - Gynecological infections, including endometritis, pelvic cellulitis and other infections of the female genital tract - Intraabdominal infections - CNS infections - Severe and life-threatening infections
BRU13101160P	Premarin Tablet 0.625mg	1. Moderate to severe vasomotor symptoms associated with estrogen deficiency. 2. Prevention and management of osteoporosis associated with estrogen deficiency. When prescribing solely for the prevention of postmenopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and for whom non-estrogen medications are not considered to be appropriate. When prescribing solely for the management of post-menopausal osteoporosis, nonestrogen medications should be first considered. 3. Atrophic vaginitis and atrophic urethritis. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered. 4. Female hypoestrogenism. ERT and HRT should not be initiated or continued to prevent coronary heart disease (see also Cardiovascular risk and section DEMENTIA) The benefits and risks of ERT and HRT must always be carefully weighed, including consideration of the emergence of risks as therapy continues (see SPECIAL WARNINGS). Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman. In the absence of comparable data, the risks of HRT should be assumed to be similar to all estrogens and estrogen/progestin combinations.
BRU13101161PS1; BRU13101161PS2	Revlimid® Capsules 10mg	Revlimid® (lenalidomide) in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
BRU13101162P	Pharmaniaga Cephalexin Suspension 125mg	Cephalexin is used to treat septicaemia, bone and joint infections, including burn wound infections and urinary tract infections caused by susceptible bacterial organisms. They are not effective in treating meningitis. Cephalexin is used as a possible alternative to the penicillins for staphylococcus and nonenterococcal streptococcal infections including pneumonia, bone and joint infections, and bacterial endocarditis.
BRU13121167P	Copastin Film Coated Tablet 10mg	For unproductive cough induced by common cold, acute and chronic bronchitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU13121168P	Ucort Cream	For the treatment of all dry ichthyotic, eczematous conditions of the skin, including atopic, infantile, chronic allergic and irritant eczema, asteatotic, hyperkeratotic and lichenified eczema, neurodermatitis and prurigo.
BRU13121169P	Pradaxa® Hard Capsules 150mg	Reduction of the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.
BRU13121170P	Pradaxa® Hard Capsules 110mg	Primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery. Reduction of the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.
BRU13121172NP	Dianeal Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution With 1.5% Dextrose	Ambu-Flex Container: Dianeal Low Calcium Peritoneal Dialysis Solutions are indicated for use in chronic renal failure patients being maintained on peritoneal dialysis. Ultrabag Container: Dianeal Low Calcium Peritoneal Dialysis Solutions in Ultrabag containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.
BRU13121174P	Temodal Capsules 100mg	• Newly diagnosed glioblastoma multiforme concomitantly with radiotherapy & subsequently as monotherapy treatment. • Malignant glioma such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.
BRU13121177P	Cyclogyl® 1% Sterile Ophthalmic Solution	For mydriasis and cycloplegia in diagnostic procedures.
BRU13121178P	Betawin Tablet 50mg	Hypertension, angina pectoris, suspected or definite myocardial infarction, migraine prophylaxis.
BRU13121179P	Imigran FD Tablets 50mg	Sumatriptan fast disintegrating tablets are indicated for the acute relief of migraine attacks with or without aura, including the acute treatment of migraine attacks associated with the menstrual period in women.
BRU13121180P; BRU13121180PS2	Glucovance Tablet 500mg/5mg	Glucovance 500mg/5mg is indicated as second-line therapy when diet, exercise and initial treatment with a sulfonylurea or metformin do not result in adequate glycaemic control in patients with type 2 diabetes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU13121182P	Hycamtin Injection 4mg	Hycamtin is indicated for the treatment of: • metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy. • small cell lung cancer sensitive disease after failure of first-line chemotherapy. In clinical studies submitted to support approval, sensitive disease was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the Phase III study) or at least 90 days (in the Phase II studies) after chemotherapy (*see Clinical Studies Section*). Hycamtin in combination with cisplatin is indicated for the treatment of patients with histologically confirmed Stage IV-B, recurrent, or persistent carcinoma of the cervix, which is not amenable to curative treatment with surgery and/or radiation therapy. For efficacy data see *Clinical Studies* .
BRU13121187NP	B. Braun 10% Glucose Intravenous Infusion B.P.	- Administration of glucose for caloric support - Therapy of hypoglycaemia - Vehicle solution for compatible medicinal products
BRU13121192NP	Nutriflex Lipid Peri Emulsion For Infusion	Supply of energy, essential fatty acids, amino acids, electrolytes and fluids during parenteral nutrition for patients with mild to moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.
BRU14011193PS1	Alimta 500mg Powder For Solution For Infusion	<u>Malignant pleural mesothelioma</u> ALIMTA in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. <u>Non-small cell lung cancer</u> ALIMTA in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. ALIMTA is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. ALIMTA is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. ALIMTA in combination with pembrolizumab and platinum chemotherapy, is indicated for the first line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.
BRU14011197NP	Axcel Eviline Forte Suspension	Eviline Forte is an antacid / deflatulent for symptomatic treatment of peptic ulcer, dyspepsia of functional or organic origin, heartburn in hiatus hernia or pregnancy, flatulence and abdominal distension, gastension, gastritis oesophagitis and other conditions where hyperacidity or flatulence may be present.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14011198NP	Bepanthen® First Aid Cream	Bepanthen® First Aid is used for the treatment of: • Superficial / minor wounds of any kind when there is a risk of infection: e.g. abrasions, small cuts, scratches, fissures, rhagades, mild burns, sores and ulcers. • Infected skin irritations. • Skin damage & external surgical wounds, in minor surgery.
BRU14011199NP; BRU14011199NPS2	Dextrose 5% And Sodium Chloride 0.9% Injection USP	Dextrose and Sodium Chloride Injection is indicated as a source of water, electrolytes, and calories.
BRU14011200NP	Macgel® Tablet	Hyperacidity, peptic and duodenal ulcer, gastritis, flatulence.
BRU14011203P	Betaserc 24mg Tablet	Meniere's syndrome as defined by the following core symptoms: Vertigo (with nausea/vomiting), hearing loss (hardness of hearing) and tinnitus (ringing in the ears). Symptomatic treatment of vestibular vertigo.
BRU14011204P	Humalog Mix50 100 Units/ml Kwikpen	Treatment of patient with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis.
BRU14011206P	Seretide™ Evohaler™ 25/50mcg	**Asthma (Reversible Obstructive Airways Disease)** *SERETID* E is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and a This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** *SERETIDE* is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU14011207PS1	Tobrex® Eye Drops Solution	Tobrex® Opthalmic Solution is a topical antibiotic indicated in the treatment of external infections of the eye and its adnexa caused by susceptible bacteria. Appropriate monitoring of bacterial response to topical antibiotic therapy should accompany the use of Tobrex® Ophthalmic Solution. Clinical studies have shown tobramycin to be safe and effective for use in children.

BRU14011208P	Pneumovax 23	Pneumovax 23 is indicated for vaccination against pneumococcal disease caused by those pneumococcal types included in the vaccine. Effectiveness of the vaccine in the prevention of pneumococcal pneumonia and pneumococcal bacteremia has been demonstrated in controlled trials in South Africa, France and in case-controlled studies. Pneumovax 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine. If it is known that a person has not received any pneumococcal vaccine or if earlier pneumococcal vaccination status is unknown, then persons in the categories listed below should be administered pneumococcal vaccine; however, if a person has received a primary dose of pneumococcal vaccine, before administering an additional dose of vaccine, please refer to the Revaccination section. Vaccination with Pneumovax 23 is recommended for selected individuals as follows: *Immunocompetent persons* : routine vaccination for persons 50 years of age or older persons aged ≥ 2years with chronic cardiovascular disease (including congestive heart failure and cardiomyopathies), chronic pulmonary disease (including chronic obstructive pulmonary disease and emphysema), or diabetes mellitus persons aged ≥ 2years with alcoholism, chronic liver disease (including cirrhosis) or cerebrospinal fluid leaks persons aged ≥ 2years with functional or anatomic asplenia (including sickle cell disease and splenectomy) persons aged ≥ 2years living in special environments or social settings (including Alaskan Natives and certain American Indian populations) *Immunocompromised persons* : persons aged ≥ 2years, including those with HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure or nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids); and those who have received an organ or bone marrow transplant (for selected groups, see indications and usage, Timing of Vaccination). Pneumovax 23 may not be effective in preventing infection resulting from basilar skull fracture or from external communication with cerebrospinal fluid.

BRU14011209P	Neupogen Pre-Filled Syringe 30MU/0.5ml	*Established cytotoxic chemotherapy* Neupogen is indicated for reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia and its clinical sequelae in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia (see section 2.5.3 Paediatric Use). *Peripheral blood progenitor cell mobilisation (PBPC)* Neupogen is indicated for the mobilisation of autologous peripheral blood progenitor cells alone, or following myelosuppressive chemotherapy and the mobilisation of peripheral blood progenitor cells in normal donors (allogenic PBPC). *Severe chronic neutropenia (SCN)* Long term administration of Neupogen is indicated in patients, children or adults, with severe congenital, cyclic or idiopathic neutropenia with an Absolute Neutrophil Count (ANC) ≤ 0.5x109/l, and a history of severe or recurrent infections, to increase neutrophil counts and to reduce the incidence and duration of infection-related events. *HIV infection* Neupogen is indicated for the treatment of persistent neutropenia ((ANC) ≤ 1.0 x109/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections, when other options to manage neutropenia are inappropriate.
BRU14011212P	Axcel Chlorpheniramine-4 Syrup	For allergic conditions including hay fever, urticaria, angioedema, vasomotor rhinitis, allergic eczema, atopic and contact dermatitis, drug and serum reactions, insect bites and pruritus.

BRU14021215P	Havrix 1440 Vaccine	Havrix is indicated for active immunization against hepatitis A virus (HAV) infection in subjects at risk of exposure to HAV. Havrix will not prevent hepatitis infection caused by other agents such as hepatitis B virus, hepatitis C, hepatitis E virus or other pathogens known to infect the liver. In areas of low to intermediate prevalence of hepatitis A, immunisation with Havrix is particularly recommended in subjects who are, or will be, at increased risk of infection such as: • Travellers. Persons travelling to areas where the prevalence of hepatitis A is high. The areas include Africa, Asia, the Mediterranean basin, the Middle East, Central and South America. • Armed Forces. Armed Forces personnel who travel to higher endemicity areas or to areas where hygiene is poor have an increased risk of HAV infection. Active immunisation is indicated for these individuals. • Persons for whom hepatitis A is an occupational hazard or for whom there is an increased risk of transmission. These include employees in day-care centres, nursing, medical and paramedical personnel in hospitals and institutions, especially gastroenterology and paediatric units, sewage workers, food handlers, among others. • Persons at increased risk due to their sexual behaviour. Homosexuals, persons with multiple sexual partners. • Haemophiliacs. • Abusers of Injectable Drugs. • Contacts of Infected Persons. Since virus shedding of infected persons may occur for a prolonged period, active immunisation of close contacts is recommended. • Persons who require protection as part of hepatitis A outbreak control or because of regionally elevated morbidity. • Specific population groups known to have a higher incidence of hepatitis A. For example American Indians, Eskimos, recognised community-wide HAV epidemics. • Subjects with chronic liver disease or who are at risk of developing chronic liver disease (e.g. Hepatitis B (HB) and Hepatitis C(HC) chronic carriers and alcohol abusers). In areas of intermediate to high prevalence of hepatitis A (e.g. Africa, Asia, the Mediterranean basin, the Middle East, Central and South America) susceptible individuals may be considered for active immunisation.
BRU14021216P	Co-Plavix® 75/100 Film-Coated Tablets	CoPlavix is indicated for the secondary prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). CoPlavix is a fixed-dose combination medicinal product for continuation of therapy in: • Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction) including patients undergoing a stent placement following percutaneous coronary intervention • ST segment elevation acute myocardial infarction in medically treated patients eligible for thrombolytic therapy For further information please refer to *Pharmacodynamic properties* .

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14021217P	Votrient™ Film-Coated Tablets 400mg	**Renal cell carcinoma (RCC)** Votrient is indicated for the treatment of patients with advanced and/or metastatic renal cell carcinoma (RCC). **Soft tissue sarcoma (STS)** Votrient is indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. The Phase III trial population excluded patients with gastrointestinal stromal tumor (GIST) or adipocytic STS.
BRU14021219PS1; BRU14021219PS2; BRU14021219PS3	Novorapid® Flexpen® 100IU/ml	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.
BRU14021220P	Omelon Enteric Microencapsulated Capsule 20mg	Treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy treatment of reflux oesophagitis, Zollinger-Ellison syndrome, eradication of Helicobacter pylori and long term treatment for recurrent duodenal ulcer.
BRU14021223P	Invega® Sustenna Prolonged Release Suspension For Intramuscular Injection 50mg/0.5ml	INVEGA SUSTENNA is indicated for the acute and maintenance treatment of schizophrenia in adults. INVEGE SUSTENNA is indicated for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.
BRU14021224P	Invega® Sustenna Prolonged Release Suspension For Intramuscular Injection 75mg/0.75ml	INVEGA SUSTENNA is indicated for the acute and maintenance treatment of schizophrenia in adults. INVEGE SUSTENNA is indicated for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.
BRU14021225P	Invega® Sustenna Prolonged Release Suspension For Intramuscular Injection 100mg/1.0ml	INVEGA SUSTENNA is indicated for the acute and maintenance treatment of schizophrenia in adults. INVEGE SUSTENNA is indicated for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.
BRU14021230NP	Axcel Eviline Tablet	Axcel Eviline is an antacid/deflatulent for symptomatic treatment of peptic ulcer, dyspepsia of functional or organic origin, heartburn in hiatus hernia or pregnancy, flatulence and abdominal distension, gastritis oesophagitis and other conditions where hyperacidity or flatulence may be present.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14021231P	Axcel Loratadine Syrup	Relief of symptoms associated with allergic rhinitis eg. Sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching & burning, chronic urticaria and other allergic dermatologic disorders.
BRU14021232P	Cymbalta Capsule 30mg	Treatment of major depressive disorder. Management of neuropathic pain associated with diabetic peripheral neuropathy in adults. Treatment of generalised anxiety disorder.
BRU14021233P	Tykerb™ Tablets 250mg	TYKERB is indicated in combination with: • capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. Limitations of Use: Patients should have disease progression on trastuzumab prior to initiation of treatment with TYKERB in combination with capecitabine. • letrozole for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated. TYKERB in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.
BRU14021235P	Dostinex Tablet 0.5mg	1. Inhibition/Suppression of Physiological Lactation • Inhibition of physiological lactation soon after parturition • Suppression of established lactation 2. Treatment of Hyperprolactinaemic Disorders
BRU14021236NP; BRU14021236NPS2	Lactated Ringer’s Injection USP	Lactated Ringer's Injection USP is indicated as a source of water and electrolytes or as an alkalinizing agent.

BRU14021237P	Imuran 50mg Tablet	Azathioprine is used as an immunosuppressant antimetabolite either alone or, more commonly, in combination with other agents (usually corticosteroids) and procedures which influence the immune response. Therapeutic effect may be evident only after weeks or months and can include a steroid-sparing effect, thereby reducing the toxicity associated with high dosage and prolonged usage of corticosteroids. Azathioprine, in combination with corticosteroids and/or other immunosuppressive agents and procedures, is indicated to enhance the survival of organ transplants, such as renal transplants, cardiac transplants and hepatic transplants. It also reduces the corticosteroid requirements of renal transplant recipients. Azathioprine, either alone or more usually in combination with corticosteroids and/or other drugs and procedures, has been used with clinical benefit (which may include reduction of dosage or discontinuation of corticosteroids) in a proportion of patients suffering from the following: • Severe rheumatoid arthritis • Systemic lupus erythematosus • Dermatomyositis and polymyositis • Auto-immune chronic active hepatitis • Pemphigus vulgaris • Polyarteritis nodosa • Auto-immune haemolytic anaemia • Chronic refractory idiopathic thrombocytopenic purpura
BRU14021238NP	Axcel Dicyclomine-S Syrup	Relief of gastro-intestinal colic, flatulence & abdominal discomfort due to entrapped gas.
BRU14021239P	Humulin R Injection 100IU/ml	For the treatment of patients with diabetes mellitus for whom diet and/or oral agents are not sufficient.
BRU14021240NP	5% Dextrose And 0.45% Sodium Chloride Injection, USP	Dextrose and Sodium Chloride Injection is indicated as a source of water, electrolytes and calories.
BRU14021241P	Giona Easyhaler 200mcg/Dose Inhalation Powder	Treatment of mild, moderate and severe asthma.
BRU14021243NP	Neurobion Tablet	It is indicated for nerve pain expressed in one or more of the following symptoms: pricking/tingling sensation, numbness, muscle stiffness, muscle cramp, impaired sensation.
BRU14021244P	Gastrazole Omeprazole For Injection 40mg/Vial	Treatment of duodenal and gastric ulcer, NSAID-associated gastric acid and duodenal ulcers or erosions, Helicobacter pylori eradication in peptic ulcer disease, reflux oesophagitis, symptomatic gastro-oesophageal reflux disease, acid related dyspepsia and Zollinger-Ellison syndrome.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14021245P	Keppra Concentrate For Solution For Infusion 500mg/5ml	Keppra is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy. Keppra is indicated as adjunctive therapy • in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy. • in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • in the treatment of primary generalised tonic-clonic seizures in adults and children from 12 years of age with Idiopathic Generalised Epilepsy. Keppra Concentrate is an alternative for patients (adults and children from 4 years of age) when oral administration is temporarily not feasible.
BRU14021246P	Imojev Japanese Encephalitis Vaccine (Live, Attenuated)	IMOJEV is indicated for prophylaxis of Japanese encephalitis caused by the Japanese encephalitis virus, in persons from 9 months of age and over.
BRU14021247P	Pradaxa® Hard Capsules 75mg	Primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.
BRU14021248P	Axcel Flemin Expectorant	Relief of cough & alleviate nasal & bronchial congestion.

BRU14031249P	Tygacil (Tigecycline) 50mg Lyophilised Powder For Intravenous Infusion	Tigecycline is indicated for the treatment of the following infections caused by susceptible strains of the designated microorganisms in the conditions listed below for patients 18 years of age and older: Complicated skin and skin structure infections caused by *Escherichia coli, Enterococcus faecalis* (vancomycin-susceptible isolates only), *Staphylococcus aureus* (methicillin-susceptible and –resistant isolates), *Streptococcus agalactiae, Streptococcus anginosus* grp. (includes *S. anginosus, S. intermedius, and S. constellatus*), *Streptococcus pyogenes, Enterobacter cloacae, Klebsiella pneumoniae* , and *Bacteroides fragilis* . Complicated intra-abdominal infections caused by *Citrobacter freundii, Enterobacter cloacae, E. coli, Klebsiella oxytoca, Klebsiella pneumoniae, Enterococcus faecalis* (vancomycin-susceptible isolates), *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates only), *Streptococcus anginosus* grp. (includes *S. anginosus, S. intermedius, and S. constellatus*), *Bacteroides fragilis, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Clostridium perfringens* , and *Peptostreptococcus micros* . Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to tigecycline. Tigecycline may be initiated as empiric monotherapy before results of these tests are known. To reduce the development of drug-resistant bacteria and maintain the effectiveness of tigecycline and other antibacterial drugs, tigecycline should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
BRU14031250PS1; BRU14031250PS2; BRU14031250PS3	Levemir Flexpen 100IU/ml	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.
BRU14031253P	Humulin N Injection 100IU/mL	For the treatment of patients with diabetes mellitus for whom diet and/or oral agents are not sufficient.
BRU14031256P	Gonal-F 300IU/0.5ml (22mcg/0.5ml) Solution For Injection In A Pre-Filled Pen	In adult women • Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. • Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intrafallopian transfer.
BRU14031257P	Gonal-F 900IU/1.5ml (66mcg/1.5ml) Solution For Injection In A Pre-Filled Pen	In adult women • Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. • Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intrafallopian transfer.

BRU14031261P	Prograf Capsule 1mg	Primary immunosuppression in liver and kidney allograft recipients and liver and kidney allograft rejection resistant to conventional immunosuppressive agents.
BRU14031263P	Patanol 0.1% Olopatadine Hydrochloride Sterile Ophthalmic Solution	Patanol eye drops contains olopatadine, a relatively selective H1-receptor antagonist and inhibitor of histamine release from the mast cell. Patanol eye drops is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.
BRU14031264PS1	Travatan® Eye Drops 40mcg/ml	Decrease of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.
BRU14031268P	Elonva Solution For Injection 100mcg/0.5ml	Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in Assisted Reproductive Technology (ART) program.
BRU14031269P	Menveo Powder & Solution For Solution For Injection	Menveo is indicated for active immunization of children (from 2 years of age) and adults at risk of exposure to Neisseria meningitides groups A, C, W135 and Y, to prevent invasive disease. The use of this vaccine should be in accordance with official recommendations.

BRU14031270P	Enbrel® 50mg Solution For Injection In Pre-Filled Syringe	*Rheumatoid arthritis* Treatment of signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis. Enbrel can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. *Polyarticular juvenile idiopathic arthritis* Treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Enbrel has not been studied in children aged less than 2 years. *Psoriatic arthritis* Enbrel is indicated for reducing signs and symptoms of active arthritis in patients with psoriatic arthritis. Enbrel can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. *Axial Spondyloarthritis* *Ankylosing spondylitis* Treatment of active ankylosing spondylitis in adults. *Non-radiographic axial spondyloarthritis* Treatment of adults with active* non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs NSAIDs). *Active disease is defined as a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of ≥4. *Plaque psoriasis* Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA (see Pharmacodynamic Properties). *Pediatric plaque psoriasis* Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

BRU14031272P	Seretide Evohaler 25/250mcg	**Asthma (Reversible Obstructive Airways Disease)** *SERETIDE* is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** *SERETIDE* is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU14031274PS2	Galvus Met 50/1000mg Film-Coated Tablet	Galvus Met is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus: - as initial therapy when diabetes is not adequately controlled by diet and exercise alone - in patients who are inadequately controlled with metformin hydrochloride alone - in patients who are already being treated with the combination of vildagliptin and metformin hydrochloride, as separate tablets. - in combination with other medicinal products for the treatment of diabetes, including insulin a when these do not provide adequate glycaemic control.
BRU14031275PS2	Galvus Met 50/850mg Film-Coated Tablet	Galvus Met is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus: - as initial therapy when diabetes is not adequately controlled by diet and exercise alone - in patients who are inadequately controlled with metformin hydrochloride alone - in patients who are already being treated with the combination of vildagliptin and metformin hydrochloride, as separate tablets. - in combination with other medicinal products for the treatment of diabetes, including insulin a when these do not provide adequate glycaemic control.
BRU14031276P	Galvus 50mg Tablet	Galvus is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus: • As monotherapy • As combination therapy - o Initial combination with metformin when diabetes is not adequately controlled by diet and exercise alone o In combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control.
BRU14031279NP	Axcel Paracetamol-250 Suspension (Orange)	For the relief of fever, symptoms of cold and influenza, teething pain and headache.

BRU14031280P	Lamictal Dispersible Tablets 25mg	**EPILEPSY** **• Adults and Adolescents** *LAMICTAL* is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. **• Children (2 to 12 years of age)** *LAMICTAL* is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalised seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome (above 3 years of age only). Initial monotherapy treatment in newly diagnosed paediatric patients is not recommended. After epileptic control has been achieved during adjunctive therapy, concomitant anti- epileptic drugs (AEDs) may be withdrawn and patients continued on *LAMICTAL* monotherapy. If *LAMICTAL* 2 mg Chewable Dispersible Tablet is not available and the calculated dose in children is less than 2.5 mg daily, then *LAMICTAL* cannot be used. DO NOT attempt to administer partial quantities of the dispersible tablets. **BIPOLAR DISORDER** **• Adults (18 years of age and over)** *LAMICTAL* is indicated for the prevention of mood episodes in patients with bipolar disorder, predominantly by preventing depressive episodes.
BRU14031284P	Xalatan Eye Drops	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma, chronic angle closure glaucoma and ocular hypertension. Reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma.
BRU14041285P	Giona Easyhaler® 100mcg/Dose Inhalation Powder	Treatment of mild, moderate, and severe asthma.
BRU14041286P	Axcel Nasatab Tablet	Symptomatic relief of headache, fever and pain, sinus and nasal congestion associated with sinusitis or common cold.
BRU14041287P	Xarelto™ Film-Coated Tablet 15mg	Xarelto is indicated for prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation. There are limited data on the relative effectiveness of Xarelto and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well-controlled. Xarelto is indicated for the treatment of Deep Vein Thrombosis (DVT) and pulmonary embolism (PE), and for the prevention of recurrent DVT, PE in adults.

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BRU14041288P	Xarelto™ Film-Coated Tablet 20mg	Xarelto is indicated for prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation. There are limited data on the relative effectiveness of Xarelto and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well-controlled. Xarelto is indicated for the treatment of Deep Vein Thrombosis (DVT) and pulmonary embolism (PE), and for the prevention of recurrent DVT, PE in adults.
BRU14041291NP	Sodium Chloride Injection USP 0.9% In Mini-Bag Plus Container	0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes and may also be used as diluent for reconstitution of a powdered or liquid (up to 10 mL) drug product packaged in a vial with a 13 mm or 20 mm closure.
BRU14041293P	Endoxan® Injection 200mg/Vial	Endoxan is used within a combination chemotherapy regimen or as monotherapy in • **Leukaemias**: acute or chronic lymphocytic and myelogenous leukaemias • **Malignant lymphomas**: Hodgkin's disease, non-Hodgkin's lymphomas, plasmacytoma • **Metastasizing and non-metastasizing malignant solid tumours**: ovarian cancer, testicular cancer, breast cancer, small cell lung cancer, neuroblastoma, Ewing's sarcoma • **Progressive 'autoimmune diseases'**: eg. Rheumatoid arthritis, psoriatic arthropathy, systemic lupus erythematosus, scleroderma, systemic vasculitides (eg. With nephrotic syndrome), certain types of glomerulonephritis (eg. with nephrotic syndrome), myasthenia gravis, autoimmune haemolytic anaemia, cold agglutinin diseases. • **Immunosuppressive treatment in organ transplantations**
BRU14041294P	Certican Tablet 0.25mg	**Kidney and heart transplantation** Certican is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogenic renal or cardiac transplant. In kidney and heart transplantation, Certican should be used in combination with ciclosporin for microemulsion and corticosteroids. **Liver transplantation** Certican is indicated for the prophylaxis of organ rejection in adult patients receiving a hepatic transplant. In liver transplantation, Certican should be used in combination with tacrolimus and corticosteroids.
BRU14041295P	Certican Tablet 0.75mg	**Kidney and heart transplantation** Certican is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogenic renal or cardiac transplant. In kidney and heart transplantation, Certican should be used in combination with ciclosporin for microemulsion and corticosteroids. **Liver transplantation** Certican is indicated for the prophylaxis of organ rejection in adult patients receiving a hepatic transplant. In liver transplantation, Certican should be used in combination with tacrolimus and corticosteroids.

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BRU14041297PS1	DuoTrav Eye Drops Solution	Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.
BRU14041302P	Tasigna Capsule 150mg	Tasigna is indicated for: •The treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP). Clinical effectiveness of TASIGNA in adults with newly diagnosed Ph+ CML-CP is based on major molecular response rate at 12 months and complete cytogenetic response rate by 12 months. •The treatment of pediatric patients 2 years of age and older with newly diagnosed Ph+ CML-CP. Clinical effectiveness of TASIGNA in pediatric patients with newly diagnosed Ph+ CML-CP is based on major molecular response by 12 cycles and complete cytogenetic response at 12 cycles. •The treatment of chronic phase (CP) and accelerated phase (AP) Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib. Clinical effectiveness of TASIGNA in adults with imatinib-resistant or -intolerant Ph+ CML-CP was based on the unconfirmed major cytogenetic and complete hematologic response rates. Clinical effectiveness of TASIGNA in imatinib-resistant or -intolerant Ph+ CML-AP for adult patients was based on the confirmed hematologic response rates and the unconfirmed major cytogenetic response rates. •The treatment of pediatric patients 2 years of age and older with Ph+ CML-CP with resistance or intolerance to prior therapy including imatinib. Clinical effectiveness of TASIGNA in pediatric patients with imatinib-resistant or intolerant Ph+ CML-CP was based on the MMR rate at 6 cycles. No overall survival benefit has been demonstrated.
BRU14041303P	Tasigna Capsule 200mg	Tasigna is indicated for: •The treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP). Clinical effectiveness of TASIGNA in adults with newly diagnosed Ph+ CML-CP is based on major molecular response rate at 12 months and complete cytogenetic response rate by 12 months. •The treatment of pediatric patients 2 years of age and older with newly diagnosed Ph+ CML-CP. Clinical effectiveness of TASIGNA in pediatric patients with newly diagnosed Ph+ CML-CP is based on major molecular response by 12 cycles and complete cytogenetic response at 12 cycles. •The treatment of chronic phase (CP) and accelerated phase (AP) Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib. Clinical effectiveness of TASIGNA in adults with imatinib-resistant or -intolerant Ph+ CML-CP was based on the unconfirmed major cytogenetic and complete hematologic response rates. Clinical effectiveness of TASIGNA in imatinib-resistant or -intolerant Ph+ CML-AP for adult patients was based on the confirmed hematologic response rates and the unconfirmed major cytogenetic response rates. •The treatment of pediatric patients 2 years of age and older with Ph+ CML-CP with resistance or intolerance to prior therapy including imatinib. Clinical effectiveness of TASIGNA in pediatric patients with imatinib-resistant or intolerant Ph+ CML-CP was based on the MMR rate at 6 cycles. No overall survival benefit has been demonstrated.
BRU14041304NP	Infusol NSD5	Dehydration; Sodium and chloride depletion; Calorie supply; Vehicle solution for supplementary medication.

BRU14041305NP	Lactul Solution	For the treatment of constipation and hepatic encephalopathy.
BRU14041307P	Alimta 100mg Powder For Solution For Infusion	Malignant pleural mesothelioma ALIMTA in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. Non-small cell lung cancer ALIMTA in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. ALIMTA is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. ALIMTA is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. ALIMTA in combination with pembrolizumab and platinum chemotherapy, is indicated for the first line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.
BRU14041313P	YSP Ibuprofen Suspension 20mg/ml	Relief of fever, pain, muscle and joint inflammation.
BRU14041314NP; BRU14041314NPS2	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. It is also indicated for use as a priming solution in hemodialysis procedures.
BRU14041315P	Rivadem 3mg Capsule	Rivadem (Rivastigmine Capsules) is indicated for the treatment of mild to moderate dementia of the Alzheimer's type.
BRU14041316P	Rivadem 1.5mg Capsule	Rivadem (Rivastigmine Capsules) is indicated for the treatment of mild to moderate dementia of the Alzheimer's type.

BRU14071320PS2	Protopic Ointment 0.03%	Protopic 0.03% ointment is indicated in adults, adolescents and children from the age of 2 years. Flare treatment Adults and adolescents (16 years of age and above) Treatment of moderate to severe atopic dermatitis in adults and adolescents who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids. *Children (2 years of age and above)* Treatment of moderate to severe atopic dermatitis in children (2 years of age and above) who failed to respond adequately to conventional therapies such as topical corticosteroids. Maintenance treatment Treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected).
BRU14071324P	Luvox® Film-Coated Tablets 50mg	• Treatment of depressive illness and the symptoms of depressive disorder. • Treatment of symptoms of obsessive compulsive disorder (OCD).
BRU14071325P	Luvox® Film-Coated Tablets 100mg	• Treatment of depressive illness and the symptoms of depressive disorder. • Treatment of symptoms of obsessive compulsive disorder (OCD).
BRU14071326P	TobraDex® Eye Ointment	TOBRADEX® Ointment is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns or penetration of foreign bodies. The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye. The particular anti-infective drug in this product is active against the following common bacterial eye pathogens: Staphylococci, including S. *aureus* and S. *epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains. Streptococci, including some of the Group A beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae* . *Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis. Morganella morganii* , most *Proteus vulgaris* strains, *Haemophilus influenzae* and *H. aegyptius, Moraxella lacunata* , and *Acinetobacter calcoaceticus (Herellea vaginacola)* and some *Neisseria* species.

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BRU14071328P	Lanvis® Tablet 40mg	Lanvis is indicated primarily for the treatment of acute leukaemias especially, acute myelogenous leukaemia and acute lymphoblastic leukaemia.
BRU14071329NP	Axcel Papain Tablet	In conjunction with other physical or chemotherapeutic measures for treatment of oedema and inflammation.
BRU14071330P	Humalog® KwikPen™ 100 Units/mL	For the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Humalog is also indicated for the initial stabilisation of diabetes mellitus.
BRU14071331P	Shincort Injection 40mg/ml (1ml Amp)	Rheumatoid arthritis, synovitis, allergic rhinitis, allergic asthma, allergic dermatitis, pemphigus, allergic and inflammatory ophthalmic diseases.
BRU14071332P	Emend® I.V. Powder For Solution For Infusion 150mg	EMEND I.V. is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of: • highly emetogenic cancer chemotherapy. • moderately emetogenic cancer chemotherapy. EMEND I.V. should be given in combination with a corticosteroid and a 5-HT_3 antagonist.
BRU14071333PS1	Zytiga Tablets 250mg	ZYTIGA is indicated with prednisone or prednisolone for • the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated (see section 5.1). • the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. ZYTIGA is also indicated in combination with prednisone or prednisolone and androgen deprivation therapy (ADT) for the treatment of patients with newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) who may have received up to 3 months of prior ADT.
BRU14071335P	Anlodin Tablet 5mg	Amlodipine is indicated in the treatment of hypertension and, in most cases, can be used as monotherapy. Patients insufficiently controlled with a single antihypertensive e.g. thiazide diuretic, beta-blockers or angiotensin-converting enzyme inhibitors, may benefit from the addition of amlodipine. Amlodipine can also be used as first line treatment of myocardial ischemia, both in cases of fixed obstruction (stable angina), and/or in cases following vasoconstriction or vasospasm (Prinzmetal's angina or variant angina). Amlodipine can therefore be used in cases where the clinical picture suggests a possible vasospastic component even if there is no confirmation of this clinical situation. Amlodipine can be used alone or in combination with other anti-angina drugs, in patients suffering from angina who do not respond to nitrates or adequate doses of beta-blockers.

BRU14071336P	Aldara Cream 5% w/w	Aldara 5% cream is indicated for 1. Treatment of external genital and perianal warts/condyloma accuminata in adults. 2. Treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratosis on the face or scalp in immunocompetent adults. 3. Treatment of biopsy-confirmed, primary superficial basal cell carcinoma (sBCC) in immunocompetent adults, with a maximum tumor diameter of 2.0 cm, located on the trunk (excluding anogenital skin), neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured. The histological diagnosis of superficial basal cell carcinoma should be established prior to treatment, since safety and efficacy of Aldara Cream have not been established for other types of basal cell carcinomas, including nodular and morpheaform (fibrosing or sclerosing) types.
BRU14071337P	Premarin Tablet 0.3mg	1. Moderate to severe vasomotor symptoms associated with estrogen deficiency. 2. Prevention and management of osteoporosis associated with estrogen deficiency. When prescribing solely for the prevention of postmenopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and for whom non-estrogen medications are not considered to be appropriate. When prescribing solely for the management of post-menopausal osteoporosis, nonestrogen medications should be first considered. 3. Atrophic vaginitis and atrophic urethritis. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered. 4. Female hypoestrogenism. ERT and HRT should not be initiated or continued to prevent coronary heart disease (see also Cardiovascular risk and section DEMENTIA). The benefits and risks of ERT and HRT must always be carefully weighed, including consideration of the emergence of risks as therapy continues (see SPECIAL WARNINGS). Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman. In the absence of comparable data, the risks of HRT should be assumed to be similar to all estrogens and estrogen/progestin combinations.
BRU14071342P	Axcel Ibuprofen Paediatric Syrup	Relief of fever such as fever associated with cold and flu; and pain such as pain from teething and toothache, earache, sore throats, headache and minor aches and sprains. Also indicated for the relief of inflammation of muscles and joints.
BRU14071346P	YSP Hydrocort Cream 1% w/w	Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
BRU14071348P	Pharmaniaga Atropine Sulphate 1mg/ml	Pre-anaesthetic medication usually in conjugation with morphine sulphate. In conjugation with neostigmine methyl sulphate to reverse the effects of non-depolarising muscle relaxants. Smooth muscle spasm in conditions such as renal and biliary colic. In the management of arrhythmias and in the treatment of bradycardia or asystole due to overdosage with parasympathomimetic agents. Atropine has also been used in the suppression of gastro-intestinal motility in the treatment of peptic ulcer, and diagnosis of colicky pain, as an antidote in carbamate and (with pralidoxime) organo-phosphorus insecticide poisoning.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14071355P	Axcel Dexchlorpheniramine Tablet	For allergic conditions including hay fever, urticaria, angioedema, vasomotor rhinitis, allergic eczema, atopic and contact dermatitis, drug and serum reactions, insect bites and pruritus.
BRU14071358NP	20% Glucose Intravenous Infusion BP	- Administration of glucose for caloric support. - Carbohydrate component in parenteral nutrition regimens. - Therapy of hypoglycaemia.
BRU14071360P	Maxidex Sterile Opthalmic Suspension	MAXIDEX contains dexamethasone, a synthetic corticosteroid. MAXIDEX is indicated in the management of conditions generally responsive to corticosteroids such as: • Certain inflammatory eye conditions of the anterior segment: acute and chronic anterior uveitis, iridocyclitis, iritis and cyclitis, herpes zoster ophthalmicus. • Certain external diseases such as phlyctenular kerato-conjunctivitis, nonpurulent conjunctivitis, including vernal, allergic, catarrhal. It is very effective where allergy is a main factor. • Recurrent marginal ulceration of toxic or allergic etiology. • Thermal and chemical burns. • Post-operatively to reduce inflammatory reactions.
BRU14071361P	Heparinol 1000IU/ml	Heparin is indicated for prophylaxis and treatment of thrombo-embolic disorders such as thrombophlebitis, pulmonary embolism, myocardial infarction, arterial embolism and other occlusive vascular disease. It is also used to prevent thrombo-embolic complication from cardiac and vascular surgery, dialysis, frostbite and other perfusion procedures. Heparin is also used as anticoagulant in blood transfusions and for laboratory purposes.
BRU14071367P	Invega Sustenna Prolonged Release Suspension For IM Injection 150mg/1.5ml	INVEGA SUSTENNA is indicated for the acute and maintenance treatment of schizophrenia in adults. INVEGE SUSTENNA is indicated for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.
BRU14071368P	Yondelis® Powder for Injection 1mg/vial	YONDELIS® is indicated for the treatment of adult patients with advanced soft tissue sarcoma (STS), after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients. YONDELIS® in combination with pegylated liposomal doxorubicin hydrochloride (PLD) is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer.

BRU14071369P; BRU14071369PS2	Trajenta Film-Coated Tablet 5mg	Trajenta is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
BRU14071372PS2	Invega® Extended-Release Tablet 9mg	INVEGA® is indicated for the treatment of schizophrenia in adolescents 15 years and older, including acute treatment and recurrence prevention. INVEGA® is indicated for the treatment of acute exacerbations of schizoaffective disorder as monotherapy and in combination with antidepressants and/or mood stabilizers (lithium and valproate).
BRU14071373PS2	Invega® Extended-Release Tablet 3mg	INVEGA® is indicated for the treatment of schizophrenia in adolescents 15 years and older, including acute treatment and recurrence prevention. INVEGA® is indicated for the treatment of acute exacerbations of schizoaffective disorder as monotherapy and in combination with antidepressants and/or mood stabilizers (lithium and valproate).
BRU14071374PS2	Invega® Extended-Release Tablet 6mg	INVEGA® is indicated for the treatment of schizophrenia in adolescents 15 years and older, including acute treatment and recurrence prevention. INVEGA® is indicated for the treatment of acute exacerbations of schizoaffective disorder as monotherapy and in combination with antidepressants and/or mood stabilizers (lithium and valproate).
BRU14071375P	Lucentis 10mg/ml Solution For Injection	Lucentis is indicated in adults for: • the treatment of neovascular (wet) age-related macular degeneration (AMD), • the treatment of visual impairment due to diabetic macular oedema (DME), • the treatment of proliferative diabetic retinopathy (PDR) • the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (RVO) • the treatment of visual impairment due to choroidal neovascularization (CNV) Lucentis is indicated in preterm infants for: • The treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 3+) or AP-ROP (aggressive posterior ROP) disease.
BRU14071376PS2	Onbrez Breezhaler 150mcg Inhalation Powder, Hard Capsule	Onbrez Breezhaler is a long-acting $beta_2$-agonist indicated for maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD).
BRU14071378P	Requip PD 24 Hour™ Prolonged Release Tablet 2mg	• REQUIP PD 24 HOUR is indicated for the treatment of idiopathic Parkinson's disease. • REQUIP PD 24 HOUR may be used alone (without levodopa [L-dopa]) in the treatment of idiopathic Parkinson's disease. • Addition of REQUIP PD 24 HOUR to levodopa may be used to control 'on-off' fluctuations and permit a reduction in the total daily dose of L-Dopa.

BRU14071379P	Difflam Anti-Inflammatory Anti-Bacterial Lozenges (Raspberry)	For the temporary relief of painful conditions of the oral cavity including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, post-orosurgical and periodontal procedures, pharyngitis, swelling, redness and inflammatory conditions.
BRU14071380P	Vfend Powder For Oral Suspension 40mg/ml	Voriconazole is a broad spectrum, triazole antifungal agent and is indicated in adults and children aged 2 years and above as follows: Treatment of invasive aspergillosis; Treatment of fluconazole-resistant serious invasive *Candida* infections (including C. *krusei*); Treatment of serious *Candida* infections including esophageal candidiasis; Treatment of candidemia in non-neutropenic patients and the following *Candida* infections: disseminated infection in skin and infections in abdomen, kidney, bladder wall and wounds; Treatment of serious fungal infections caused by *Scedosporium* spp. and *Fusarium* spp.; Prevention of breakthrough of fungal infections in febrile high-risk neutropenic patients. Prophylaxis in patients ≥12 years old who are at high risk of developing invasive fungal infections. The indication is based on a study which includes patients ≥12 years old undergoing haematopoietic stem cell transplantation. Voriconazole should be administered primarily to immunocompromised patients with progressive, possibly life-threatening infections.

BRU14071381P	Norditropin® NordiFlex Solution For Injection 10mg/1.5ml	Children: Growth failure due to growth hormone deficiency (GHD) Growth failure in girls due to gonadal dysgenesis (Turner syndrome) Growth retardation in prepubertal children due to chronic renal disease. Growth disturbance (current height standard deviation score (SDS) < -2.5 and parental adjusted height SDS < -1) in short children born small for gestational age (SGA), with a birth weight and/or length below -2 standard deviation SD, who failed to show catch-up growth (height velocity standard deviation (HV SDS) < 0 during the last year) by 4 years of age or later. Adults: <u>Childhood onset growth hormone deficiency:</u> Patients with childhood onset GHD should be re-evaluated for growth hormone secretory capacity after growth completion. Testing is not required for those with more than three pituitary hormone deficits, with severe GHD due to a defined genetic cause, due to structural hypothalamic pituitary abnormalities, due to central nervous system tumours or due to high-dose cranial irradiation, or with GHD secondary to a pituitary/hypothalamic disease or insult, if measurements of serum insulin-like growth factor 1 (IGF-1) is <-2 SDS after at least four weeks off growth hormone treatment. In all other patients an IGF-1 measurement and one growth hormone stimulation test is required. <u>Adult onset growth hormone deficiency:</u> Pronounced GHD in known hypothalamic-pituitary disease, cranial irradiation and traumatic brain injury. GHD should be associated with one other deficient axis, other than prolactin. GHD should be demonstrated by one provocative test after institution of adequate replacement therapy for any other deficient axis. In adults, the insulin tolerance test is the provocative test of choice. When the insulin tolerance test is contraindicated, alternative provocative tests must be used. The combined arginine-growth hormone releasing hormone is recommended. An arginine or glucagon test may also be considered; however, these tests have less established diagnostic value than the insulin tolerance test.
BRU14071382P	Alphagan P Ophthalmic Solution 0.15%	ALPHAGAN P is indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
BRU14071383P	Mapenem® IV Injection 500mg	Infections caused by pathogens sensitive to Meropenem including: 1. Intra-abdominal Infection 2. Skin and Skin Structure Infection 3. Lower respiratory tract infections including bronchitis, pneumonia and Hospital-acquired pneumonia 4. Meningitis 5. Urinary tract infections 6. Gynaecological Infections including endometritis and pelvic inflammatory disease 7. Bacterial septicaemia 8. Empiric therapy in febrile neutropenia

BRU14071385P	Topamax® 25 Tablet 25mg	**Epilepsy** TOPAMAX is indicated as monotherapy in patients with newly diagnosed epilepsy or for conversion to monotherapy in patients with epilepsy. TOPAMAX is indicated as adjunctive therapy for adults and children aged 2 and above with partial onset seizures or generalized tonic-clonic seizures. TOPAMAX is also indicated in adults and children as adjunctive therapy for the treatment of seizures associated with Lennox-Gastaut syndrome. **Migraine** TOPAMAX is indicated in adults for the prophylaxis of migraine headache. The usefulness of TOPAMAX in the acute treatment of migraine headache has not been studied.
BRU14071386P	Tussils 5 Lozenge 5mg	To control non-productive cough.
BRU14071387P	Kivexa Tablets 600mg/300mg	Kivexa is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults, adolescents and children weighing at least 25kg. Before initiating treatment with abacavir, screening for carriage of the HLA-B*5701 allele should be performed in any HIV-infected patient, irrespective of racial origin. Abacavir should not be used in patients known to carry the HLA-B*5701 allele.
BRU14071390P	Axcel Diclofenac-50 Tablet	Inflammatory, degenerative and non-articular forms of rheumatism and juvenile arthritis. Acute gout. Post-traumatic and post-operative inflammatory and swelling. Primary dysmenorrhea.
BRU14071394P	Duodart Capsules 0.5mg/0.4mg	Duodart is indicated as combination therapy for the treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH). Duodart reduces the risk of acute urinary retention and the need for surgery in patients with moderate to severe symptoms of BPH.
BRU14071395P	Axcel Metronidazole-400 Tablet	Treatment of protozoal infection, intestinal and extra-intestinal amoebiasis, lambliasis, acute ulcerative gingivitis, urogenital trichomoniasis, glardiasis, and Vincent's infection.

BRU14071396P	Cefazolin Sandoz 1g Vial	Cefazolin is indicated in a number of infections caused by cefazolin-sensitive microorganisms. These include: - Infections of the respiratory tract like bronchitis and pneumonia - Infections of the urogenital tract like pyelonephritis, cystitis, urethritis and prostatitis - Infections of the skin and soft tissues - Infections of the bile ducts - Bone and joint infections - Endocarditis - Systemic septic infections - Perioperative prophylaxis (hysterectomy, cholecystectomy, open-heart surgery, bone and joint surgery). Use of cefazolin should be restricted to cases needing to be treated parenterally. Consideration should be given to official guidance (e.g. national recommendations) on the appropriate use of antibacterial agents. Susceptibility of the causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available.
BRU14071397PS1; BRU14071397PS3; BRU14071397PS4	MABTHERA Concentrate For Solution For Infusion 500mg/50ml	**MabThera IV and MabThera SC** Non-Hodgkin's Lymphoma: MabThera IV and MabThera SC are indicated for the treatment of: • patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma (DLCL) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) chemotherapy. • previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. MabThera IV and MabThera SC maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy. **MabThera IV only** Non-Hodgkin's Lymphoma: MabThera IV is indicated for the treatment of patients with relapsed or chemoresistant indolent B-cell non-Hodgkin's lymphomas. Chronic Lymphocytic Leukaemia: MabThera IV is indicated in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL. Rheumatoid Arthritis: MabThera IV in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumour necrosis factor (TNF) inhibitor therapies.
BRU14071398P	Lamitor 100mg Tablet	LAMITOR is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalized seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome.

BRU14071399PS2	Vigamox® Ophthalmic Solution 0.5%	VIGAMOX Solution is indicated for the treatment of patients 1 year of age and older with bacterial conjunctivitis caused by susceptible strains of the following organisms. **Gram-positive bacteria**: *Corynebacterium* species† *Microbacterium* species *Micrococcus luteus* † [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains] *Staphylococcus aureus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus epidermidis* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus haemolyticus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus hominis* † [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] Staphylococcus warneri† [including erythromycin resistant strains] *Streptococcus miti* s† [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains] *Streptococcus pneumoniae* [including penicillin, erythromycin, gentamicin, tetracycline and/or trimethoprim resistant strains] *Streptococcus viridans* [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains] **Gram-negative bacteria**: *Acinetobacter* species *Haemophilus 'alconae'* [including ampicillin resistant strains] *Haemophilus influenza* e [including ampicillin resistant strains] *Klebsiella pneumoniae* † *Moraxella catarrhalis* † *Pseudomonas aeruginosa* * **Other microorganisms**: *Chlamydia trachomatis* †Efficacy for this organism was studied in fewer than 10 infections Preoperative and postoperative sterilization (when prophylactic antibiotic treatment is required).
BRU14071401PS2	Voltaren Emulgel 1%	Treatment of i) Localised forms of soft-tissue rheumatism, eg. tendovaginitis, shoulder-hand syndrome, bursitis, and periarthropathy; ii) Localised rheumatic disease eg. osteo-arthritis of the spine and peripheral joints; iii) Post-traumatic inflammation of the tendons, ligaments, muscles and joints, eg. due to sprains, strains or bruises.

BRU14071402P	Imexa Film-Coated Tablet 250mg	Imexa is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present). In sexually transmitted diseases in men and women, Imexa is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated in the treatment of uncomplicated genital infection due to non-multiresistant *Neisseria gonorrhoea* , concurrent infection with Treponema pallidum should be excluded. Imexa is indicated, either alone or in combination with rifabutin, for prophylaxis against *Mycobacterium avium – Intracellulare complex* (MAC) infection, an opportunistic infection prevalent in patients with advanced human immunodeficiency virus (HIV).
BRU14071403P	Cymbalta Capsule 60mg	Treatment of major depressive disorder. Management of neuropathic pain associated with diabetic peripheral neuropathy in adults. Treatment of generalised anxiety disorder.
BRU14071405P	Setrof Tablet 50mg	For treatment of symptoms of depression including depression accompanied by symptoms of anxiety. For treatment of obsessions and compulsions in patients with obsessive-compulsive disorder (OCD). For treatment of panic disorder with or without agoraphia.
BRU14071410P	Lovastin Tablet 20mg	For the reduction of elevated total and LDL cholesterol levels in patients with primary hypercholesterolemia (Type IIa and IIb), when the response to diet and other non-pharmacological measures alone has been inadequate. Lovastin may be useful to reduce elevated LDL cholesterol levels in patients with combined hypercholesterolemia and hypertriglyceridemia. Before instituting attempt with Lovastatin, an attempt should be made to control hypercholesterolemia with appropriate diet, exercise, weight reduction in obese patients.
BRU14071411P	Requip Tablet 0.25mg	Requip is indicated for the treatment of idiopathic Parkinson's disease: • Requip may be used alone (without levodopa [L-Dopa]) in the treatment of idiopathic Parkinson's disease. • Addition of Requip to levodopa may be used to control 'on-off' fluctuations and permit a reduction in the total daily dose of L-Dopa. Treatment of Restless Legs Syndrome: • Ropinirole is indicated for the treatment of idiopathic/primary Restless Legs Syndrome.
BRU14071412NP	Zoben Tablet 200mg	Albendazole is used in the treatment of roundworm, pinworm, hookworm, threadworm, (strongyloidiasis), and whipworm infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14071414P	Garbose Tablet 50mg	Additional therapy in association with diet in patients with diabetes mellitus.
BRU14081416PS2	Sevorane Inhalation Liquid	Sevoflurane may be used for induction and maintenance of general anaesthesia in adult and pediatric patients for inpatient and outpatient surgery.
BRU14081417PS2	Emend Tri-Pack Capsule	EMEND is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of: • highly emetogenic cancer chemotherapy. • moderately emetogenic cancer chemotherapy. EMEND should be given in combination with a corticosteroid and a 5-HT_3 antagonist.
BRU14081418PS2	Protopic Ointment 0.1%	Protopic 0.1 % ointment is indicated in adults and adolescents (16 years of age and above). <u>Flare treatment</u> Adults and adolescents (16 years of age and above) Treatment of moderate to severe atopic dermatitis in adults and adolescents who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids. *Children (2 years of age and above)* Treatment of moderate to severe atopic dermatitis in children (2 years of age and above) who failed to respond adequately to conventional therapies such as topical corticosteroids. <u>Maintenance treatment</u> Treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected).
BRU14081419PS2	Exforge HCT 10/160/12.5mg Film-Coated Tablet	Treatment of essential hypertension. This fixed combination drug is not indicated for the initial therapy of hypertension.
BRU14081420PS2	Exforge HCT 10/160/25mg Film-Coated Tablet	Treatment of essential hypertension. This fixed combination drug is not indicated for the initial therapy of hypertension.
BRU14081421PS2	Exforge HCT 5/160/12.5mg Film-Coated Tablet	Treatment of essential hypertension. This fixed combination drug is not indicated for the initial therapy of hypertension.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14081424P	Luveris For Injection 75IU/Vial (Revised Formula)	Luveris® in association with a follicle stimulating hormone (FSH) preparation is Indicated for the stimulation of follicular development in women with severe LH and FSH deficiency.
BRU14081425P	Lipanthyl Penta 145 Film-Coated Tablet	LIPANTHYLR PENTA 145, film-coated tablet is indicated as an adjunct to diet and other non-pharmacological treatment (e.g. exercise, weight reduction) for the following: - Treatment of severe hypertriglyceridaemia with or without low HDL cholesterol. - Mixed hyperlipidaemia when a statin is contraindicated or not tolerated - Mixed hyperlipidaemia in patients at high cardiovascular risk in addition to a statin when triglycerides and HDL cholesterol are not adequately controlled. LIPANTHYLR PENTA 145, film-coated tablet is indicated for the reduction in the progression of diabetic retinopathy in patients with type 2 diabetes and existing diabetic retinopathy. LIPANTHYLR PENTA 145, film-coated tablet does not replace the appropriate control of blood pressure, blood glucose and blood lipids in reducing the progression of diabetic.
BRU14081428PS1; BRU14081428PS2; BRU14081428PS3	Janumet™ Tablet 50mg/850mg	JANUMET is indicated as initial therapy in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise do not provide adequate glycemic control. JANUMET is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin. JANUMET is also indicated in combination with a sulfonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in adult patients with type 2 diabetes mellitus inadequately controlled with any two of the three agents: metformin, sitagliptin, or a sulfonylurea. JANUMET is indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycemic control in patients when insulin and metformin alone do not provide adequate glycemic control. *Important Limitations of Use* JANUMET should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. JANUMET has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUMET.

BRU14081429PS1; BRU14081429PS2; BRU14081429PS3	Janumet™ Tablet 50mg/500mg	JANUMET is indicated as initial therapy in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise do not provide adequate glycemic control. JANUMET is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin. JANUMET is also indicated in combination with a sulfonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in adult patients with type 2 diabetes mellitus inadequately controlled with any two of the three agents: metformin, sitagliptin, or a sulfonylurea. JANUMET is indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycemic control in patients when insulin and metformin alone do not provide adequate glycemic control. *Important Limitations of Use* JANUMET should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. JANUMET has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUMET.
BRU14081430PS1; BRU14081430PS2; BRU14081430PS3	Janumet™ Tablet 50mg/1000mg	JANUMET is indicated as initial therapy in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise do not provide adequate glycemic control. JANUMET is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin. JANUMET is also indicated in combination with a sulfonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in adult patients with type 2 diabetes mellitus inadequately controlled with any two of the three agents: metformin, sitagliptin, or a sulfonylurea. JANUMET is indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycemic control in patients when insulin and metformin alone do not provide adequate glycemic control. *Important Limitations of Use* JANUMET should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. JANUMET has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUMET.

BRU14081432PS1; BRU14081432PS3; BRU14081432PS4	Mabthera Concentrate For Solution For Infusion 100mg/10ml	**MabThera IV and MabThera SC** Non-Hodgkin's Lymphoma: MabThera IV and MabThera SC are indicated for the treatment of: • patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma (DLCL) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) chemotherapy. • previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. MabThera IV and MabThera SC maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy. **MabThera IV only** Non-Hodgkin's Lymphoma: MabThera IV is indicated for the treatment of patients with relapsed or chemoresistant indolent B-cell non-Hodgkin's lymphomas. Chronic Lymphocytic Leukaemia: MabThera IV is indicated in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL. Rheumatoid Arthritis: MabThera IV in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumour necrosis factor (TNF) inhibitor therapies.
BRU14081433P	Eraxis™ 100mg For Injection	Treatment of invasive candidiasis, including candidemia, in adult and in paediatric patients aged 1 month to <18 years old.
BRU14081434P	Moxiclav 1g Tablet	MOXICLAV is indicated for the treatment of bacterial infections such as: • Upper respiratory tract infections (including ENT): tonsillitis, sinusitis, otitis media. • Lower respiratory tract infections: acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. • Genito-urinary tract infections: cystitis, urethritis, pyelonephritis. • Skin and soft tissue infections, e.g. boils, abscesses, cellulites, wound infections. • Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis.
BRU14081439P	Carzepin 200mg Tablet	For treatment of: - Partial seizures with complex symptomatology (psychomotor, temporal lobe) - Generalized tonic-clonic seizures (grand mal) - Mixed seizure patterns - Pain due to trigeminal neuralgia and glossopharyngeal neuralgia

BRU14081441P	Lamictal 100mg Tablet	**EPILEPSY** **• Adults and Adolescents** LAMICTAL is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. **• Children (2 to 12 years of age)** LAMICTAL is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalised seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome (above 3 years of age only). Initial monotherapy treatment in newly diagnosed paediatric patients is not recommended. After epileptic control has been achieved during adjunctive therapy, concomitant anti- epileptic drugs (AEDs) may be withdrawn and patients continued on LAMICTAL monotherapy. If LAMICTAL 2 mg Chewable Dispersible Tablet is not available and the calculated dose in children is less than 2.5 mg daily, then LAMICTAL cannot be used. DO NOT attempt to administer partial quantities of the dispersible tablets. **BIPOLAR DISORDER** **• Adults (18 years of age and over)** LAMICTAL is indicated for the prevention of mood episodes in patients with bipolar disorder, predominantly by preventing depressive episodes.
BRU14081442P	Axcel Loratadine Tablet 10mg	Relief of symptoms associated with allergic rhinitis e.g. sneezing, nasal discharge (rhinorrhoea) and itching, as well as ocular itching & burning, chronic urticarial and other allergic dermatologic disorders.
BRU14081447P	Axcel Cefaclor-125 Suspension	Treatment of the following infections caused by susceptible organisms: otitis media, lower respiratory tract infections, pharyngitis and tonsillitis; urinary tract infection, skin and soft tissue infections. Cefaclor is generally effective in the eradication of streptococci from the nasopharynx.
BRU14081451P	Axcel Cetirizine Syrup 5mg/5ml	For symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticarial of allergic origin.
BRU14081453P	Sunex Cough Syrup	It is indicated as an expectorant for control of cough due to cold or allergy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14081456P	Nurofen For Children 100mg/5ml	Indicated for the reduction of fever (including that associated with immunization), and the relief of pain from teething, toothache, earache, sore throats, minor aches and sprains.
BRU14081457P	Axcel Salbutamol Syrup	For the relief of bronchospasm in asthma, chronic bronchitis and other conditions involving airways obstruction.
BRU14081459P	Clamentin Powder For Syrup 31.25mg/ml	For the treatment of infections caused by staphylococci, *streptococcus pneumoniae* , *streptococcus meningitis* and other susceptible pathogens. Clamentin is indicated for short-term treatment of bacterial infections at the following sites: Upper Respiratory Tract Infections e.g. Sinusitis, tonsillitis, otitis media. Lower Respiratory Tract Infections e.g. Acute and chronic bronchitis, lobar and bronchopneumonia, empyema, lung abscess. Skin and Soft Tissue Infections e.g. Boils, abscesses, cellulites, wound infections, intra-abdominal sepsis. Genito-Urinary Tract Infections e.g. Cystitis, urethritis, pyelonephritis, septic abortion, puerperal sepsis, pelvic infections, chancroid, gonorrhoea. Other Infections e.g. Osteomyelitis, septicaemia, peritonitis, post-operative infections.
BRU14081460P	Clarimycin Film Coated Tablet 500mg	Treatment of infections caused by pathogens sensitive to Clarithromycin. Infections of nose-pharinx tract (tonsillitis, pharyngitis), and of paranasal sinuses. Infections of lower respiratory tract: bronchitis, bacterial pneumonia and atypical pneumonia. Skin infections: impetigo, erysipelas, folliculitis, furunculosis and septic wounds.
BRU14081461NP	Mentar Shampoo	For the control of dandruff, seborrhoea and psoriasis.
BRU14081462NP	Menzza Cream	Menzza Cream is indicated for the relief of joint and muscular pains, sprains and strains as well as pain associated with rheumatism and arthritis. Menzza Cream is also suitable for the temporary relief of pain associated with musculoskeletal soreness and discomfort.
BRU14081465NP	Bayer Aspirin Tablet 500mg	Temporary relief of headaches, toothache, neuralgia and muscular pains as well as colds, influenza complaints, and fever.

BRU14081467P	Tobradex® Eye Drops Suspension	TOBRADEX® Ophthalmic Suspension is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns or penetration of foreign bodies. The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye. The particular anti-infective drug in this product is active against the following common bacterial eye pathogens: Staphylococci, including S. *aureus* and S. *epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains. Streptococci, including some of the Group A beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae* . *Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis. Morganella morganii* , most *Proteus vulgaris* strains, *Haemophilus influenzae* and *H. aegyptius, Moraxella lacunata* , and *Acinetobacter calcoaceticus (Herellea vaginacola)* and some *Neisseria* species.

BRU14081470P	Rotaqor 10mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Fredrickson Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia when response to diet and other non-pharmacological measures are inadequate. *Prevention of Cardiovascular Disease* In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: - reduce the risk of non-fatal myocardial infarction, - reduce the risk of fatal and non-fatal stroke, - reduce the risk for revascularization procedures, - reduce the risk of hospitalization for CHF, - reduce the risk of angina. *Pediatric Patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains ≥ 190 mg/dL or b. LDL-C remains ≥ 160 mg/dL and: • there is a positive family history of premature cardiovascular disease or • two or more other CVD risk factors are present in the pediatric patient
BRU14081473P	Clofenac SR Tablet 100mg	Used for relief of pain and inflammation in conditions such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout and following some surgical procedures.

BRU14081474P	Strepsils Max Plus Lozenges	For the symptomatic relief of mouth and throat infections including severe sore throats.
BRU14081475NP	Cera-Scalp Ointment	For the treatment of common scaly skin disorders of the scalp such as psoriasis, eczema, seborrhoeic dermatitis and dandruff.
BRU14091477P	Suprane Inhalation Liquid 100%	Suprane (desflurane) is indicated as an inhalation agent for induction and/or maintenance of anaesthesia in adults and maintenance of anaesthesia for inpatient and outpatient in adults and maintenance of anaesthesia in infants and children.
BRU14091479PS1; BRU14091479PS2; BRU14091479PS3	Cetrotide Injection 0.25mg	Prevention of premature ovulation in patients undergoing a controlled ovarian stimulation, followed by pick-up and assisted reproductive techniques. In clinical trials Cetrotide 0.25mg was used with human menopausal gonadotropin (HMG), however, limited experience with recombinant FSH suggested similar efficacy.
BRU14091481P	Xolair Powder And Solvent For Solution For Injection	**Allergic Asthma** **<u>Adults and adolescents (12 years of age and above)</u>** Xolair (omalizumab) is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids (ICS). **<u>Children (6 to < 12 years of age)</u>** Xolair is indicated as add-on therapy to improve asthma control with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions. **Chronic rhinosinusitis with nasal polyps (CRSwNP)** Xolair is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with CRSwNP for whom therapy with INC does not provide adequate disease control. **Chronic Spontaneous Urticaria (CSU)** Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.
BRU14091483P	Pengesic 50 Capsule	Pengesic 50 Capsule is used in the treatment of moderate to severe acute or chronic pain and in painful diagnostic or therapeutic measures.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14091486P	Crinone Progestrone Vaginal Gel 8%	Treatment of disorders associated with progesterone deficiency, such as: - infertility due to inadequate luteal phase. - for use during in-vitro fertilisation, where infertility is mainly due to tubal, idiopathic or endometriosis linked sterility associated with normal ovulatory cycles.
BRU14091487NP	Pinetarsol Gel	Pinetarsol Gel is a soap free cleansing gel that can be used as an adjunct treatment to help relieve itchy and inflamed skin conditions including dermatitis, inflamed scaly skin, jock itch, anal and genital itching and other minor skin irritations. Can be used in the shower, bath or hand basin. pH 6 to maintain the skin's natural protection. Pinetarsol Gel is a soap alternative. Avoid using soap as soap may irritate tender inflamed skin.
BRU14091488P	Defungo Vaginal Tablet	• Infections vaginal discharge • Vaginalis due to fungi – mainly Candida and/or Trichomonas, superinfections with sensitive clotrimazole-bacteria.
BRU14091490P	Trileptal® 600mg Film-Coated Tablet	Trileptal is indicated for the treatment of partial seizures (which include the seizure subtypes of simple, complex and partial seizures evolving to secondarily generalized seizures) and generalized tonic-clonic seizures, in adults and children. Trileptal is indicated as a first-line antielpileptic medicinal product for use as monotherapy or adjunctive therapy. Trileptal can replace other antiepileptic medicinal products when current therapy provides insufficient seizure control.
BRU14091494P	Eprex® 10000 Prefilled Syringes 10,000IU/1ml	• Treatment of anemia associated with chronic renal failure in adult hemodialysis, peritoneal dialysis and predialysis patients and pediatric patients on hemodialysis. • Treatment of anemia and reduction of transfusion in adult cancer patients with non-myeloid malignancies receiving chemotherapy. • Treatment of anemia in HIV-infected patients being treated with zidovudine who have endogenous erythropoietin levels ≤ 500 mIU/mL. • To facilitate autologous blood collection within a predeposit program and decrease the risk of receiving allogeneic blood transfusions in patients with hematocrits of 33 - 39%, who are scheduled for major elective surgery and are expected to require more blood than that which can be obtained through autologous blood collection techniques in the absence of Eprex. • Eprex is indicated in adult patients with mild to moderate anemia (hemoglobin > 10 to ≤ 13 g/dL) scheduled for elective surgery with an expected moderate blood loss (2 - 4 units or 900 to 1800 mL) to reduce exposure to allogeneic blood transfusions and to facilitate erythropoietic recovery). • Eprex is indicated for the treatment of anemia (hemoglobin concentration of ≤ 10 g/dL) in adults with low- or intermediate-1-risk myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/mL).
BRU14091502P	Loradine Tablet 10mg	Relief of symptoms associated with allergic rhinitis e.g. sneezing, nasal discharge and itching, as well as ocular itching and burning. Chronic urticarial and other allergic dermatologic disorders.
BRU14091511NP	0.9% Sodium Chloride Injection, B.P. (10ml)	Solvent or diluent for compatible electrolyte concentrates or drugs.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14091512NP	Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution)	- Fluid substitution under the conditions of undisturbed acid-base balance or mild acidosis. - Isotonic and hypotonic dehydration. - Short term intravascular volume replacement. - Vehicle solution for compatible electrolyte concentrates and drugs.
BRU14091519P	Afinitor 5mg Tablet	AFINITOR tablets are indicated for the ♦treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole. ♦treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with VEGF-targeted therapy. ♦treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic disease. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors. ♦treatment of adult patients with progressive, well-differentiated (Grade 1 or Grade 2), non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin with unresectable, locally advanced or metastatic disease. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors. ♦treatment of adult and pediatric patients, 1 years of age and older, with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not candidates for curative surgical resection. The effectiveness of AFINITOR is based on an analysis of change in SEGA volume (see section CLINICAL STUDIES). Clinical benefit such as improvement in disease-related symptoms or increase in overall survival has not been demonstrated. ♦treatment of adult patients with renal angiomyolipoma (AML) and tuberous sclerosis complex (TSC), not requiring immediate surgery. The effectiveness of AFINITOR in the treatment of renal angiomylipoma is based on an analysis of durable objective responses in patients treated for a median of 8.3 months. Further follow-up of patients is required to determine long-term outcomes.
BRU14091526P	Glucomet Tablet 500mg	Treatment of type 2 diabetes mellitus in adults, when dietary management and exercise alone does not result in adequate glycaemic control. Metformin may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin. A reduction of diabetic complications has been shown on overweight type-2 diabetic patients treated with metformin as 1st line therapy after diet failure. In type I diabetes, metformin may be given as an adjuvant to patients whose symptoms are poorly controlled.
BRU14091527P	Quemox Tablet 500mg	Quemox (Mebendazole) is very specifically indicated for the treatment of *Trichuris trichiura* (whipworm), *Enterobius vermicularis* (pinworm), *Ascaris lumbricoides* (roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm) and *Strongyloides stercoralis* (threadworm) in single and / or mixed infestations in adults and children.

BRU14091529NP	Strepsils Cool Lozenges	For relief of sore throats.
BRU14091530NP	Strepsils Sugar Free Lemon Lozenges	An antiseptic lozenge for the symptomatic relief of mouth and throat infections including sore throat.
BRU14091534P	Deplatt Tablet 75mg	Clopidogrel is indicated to prevent atherothrombotic events in adults as given below. • Patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease. • Patients suffering from acute coronary syndrome: - Non-ST segment elevation acute coronary syndrome (unstable angina or non-Qwave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention. - ST segment elevation acute myocardial infarction, in combination with acetylsalicylic acid (ASA) in medically treated patients eligible for thrombolytic therapy.

BRU14091540P	Zarator 10mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (*Fredrickson* Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD), such as age, smoking, hypertension, low HDLC, or a family history of early CHD, ZARATOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease, such as retinopathy, albuminuria, smoking, or hypertension, ZARATOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina *Pediatric Patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and post-menarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if, after an adequate trial of diet therapy the following findings are present: LDL-C remains ≥190 mg/dL or LDL-C remains ≥160 mg/dL and: • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient

BRU14091541P	Zarator 20mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (*Fredrickson* Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD), such as age, smoking, hypertension, low HDLC, or a family history of early CHD, ZARATOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease, such as retinopathy, albuminuria, smoking, or hypertension, ZARATOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina *Pediatric Patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and post-menarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if, after an adequate trial of diet therapy the following findings are present: LDL-C remains ≥190 mg/dL or LDL-C remains ≥160 mg/dL and: • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient

BRU14091542P	Zarator 40mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (*Fredrickson* Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD), such as age, smoking, hypertension, low HDLC, or a family history of early CHD, ZARATOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease, such as retinopathy, albuminuria, smoking, or hypertension, ZARATOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina *Pediatric Patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and post-menarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if, after an adequate trial of diet therapy the following findings are present: LDL-C remains ≥190 mg/dL or LDL-C remains ≥160 mg/dL and: • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient

BRU14091543P	Zarator 80mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (*Fredrickson* Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD), such as age, smoking, hypertension, low HDLC, or a family history of early CHD, ZARATOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease, such as retinopathy, albuminuria, smoking, or hypertension, ZARATOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina *Pediatric Patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and post-menarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if, after an adequate trial of diet therapy the following findings are present: LDL-C remains ≥190 mg/dL or LDL-C remains ≥160 mg/dL and: • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient

BRU14111546P	Binocrit Solution For Injection 2000 IU/ml in Pre-Filled Syringe	• Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adult hemodialysis, peritoneal dialysis and predialysis patients and pediatric patients on hemodialysis. • Treatment of anemia and reduction of transfusion in adult cancer patients with non-myeloid malignancies receiving chemotherapy. • To facilitate autologous blood collection within a predeposit program and decrease the risk of receiving allogeneic blood transfusions in patients with hematocrits of 33 - 39%, who are scheduled for major elective surgery and are expected to require more blood than that which can be obtained through autologous blood collection techniques in the absence of Binocrit. • Binocrit is indicated in adult patients with mild to moderate anemia (hemoglobin > 10 to ≤ 13 g/dL) scheduled for elective surgery with an expected moderate blood loss (2 - 4 units or 900 to 1800 mL) to reduce exposure to allogeneic blood transfusions and to facilitate erythropoietic recovery). • Binocrit is indicated for the treatment of anaemia (haemoglobin concentration of ≤ 10 g/dl) in adults with low- or intermediate-1-risk primary myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/ml).
BRU14111547P	Binocrit Solution For Injection 4000 IU/0.4ml In Pre-Filled Syringe	• Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adult hemodialysis, peritoneal dialysis and predialysis patients and pediatric patients on hemodialysis. • Treatment of anemia and reduction of transfusion in adult cancer patients with non-myeloid malignancies receiving chemotherapy. • To facilitate autologous blood collection within a predeposit program and decrease the risk of receiving allogeneic blood transfusions in patients with hematocrits of 33 - 39%, who are scheduled for major elective surgery and are expected to require more blood than that which can be obtained through autologous blood collection techniques in the absence of Binocrit. • Binocrit is indicated in adult patients with mild to moderate anemia (hemoglobin > 10 to ≤ 13 g/dL) scheduled for elective surgery with an expected moderate blood loss (2 - 4 units or 900 to 1800 mL) to reduce exposure to allogeneic blood transfusions and to facilitate erythropoietic recovery). • Binocrit is indicated for the treatment of anaemia (haemoglobin concentration of ≤ 10 g/dl) in adults with low- or intermediate-1-risk primary myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/ml).
BRU14111553P	Dynastat Injection 40mg	Management of post-operative pain in the immediate post-operative setting only with the exception of patients undergoing coronary artery bypass grafting (CABG) procedures and in those patients with elevated cardiovascular risk such as those with congestive heart failure (NYHA II-IV), established ischaemic heart disease and/or cerebrovascular disease.

BRU14111554P	Invanz Powder For Injection 1g/Vial	Treatment Invanz for injection 1g/vial is indicated for the treatment of patients with moderate to severe infections caused by susceptible strains of microorganisms. It is also indicated in the initial empirical therapy prior to the identification of causative organisms in the infections listed below: • Complicated intra-abdominal infections • Complicated skin and skin structure infections including diabetic lower extremity infections • Community acquired pneumonia • Complicated urinary tract infections including pyelonephritis • Acute pelvic infections including postpartum endomyometritis, septic abortion and post-surgical gynaecologic infections To reduce the development of drug-resistant bacteria and maintain the effectiveness of Invanz and other antibacterial drugs, Invanz should only be used to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. Prevention Invanz is also indicated as a prophylaxis treatment for surgical site infection following elective colorectal surgery and is administered as a single intravenous dose 1 hour prior to surgery.
BRU14111555P	Humalog Mix25 100 Units/ml Kwikpen	Humalog Mix 25 is indicated for the treatment of patients with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis.
BRU14111557NP	Counterpain Cool Gel 4% w/w	Provides temporary relief from muscular aches and pains.
BRU14111558P	Trileptal 300mg Film-Coated Tablet	Trileptal is indicated for the treatment of partial seizures (which include the seizure subtypes of simple, complex and partial seizures evolving to secondarily generalized seizures) and generalized tonic-clonic seizures, in adults and children. Trileptal is indicated as a first-line antielpileptic medicinal product for use as monotherapy or adjunctive therapy. Trileptal can replace other antiepileptic medicinal products when current therapy provides insufficient seizure control.
BRU14111561NP	Strepsils Original Lozenges	For relief of sore throat for children and adults.
BRU14111562NP	Strepsils Orange with Vitamin C Lozenges	An antiseptic lozenge for relief of sore throat for children and adults.
BRU14111564P	Axcel Promethazine-5 Syrup	It is indicated in the symptomatic relief of allergy or hypersensitivity reactions such as hayfever, urticaria, angioderma, rhinitis, conjunctivitis and pruritic skin disorders; night sedation, treatment and prevention of motion sickness; vertigo of various causes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14111565P	NIMBEX™ Injection 2mg/ml (5ml)	*NIMBEX* is an intermediate-duration, non-depolarising neuromuscular blocking agent for intravenous (i.v.) administration. *NIMBEX* is indicated for use during surgical and other procedures and in intensive care. It is used as an adjunct to general anaesthesia, or sedation in the Intensive Care Unit (ICU), to relax skeletal muscles, and to facilitate tracheal intubation and mechanical ventilation. *NIMBEX* injection contains no antimicrobial preservative and is intended for single patient use.
BRU14111566P	Aggrastat Concentrate For Infusion 0.25mg/ml	AGGRASTAT, in combination with heparin, is indicated for patients with unstable angina or non-Q-wave myocardial infarction to prevent cardiac ischemic events and is also indicated for patients with coronary ischemic syndromes undergoing coronary angioplasty or atherectomy to prevent cardiac ischemic complications related to abrupt closure of the treated coronary artery.
BRU14111569NPS2	Ferinject® 50mg Iron/ml Solution For Injection/Infusion	Ferinject is indicated for the treatment of iron deficiency when: – oral iron preparations are ineffective. – oral iron preparations cannot be used. – there is a clinical need to deliver iron rapidly. The diagnosis of iron deficiency must be based on laboratory tests. [e.g., plasma ferritin levels, haemoglobin, haematocrit, red cell count, MCV, MCH and transferrin saturation (TSAT).]
BRU14111573P	Eliquis Film-Coated Tablets 2.5mg	For 2.5 mg Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery. For 2.5 mg and 5 mg Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II). Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults for haemodynamically unstable PE patients.
BRU14111575P; BRU14111575PS2	Ryzodeg Flex Touch 100 Units/ml	Treatment of diabetes mellitus in adults and adolescents from the age of 12 years and above.
BRU14111578P	Tolanz Tablet 5mg	*Adults* Olanzapine is indicated for the treatment of schizopherenia. Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Olanzapine is indicated for the treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder.

BRU14111579P	Tolanz Tablet 10mg	*Adults* Olanzapine is indicated for the treatment of schizopherenia. Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Olanzapine is indicated for the treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder.
BRU14111581P	Vaminolact Solution	Vaminolact is indicated as a source of amino acids for protein synthesis and of taurine in infants and children requiring intravenous nutrition.
BRU14111582P	Covinace Tablet 4mg	Hypertension Treatment of hypertension. Stable coronary artery disease Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation.
BRU14111583NP	Oralite Natural Oral Rehydration Salts	For replacement of body fluids and electrolytes lost in diarrhoea and vomiting.

BRU14111585PS3, BRU14111585PS4; BRU14111585PS5	Avastin 100mg/4ml	Avastin in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum. Avastin in combination with paclitaxel is indicated for the treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer. Avastin in combination with capecitabine is indicated for first-line treatment of patients with HER2-negative metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate. Patients who have received taxane and anthracycline-containing regimens in the adjuvant setting within the last 12 months should be excluded from treatment with Avastin in combination with capecitabine. The effectiveness of Avastin in metastatic breast cancer (mBC) is based on an improvement in progression-free survival. Currently, no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Avastin in breast cancer. Avastin, in combination with carboplatin and paclitaxel, is indicated for first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic nonsquamous, non-small cell lung cancer. Avastin, in combination with erlotinib, is indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations. Avastin, as a single agent is indicated for the treatment of patients with glioblastoma after relapse or disease progression following prior therapy. The effectiveness of Avastin in glioblastoma is based on an improvement in objective response rate. There are no data demonstrating an improvement in disease-related symptoms or increased survival with Avastin. Avastin in combination with interferon alfa-2a is indicated for first-line treatment of patients with advance and/or metastatic renal cell cancer. Avastin, in combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (FIGO stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. Avastin, in combination with carboplatin and gemcitabine or in combination with carboplatin and paclitaxel is indicated for the treatment of patients with recurrent, platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer who have not received prior bevacizumab or other VEGF-targeted angiogenesis inhibitors. Avastin in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin is indicated for the treatment of patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents. Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix.
BRU14111589P	Resolor Film-Coated Tablet 1mg	RESOLOR® is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14111591P	Pristiq 50mg Extended-Release Tablets	PRISTIQ, a selective serotonin and norepinephrine reuptake inhibitor (SNRI), is indicated for the treatment of major depressive disorder (MDD). The efficacy of PRISTIQ has been established in four 8-week, placebo controlled studies of outpatients who met DSM-IV criteria for major depressive disorder. A major depressive episode (DSM-IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least 5 of the following 9 symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, or a suicide attempt or suicidal ideation. The efficacy of PRISTIQ in maintaining a response in major depressive disorder for up to 24 weeks following 12 weeks of acute treatment was demonstrated in a placebo-controlled trial. Nevertheless, the physician who elects to use PRISTIQ for extended periods, i.e., beyond 9 months, should continue to periodically re-evaluate the long-term usefulness of the drug for the individual patients.
BRU14111592P	Ellquis 5mg Film-Coated Tablet	Therapeutic Indication For 2.5 mg Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery. For 2.5 mg and 5 mg Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II). Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults for haemodynamically unstable PE patients.
BRU14111593P	Pulin Film-Coated Tablet 10mg	Adult population This product is indicated for use in adults for: * Prevention of delayed chemotherapy induced nausea and vomiting (CINV) * Prevention of radiotherapy induced nausea and vomiting (RINV) * Symptomatic treatment of nausea and vomiting including acute migraine induced nausea and vomiting Pediatric population This product is indicated in children (aged 1 to 18 years) for: * Prevention of delayed chemotherapy induced nausea and vomiting (CINV) as a second-line option

BRU14111597NP	0.45% Sodium Chloride And 5% Dextrose Intravenous Infusion B.P	i) Dehydration ii) Light sodium and chloride depletion iii) Hypochloremic alkalosis iv) Vehicle solution for supplementary medication
BRU14111598PS1; BRU14111598PS2	Gonal-F 1050IU/1.75ml (77mcg/1.75ml) Powder And Solution For Injection	In adult women • Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. • Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intrafallopian transfer.
BRU14111607NP	Pharmaniaga Sodium Bicarbonate 8.4% w/v Injection	Sodium Bicarbonate 8.4% w/v Injection is indicated in the treatment of metabolic acidosis and renal calculi caused by uric acid, renal failure, diabetic coma, or following cardiac arrest.

BRU14111623P	Botox (Botulinium Toxin, Type A) Injection 100 Units/Vial	BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following therapeutic indications: • BOTOX® is indicated for the treatment of blepharospasm associated with dystonia, including benign essential blepharospasm, hemifacial spasm and VIIth nerve disorders in patients 12 years or older. • BOTOX® is indicated for the correction of strabismus in patients 12 years of age or older. • BOTOX® is indicated for the treatment of spasmodic torticollis (cervical dystonia) in adults. • BOTOX® is indicated for the treatment of dynamic equinus foot deformity due to spasticity in paediatric cerebral palsy patients, two years of age and older. • BOTOX® is indicated in the management of focal spasticity: o including wrist and hand disability due to upper limb spasticity associated with stroke in adults. o Including ankle and foot disability due to lower limb spasticity associated with stroke in adults. • BOTOX® is indicated for the management of severe hyperhidrosis of the axillae which does not respond to topical treatment with antiperspirant or antihidrotics. • BOTOX® is indicated for the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). • BOTOX® is indicated for the treatment of urinary incontinence due to neurogenic detrusor overactivity (NDO) associated with Multiple Sclerosis or Spinal Cord Injury in adults who had an inadequate response to or are intolerant of an anticholinergic medication. • BOTOX® is indicated for the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication. BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following cosmetic indications: • BOTOX® is indicated for the temporary improvement in the appearance of upper facial rhytides (glabellar lines, crow's feet and forehead lines) in adults. • BOTOX® is indicated for the temporary treatment of glabellar lines associated with corrugator and/or procerus muscle activity in adult patients below 65 years of age.

BRU14111624P	Botox (Botulinium Toxin, Type A) Injection 50 Units/Vial	BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following therapeutic indications: • BOTOX® is indicated for the treatment of blepharospasm associated with dystonia, including benign essential blepharospasm, hemifacial spasm and VIIth nerve disorders in patients 12 years or older. • BOTOX® is indicated for the correction of strabismus in patients 12 years of age or older. • BOTOX® is indicated for the treatment of spasmodic torticollis (cervical dystonia) in adults. • BOTOX® is indicated for the treatment of dynamic equinus foot deformity due to spasticity in paediatric cerebral palsy patients, two years of age and older. • BOTOX® is indicated in the management of focal spasticity: o including wrist and hand disability due to upper limb spasticity associated with stroke in adults. o Including ankle and foot disability due to lower limb spasticity associated with stroke in adults. • BOTOX® is indicated for the management of severe hyperhidrosis of the axillae which does not respond to topical treatment with antiperspirant or antihidrotics. • BOTOX® is indicated for the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). • BOTOX® is indicated for the treatment of urinary incontinence due to neurogenic detrusor overactivity (NDO) associated with Multiple Sclerosis or Spinal Cord Injury in adults who had an inadequate response to or are intolerant of an anticholinergic medication. • BOTOX® is indicated for the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication. BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following cosmetic indications: • BOTOX® is indicated for the temporary improvement in the appearance of upper facial rhytides (glabellar lines, crow's feet and forehead lines) in adults. • BOTOX® is indicated for the temporary treatment of glabellar lines associated with corrugator and/or procerus muscle activity in adult patients below 65 years of age.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14111625P	Botox (Botulinium Toxin, Type A) Injection 200 Units/Vial	BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following therapeutic indications: • BOTOX® is indicated for the treatment of blepharospasm associated with dystonia, including benign essential blepharospasm, hemifacial spasm and VIIth nerve disorders in patients 12 years or older. • BOTOX® is indicated for the correction of strabismus in patients 12 years of age or older. • BOTOX® is indicated for the treatment of spasmodic torticollis (cervical dystonia) in adults. • BOTOX® is indicated for the treatment of dynamic equinus foot deformity due to spasticity in paediatric cerebral palsy patients, two years of age and older. • BOTOX® is indicated in the management of focal spasticity: o including wrist and hand disability due to upper limb spasticity associated with stroke in adults. o Including ankle and foot disability due to lower limb spasticity associated with stroke in adults. • BOTOX® is indicated for the management of severe hyperhidrosis of the axillae which does not respond to topical treatment with antiperspirant or antihidrotics. • BOTOX® is indicated for the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). • BOTOX® is indicated for the treatment of urinary incontinence due to neurogenic detrusor overactivity (NDO) associated with Multiple Sclerosis or Spinal Cord Injury in adults who had an inadequate response to or are intolerant of an anticholinergic medication. • BOTOX® is indicated for the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication. BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following cosmetic indications: • BOTOX® is indicated for the temporary improvement in the appearance of upper facial rhytides (glabellar lines, crow's feet and forehead lines) in adults. • BOTOX® is indicated for the temporary treatment of glabellar lines associated with corrugator and/or procerus muscle activity in adult patients below 65 years of age.
BRU14111628NP	0.45% Sodium Chloride Intravenous Infusion B.P	• Hypertonic dehydration, • Vehicle solution for compatible medicinal products
BRU14111633P	Pharmaniaga Salbutamol Respirator Solution 0.5% w/v	Salbutamol Respirator Solution is indicated for the relief of bronchospasm in patients with reversible obstructive airway disease and acute bronchospasm.
BRU14111634P	Epimate 50mg Tablet	Topiramate tablets is indicated as adjunctive therapy for adults and pediatric patients ages 2-16 years with partial onset seizures, or primary generalized tonic-clonic seizures, and in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome.
BRU14111644P	Buston Injection 20mg/ml	Buston 20mg/mL Solution for Injection is indicated in acute spasm, as in renal or biliary chronic, in radiology for differential diagnosis of obstruction. It also indicated to reduce spasm and pain in pyelography, and in other diagnostic procedures where spasm may be a problem.

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BRU14111646NP	Oralite Orange Oral Rehydration Salts	For replacement of body fluids and electrolytes lost in diarrhoea and vomiting.
BRU14111648P	Pharmaniaga Cetirizine 10mg Tablet	It is used for the symptomatic relief of allergic condition including rhinitis and chronic urticaria.
BRU14111649P	Hovid Lipiduce-20 Tablet	Atorvastatin is indicated: As an adjunct therapy to diet to reduce elevated total cholesterol, LDL-cholesterol, apolipoprotein B, triglycerides and increase HDL-cholesterol in patients with: • Primary hypercholesterolemia (heterozygous familial and nonfamilial). • Combined hyperlipidaemias (Fredrickson Types IIa and IIb). • Hypertriglyceridemia (Fredrickson Type IV). • Primary dysbetalipoproteinemia (Fredrickson Type III). As an adjunct therapy with other lipid lowering treatment (e.g. LDL apheresis) in homozygous familial hypercholesterolemia to reduce total cholesterol and LDL cholesterol.

BRU14111650P	Invokana Film-Coated Tablet 100mg	Monotherapy INVOKANA (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance. Combination with Metformin or a Sulfonylurea INVOKANA is indicated in combination with metformin or a sulfonylurea in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise plus monotherapy with one of these agents does not provide adequate glycemic control. Combination with Metformin and either a Sulfonylurea or Pioglitazone INVOKANA is indicated in combination with metformin and either a sulfonylurea or pioglitazone in adult patients with type 2 diabetes mellitus to improve glycemic control when diet, exercise, and dual therapy (with metformin plus either a sulfonylurea or pioglitazone) do not provide adequate glycemic control. Combination with Insulin INVOKANA is indicated as add-on combination therapy with insulin (with or without metformin) in adult patients with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control when diet and exercise, and therapy with insulin (with or without metformin) do not provide adequate glycemic control. Add-On Combination in Patients with Established Cardiovascular Disease INVOKANA is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adult with type 2 diabetes mellitus and established cardiovascular disease (CVD). Patients with Diabetic Nephropathy INVOKANA is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of end-stage kidney disease, doubling of serum creatinine, and cardiovascular (CV) death in adult patients with type 2 diabetes mellitus and diabetic nephropathy with albuminuria (> 33.9 mg/mmol).
BRU14111655P	Risperdal Solution 1mg/ml	RISPERDAL TABLET (1MG, 2MG & 3MG) AND RISPERDAL ORAL SOLUTION 1MG/ML RISPERDAL® is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERDAL® alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISPERDAL® is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISPERDAL is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders. RISPERDAL TABLETS (1MG) AND RISPERDAL ORAL SOLUTION 1MG/ML RISPERDAL is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14121666P	Amoxicap 500 Capsule	For treatment of: 1) Ear, nose and throat infections caused by *streptococci, pneumococci* , non-*penicillinase* -producing *staphylococci* and *H.influenzae* 2) Genitourinary tract infections caused by E.Coli, P.Mirabilis, S.Faecalis 3) Skin and soft-tissues infections caused by *streptococci* , non-*penicillinase* -producing *staphylococci* and E.Coli 4) Anogenital and urethral *gonorrhoea* caused by N.Gonorrhoea
BRU14121668NP	50% Glucose Intravenous Infusion B.P.	Parental nutrition. High caloric carbohydrate therapy, especially when fluid intake is limited as for example in renal insufficiency. Hypoglycaemia.
BRU14121675P	Ziagen Oral Solution	ZIAGEN is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and children.
BRU14121686P	Decan Injection 2mg/ml	Treatment of acute or chronic rheumatism, rheumatoid arthritis, acute gout arthritis, myalgia, eczematosis, allergic dermatitis, and acute or chronic allergic and inflammatory skin disorders.
BRU14121698P	Edurant Film-Coated 25mg Tablet	EDURANT, in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml.

BRU14121699P	Invokana 300mg FCT	Monotherapy INVOKANA (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance. Combination with Metformin or a Sulfonylurea INVOKANA is indicated in combination with metformin or a sulfonylurea in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise plus monotherapy with one of these agents does not provide adequate glycemic control. Combination with Metformin and either a Sulfonylurea or Pioglitazone INVOKANA is indicated in combination with metformin and either a sulfonylurea or pioglitazone in adult patients with type 2 diabetes mellitus to improve glycemic control when diet, exercise, and dual therapy (with metformin plus either a sulfonylurea or pioglitazone) do not provide adequate glycemic control. Combination with Insulin INVOKANA is indicated as add-on combination therapy with insulin (with or without metformin) in adult patients with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control when diet and exercise, and therapy with insulin (with or without metformin) do not provide adequate glycemic control. Add-On Combination in Patients with Established Cardiovascular Disease INVOKANA is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adult with type 2 diabetes mellitus and established cardiovascular disease (CVD). Patients with Diabetic Nephropathy INVOKANA is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of end-stage kidney disease, doubling of serum creatinine, and cardiovascular (CV) death in adult patients with type 2 diabetes mellitus and diabetic nephropathy with albuminuria (> 33.9 mg/mmol).
BRU14121702NP	Septi-Sol Solution	For hand disinfection of healthcare personnel. Septi-Sol Solution is to be used as a supplement to handwashing when hands are not visibly soiled or when soap and water are not conveniently or readily available.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU14121703P	Atoris Film-Coated Tablet 20mg	<u>Hypercholesterolaemia</u> Atoris is indicated as an adjunct to diet for the reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atoris is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. <u>Prevention of cardiovascular disease</u> Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
BRU14121705P; BRU14121705PS2	Ultibro Breezhaler 110/50 mcg Inhalation Powder Hard Capsule	Ultibro Breezhaler is indicated as a once-daily maintenance bronchodilator treatment to relieve symptoms and reduce exacerbations in adult patients with chronic obstructive pulmonary disease (COPD).
BRU15011710P	Klerimed 250mg FC Tablets	Klerimed is indicated for treatment of infections caused by one or more susceptible organisms. Indications include: • Lower respiratory tract infections for example, acute and chronic bronchitis, and pneumonia. • Upper respiratory tract infections for example, sinusitis and pharyngitis. Klerimed is appropriate for initial therapy in community acquired respiratory infections and has been shown to be active in vitro against common and atypical respiratory pathogens as listed in the microbiology section. Klerimed is also indicated in skin and soft tissue infections of mild to moderate severity. Klerimed in the presence of acid suppression effected by omeprazole is also indicated for the eradication of *H. Pylori* in patients with proven duodenal ulcers.
BRU15011711P	DiSuf-B Cream	Disuf-B Cream is indicated in inflammatory dermatoses where bacterial infection is present or likely to occur. Inflammatory dermatoses include atopic eczema, discoid eczema, stasis eczema, seborrhoeic dermatitis, contact dermatitis, lichen simplex chronicus, psoriasis, discoid lupus erythematosus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU15011714P	Ospamox 250mg/5ml Granules For Suspension	Ospamox is useful in the treatment of infections caused by amoxycillin-susceptible organisms: − Acute bacterial sinusitis − Acute otitis media − Acute streptococcal tonsillitis and pharyngitis − Acute exacerbations of chronic bronchitis − Community acquired pneumonia − Acute cystitis − Asymptomatic bacteriuria in pregnancy − Acute pyelonephritis − Typhoid and paratyphoid fever − Dental abscess with spreading cellulitis − Prosthetic joint infections − Helicobacter pylori eradication − Lyme disease Amoxicillin is also indicated for the prophylaxis of endocarditis. Consideration should be given to official guidance on the appropriate use of antibacterial agents.
BRU15011724P	Forteo Injection 20mcg/80mcl	FORTEO is indicated in adults. Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and non-vertebral fractures but not hip fractures has been demonstrated. Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture.
BRU15011727P	Bactigen Eye Drops 0.3% w/v	BACTIGEN is indicated in the topical treatment of infections caused by susceptible bacteria of the external structures of the eyes and their adnexa, such as conjunctivitis, keratitis and keratoconjunctivitis, corneal ulcers, blepharitis and blepharoconjunctivitis, acute meibomianitis and dacryocystitis.
BRU15011728P	Hexaxim Suspension For Injection	Hexaxim (DTaP-IPV-HB-Hib) is indicated for primary and booster vaccination of infants and toddlers from six weeks to 24 months of age against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b (Hib). The use of this vaccine should be in accordance with official recommendations.

BRU15011730PS1; BRU15011730PS3	Bridion Solution For Injection 100mg/ml	Reversal of neuromuscular blockade induced by rocuronium or vecuronium in patients 2 years of age and older.
BRU15011738NP	Bactidol Mouthwash	For the symptomatic relief of mouth and throat infections including mouth ulcers caused by susceptible bacteria and fungus.
BRU15011743P	Pharmaniaga Germacid Cream 2%	Pharmaniaga Germacid Cream is indicated for treatment of skin lesions caused by staphylococci, streptococci, Propionibacterium acnes, Corynebacterium minutissimum, and other organisms sensitive to fusidic acid. The most important indications being: Impetigo, infected wounds, folliculitis, boils, sycosis barbae, carbuncles, hidradenitis, paronychia and erythrasma. Pharmaniaga Germacid Cream is an invisible, non-staining preparation, which is cosmetically acceptable for treatment of face and scalp infections.
BRU15011744NP	Extraneal Peritoneal Dialysis Solution 75g/l (2L Ultrabag)	Extraneal is recommended as a once daily replacement for a single Dextrose exchange as part of a CAPD or automated peritoneal dialysis (APD) regimen for the treatment of chronic renal failure, particularly for some categories of patients who have lost ultrafiltration on Dextrose solutions, because it canextend time on CAPD therapy in such patients.
BRU15011750NP	Prismasol BO	As substitution solution in continuous haemofiltration and haemodiafiltration and as dialysis solution in continuous haemodialysis for acute renal failure.

BRU15021757P	Simponi Solution For Injection 50mg/0.5ml	*Rheumatoid arthritis (RA):* SIMPONI, by SC administration, in combination with methotrexate (MTX), is indicated for: • the treatment of moderate to severe active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including methotrexate has been inadequate. • the treatment of severe, active, and progressive rheumatoid arthritis in adult patients not previously treated with MTX. SIMPONI, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function. *Psoriatic arthritis (PsA):* SIMPONI, by SC administration, alone or in combination with MTX, is indicated for: • the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate. SIMPONI has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Axial spondyloarthritis* *Ankylosing spondylitis (AS):* SIMPONI, by SC administration, is indicated for: • the treatment of severe, active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA):* SIMPONI, by SC administration, is indicated for the treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). *Ulcerative colitis (UC):* SIMPONI, by SC administration, is indicated for: • The treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.
BRU15021761P	Covapril Tablet 4mg	1. Hypertension: Treatment of hypertension. 2. Heart failure: Treatment of symptomatic heart failure. 3. Stable coronary artery disease: Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularization.
BRU15021769NP	Zellox-II Liquid Antacid	Zellox-II is indicated for relief from gastric acidity, indigestion, heartburn, flatulence and dyspepsia.
BRU15021771P	Gilenya 0.5mg Hard Capsule	Gilenya is indicated for the treatment of adult patients and pediatric patients of 10 years of age and above with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

BRU15021779P; BRU15021779PS2	Trajenta Duo 2.5mg/500mg Film-Coated Tablet	Trajenta Duo is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate (see Posology and Method of Administration and Clinical Studies).
BRU15021780P; BRU15021780PS2	Trajenta Duo 2.5mg/850mg Film-Coated Tablet	Trajenta Duo is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate (see Posology and Method of Administration and Clinical Studies).
BRU15021781P; BRU15021781PS2	Trajenta Duo 2.5mg/1000mg Film-Coated Tablet	Trajenta Duo is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate (see Posology and Method of Administration and Clinical Studies).
BRU15021786P	Giotrif 20mg Film-Coated Tablets	GIOTRIF as monotherapy is indicated for the treatment of • Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s). • Locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.
BRU15021787P	Giotrif 30mg Film-Coated Tablets	GIOTRIF as monotherapy is indicated for the treatment of • Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s). • Locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.
BRU15021788P	Giotrif 40mg Film-Coated Tablets	GIOTRIF as monotherapy is indicated for the treatment of • Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s). • Locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.
BRU15021789P	Giotrif 50mg Film-Coated Tablets	GIOTRIF as monotherapy is indicated for the treatment of • Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s). • Locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.
BRU15021793NP	SMOFlipid 20% Emulsion For Infusion	Supply of energy and essential fatty acids and omega-3 fatty acids to patients, as part of a parenteral nutrition regimen, when oral or enteral nutrition is impossible, insufficient or contra-indicated.
BRU15021794NP	Aminoven 10%	For supply of amino acids as part of a parenteral nutrition regimen.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU15021796P	Montelair 10mg Film-Coated Tablet	• For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 6 years of age and older. • Montelukast is indicated in adults and pediatric patients 6 years of age and older for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis.
BRU15021797P	Amlibon 10mg Tablet	<u>Hypertension</u> Amlodipine is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha-blocker, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme inhibitor. <u>Chronic Stable Angina</u> Amlodipine is indicated for the first line treatment of myocardial ischaemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but where vasospasm/vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or beta-blockers.
BRU15021798NP	Dianeal Low Calcium (2.5MEq/L) Peritoneal Dialysis Solution With 4.25% Dextrose (2L Ultrabag)	Dianeal Low Calcium peritoneal dialysis solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.
BRU15021799NP	Dianeal Low Calcium (2.5MEq/L) Peritoneal Dialysis Solution 2.5% Dextrose (2L Ultrabag And 2.5L Ultrabag)	Dianeal Low Calcium peritoneal dialysis solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.
BRU15021800NP	Dianeal Low Calcium (2.5MEq/L) Peritoneal Dialysis Solution 1.5% Dextrose (2L Ultrabag And 2.5L Ultrabag)	Dianeal Low Calcium peritoneal dialysis solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

BRU15021801NP	Calactate Tablet 300mg	Calcium salts are mainly in the treatment of calcium deficiency, hypocalcaemia, post-menopausal osteoporosis, and conditions requiring increased calcium demand in pregnancy lactation, old age, and growth period.
BRU15021802P	Xylid 250mg Tablet	**Upper respiratory tract infections for example**, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis. **Lower respiratory tract infections for example**, pneumonia, acute bronchitis, and acute exacerbations of chronic bronchitis. **Genito-urinary tract infections for example**, pyelonephritis, cystitis and urethritis. **Skin and soft tissue infections for example**, furunculosis, pyoderma and impetigo. **Gonorrhoea**, acute uncomplicated gonococcal urethritis and cervicitis. Xylid tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria to reduce the development of drug-resistant bacteria and maintain the effectiveness of Xylid tablets and other antibacterial drugs.
BRU15021805P	Serenata 50mg Tablet	Sertaline is indicated for the treatment of symptoms of depression, including accompanied by symptoms of anxiety, in patients with or without history of mania. Following satisfactory response, continuation with Sertraline therapy is effective in preventing relapse of the initial episode of depression or recurrence of further depressive episodes including accompanying symptoms of anxiety. Sertraline is indicated for the treatment of obsessive-compulsive disorder (OCD). Following satisfactory response, continuation with Sertraline therapy is effective in preventing relapse of the initial episode of OCD. Sertraline is indicated for the treatment of post-traumatic stress disorder (PTSD). Following satisfactory response, continuation with Sertraline therapy is effective in preventing relapse of the initial episode of PTSD.

BRU15031812P	Lamotrix 100mg Tablets	EPILEPSY * Adults and children (over 12 years of age) Lamotrigine is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. * Children (2 to 12 years of age) Lamotrigine is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalized seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. Initial monotherapy treatment in newly diagnosed paediatric patients is not recommended. After epileptic control has been achieved during adjunctive therapy, concomitant anti-epileptic drugs (AEDs) may be withdrawn and patients continued on lamotrigine monotherapy. BIPOLAR DISORDER * Adults (18 years of age and over) Lamotrix is indicated for the prevention of depressive episodes in patients with bipolar disorder. Safety and efficacy of lamotrigine in the acute treatment of mood episodes has not been established. The physician who elects to use lamotrigine for periods extending beyond 18 months should periodically re-evaluate the long-term usefulness of the drug for the individual patient.
BRU15031813P	Lamotrix 50mg Tablets	EPILEPSY * Adults and children (over 12 years of age) Lamotrigine is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. * Children (2 to 12 years of age) Lamotrigine is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalized seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. Initial monotherapy treatment in newly diagnosed paediatric patients is not recommended. After epileptic control has been achieved during adjunctive therapy, concomitant anti-epileptic drugs (AEDs) may be withdrawn and patients continued on lamotrigine monotherapy. BIPOLAR DISORDER * Adults (18 years of age and over) Lamotrix is indicated for the prevention of depressive episodes in patients with bipolar disorder. Safety and efficacy of lamotrigine in the acute treatment of mood episodes has not been established. The physician who elects to use lamotrigine for periods extending beyond 18 months should periodically re-evaluate the long-term usefulness of the drug for the individual patient.
BRU15031814P	Nimenrix™ (Meningococcal Polysaccharide Serogroups A,C,W-135, Y) Vaccine	Active immunization of individuals from 6 weeks of age against invasive meningococcal diseases caused by Neisseria meningitidis group A, C, W-135, and Y.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU15031816P	Cialis 5mg Tablet	Treatment of erectile dysfunction in adult males. In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required. Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males. CIALIS is not indicated for use by women.
BRU15031817P	Cialis 20mg Tablet	Treatment of erectile dysfunction in adult males. In order for tadalafil to be effective, sexual stimulation is required. CIALIS is not indicated for use by women.
BRU15031821P	Ometac Capsule 20mg	Treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy. Treatment of reflux oesophagitis, *Zollinger-Ellison syndrome* . Prophylactic treatment in patients with an increased risk of NSAID–associated gastric ulcers, duodenal ulcers, gastro-duodenal erosions or dyspeptic symptoms.
BRU15031825P	Saizen® Liquid 12mg (8mg/ml)	Saizen® (6 mg, 12 mg, and 20 mg) is indicated in the treatment of: • Growth failure in children caused by decreased or absent secretion of endogenous growth hormone. • Growth failure in girls with gonadal dysgenesis (Turner Syndrome), confirmed by chromosomal analysis. • Growth disturbance (current height SDS < -2.5 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS <0 during the last year) by 4 years of age or later. • Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed by a single dynamic test for growth hormone deficiency. Patients must also fulfill the following criteria: Childhood Onset: Patients who were diagnosed as growth hormone deficient during childhood, must be retested and their growth hormone deficiency confirmed before replacement therapy with Saizen is started. Adult Onset: Patients must have growth hormone deficiency as a result of hypothalamic or pituitary disease and at least one other hormone deficiency diagnosed (except for prolactin) and adequate replacement therapy instituted, before replacement therapy using growth hormone may begin. Saizen® (Only for 6 mg and 12 mg) is indicated in the treatment of: • growth failure in prepubertal children due to chronic renal failure (CRF). • growth disturbance due to idiopathic short stature (ISS).

BRU15031826P	Saizen® Liquid 6mg (5.83mg/ml)	Saizen® (6 mg, 12 mg, and 20 mg) is indicated in the treatment of: • Growth failure in children caused by decreased or absent secretion of endogenous growth hormone. • Growth failure in girls with gonadal dysgenesis (Turner Syndrome), confirmed by chromosomal analysis. • Growth disturbance (current height SDS < -2.5 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS <0 during the last year) by 4 years of age or later. • Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed by a single dynamic test for growth hormone deficiency. Patients must also fulfill the following criteria: Childhood Onset: Patients who were diagnosed as growth hormone deficient during childhood, must be retested and their growth hormone deficiency confirmed before replacement therapy with Saizen is started. Adult Onset: Patients must have growth hormone deficiency as a result of hypothalamic or pituitary disease and at least one other hormone deficiency diagnosed (except for prolactin) and adequate replacement therapy instituted, before replacement therapy using growth hormone may begin. Saizen® (Only for 6 mg and 12 mg) is indicated in the treatment of: • growth failure in prepubertal children due to chronic renal failure (CRF). • growth disturbance due to idiopathic short stature (ISS).
BRU15031827P	Torpezil Tablets 10mg	Torpezil is indicated for the treatment of mild, moderate and severe dementia in Alzheimer's disease.
BRU15031828P	Torpezil Tablets 5mg	Torpezil is indicated for the treatment of mild, moderate and severe dementia in Alzheimer's disease.

BRU15041834P	Rotaqor 20mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Fredrickson Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia when response to diet and other non-pharmacological measures are inadequate. *Prevention of Cardiovascular Disease* In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: - reduce the risk of non-fatal myocardial infarction, - reduce the risk of fatal and non-fatal stroke, - reduce the risk for revascularization procedures, - reduce the risk of hospitalization for CHF, - reduce the risk of angina. *Pediatric Patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains ≥ 190 mg/dL or b. LDL-C remains ≥ 160 mg/dL and: • there is a positive family history of premature cardiovascular disease or • two or more other CVD risk factors are present in the pediatric patient

BRU15041835P	Jakavi 20mg Tablet	Myelofibrosis (MF) Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. Polycythaemia vera (PV) Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea. Graft versus host disease (GvHD) Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).
BRU15041836P	Jakavi 15mg Tablet	Myelofibrosis (MF) Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. Polycythaemia vera (PV) Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea. Graft versus host disease (GvHD) Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).
BRU15041837P	Jakavi 5mg Tablet	Myelofibrosis (MF) Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. Polycythaemia vera (PV) Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea. Graft versus host disease (GvHD) Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU15041840P	Ciproflo 2mg/ml Solution For IV Infusion	Ciproflo 2mg/ml solution for infusion is indicated in the treatments of uncomplicated and complicated infections caused by ciprofloxacin sensitive pathogens: - Infections of the respiratory tract In the treatment of outpatients with pneumonia due to Pneumococcus ciprofloxacin should not be used as a first choice of drug. Ciprofloxacin can be regarded as advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, E.Coli, Pseudomonas, Haemophilus, Branhamella, Legionella and Staphylococcus. - Infections of the middle ear (otitis media), of the paranasal sinuses (sinusitis), especially if these are caused by gram negative organisms including Pseudomonas or by Staphylococcus. - Infections of the eyes - Infections of the kidneys and/or the efferent urinary tract - Infections of the genital organs, including adnexitis, gonorrhea, prostatitis - Infections of the abdominal cavity (eg. Infections of the gastrointestinal tract or of the biliary tract, peritonitis) - Infections of the skin and soft tissue - Infections of the bones and joints - Sepsis - Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (eg, patients on immunosuppressants or have neutropenia) - Selective intestinal decontamination in immunosuppressed patients
BRU15041841P	Omezole 20mg Capsule	Omezole 20mg capsule is indicated for: • Treatment of reflux oesophagitis • Duodenal ulcer; benign gastric ulcer • Long term treatment of pathologic gastric hypersecretion associated with Zollinger-Ellison syndrome
BRU15041844P	Pharmaniaga Loratadine Tablet 10mg	Loratadine is indicated for the relief of symptoms associated with allergic rhinitis e.g. Sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. Also indicated for the relief of symptoms and signs of chronic urticaria and other allergic dermatological disorders.
BRU15041846P	Vancotex Injection 500mg	Vancomycin is indicated in the serious or severe infections caused by susceptible strains of beta-lactam resistant staphylococci for penicillin-allergic patients, for infections caused by Vancomycin susceptible organism that are resistant to other antimicrobial drugs.
BRU15041848NP	Soluvit N Powder For Solution For Infusion	Soluvit N is indicated in adult patients and children as a supplement in intravenous nutrition to meet the daily requirements of watersoluble vitamins.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU15041850P	Estelle-35 Tablet	For the treatment of androgen-dependent diseases in women, such as moderate to severe acne, and mild forms of hirsutism. When used for the treatment of acne, Estelle-35 should only be used after topical therapy or systemic antibiotic treatments have failed. If the hirsutism has only recently appeared or has lately intensified to a considerable extent, the cause (androgen-producing tumour or an adrenal enzyme defect) must be clarified by differential diagnosis. Estelle-35 should not be prescribed for the purpose of contraception alone.
BRU15041852PS1; BRU15041852PS2	Glucophage® XR 1000mg Extended-Release Tablet	• Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with IGT* and/or IFG* who are: - at high risk for developing overt type 2 diabetes mellitus (see section 5.1) and - not suitable for intensive lifestyle modifications. Treatment with Glucophage XR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk (see section 5.1). *IGT: Impaired Glucose Tolerance; IFG: Impaired Fasting Glucose • Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. Glucophage XR may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.
BRU15041854NP	Voluven Solution For Infusion 6%	Treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient.
BRU15041861NP	ChlorHex 5% Concentrate Solution	ChlorHEX 5% is an antimicrobial agent for general antiseptic purposes. Chlorhexidine gluconate is effective against a wide range of bacteria and inhibits some viruses and is active against some fungi.
BRU15051869P	Dopatab M250 Tablet	For treatment of moderate to severe hypertension.
BRU15051878P	Loratyn-10	For relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, and ocular itching and burning).

BRU15061881P	Norditropin NordiFlex Injection 5mg/1.5ml Pre-Filled Pen, Solution For Injection	Children: Growth failure due to growth hormone deficiency (GHD) Growth failure in girls due to gonadal dysgenesis (Turner syndrome) Growth retardation in prepubertal children due to chronic renal disease. Growth disturbance (current height standard deviation score (SDS) < -2.5 and parental adjusted height SDS < -1) in short children born small for gestational age (SGA), with a birth weight and/or length below -2 standard deviation SD, who failed to show catch-up growth (height velocity standard deviation (HV SDS) < 0 during the last year) by 4 years of age or later. Adults: Childhood onset growth hormone deficiency: Patients with childhood onset GHD should be re-evaluated for growth hormone secretory capacity after growth completion. Testing is not required for those with more than three pituitary hormone deficits, with severe GHD due to a defined genetic cause, due to structural hypothalamic pituitary abnormalities, due to central nervous system tumours or due to high-dose cranial irradiation, or with GHD secondary to a pituitary/hypothalamic disease or insult, if measurements of serum insulin-like growth factor 1 (IGF-1) is <-2 SDS after at least four weeks off growth hormone treatment. In all other patients an IGF-1 measurement and one growth hormone stimulation test is required. Adult onset growth hormone deficiency: Pronounced GHD in known hypothalamic-pituitary disease, cranial irradiation and traumatic brain injury. GHD should be associated with one other deficient axis, other than prolactin. GHD should be demonstrated by one provocative test after institution of adequate replacement therapy for any other deficient axis. In adults, the insulin tolerance test is the provocative test of choice. When the insulin tolerance test is contraindicated, alternative provocative tests must be used. The combined arginine-growth hormone releasing hormone is recommended. An arginine or glucagon test may also be considered; however, these tests have less established diagnostic value than the insulin tolerance test.
BRU15061889P	Azoren 20mg/5mg Film-Coated Tablet	Treatment of essential hypertension. Azoren is indicated in adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy. Treatment should not be initiated with fixed-dose combination.
BRU15061890P	Azoren 40mg/10mg Film-Coated Tablet	Treatment of essential hypertension. Azoren is indicated in adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy. Treatment should not be initiated with fixed-dose combination.
BRU15061891P	Azoren 40mg/5mg Film-Coated Tablet	Treatment of essential hypertension. Azoren is indicated in adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy. Treatment should not be initiated with fixed-dose combination.

BRU15061897NP	Gaviscon Advance Peppermint	Gaviscon Advance Peppermint Flavour provides fast relief from heartburn and acid indigestion. It can also be used to relieve the symptoms of conditions such as hiatus hernia and reflux oesophagitis (inflamed food pipe).
BRU15071904P	Resolor Film-Coated Tablet 2mg	RESOLOR® is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.
BRU15081923P	Risperdal Tablet 1mg	RISPERDAL TABLET (1MG, 2MG & 3MG) AND RISPERDAL ORAL SOLUTION 1MG/ML RISPERDAL® is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERDAL® alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISPERDAL® is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISPERDAL is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders. RISPERDAL TABLETS (1MG) AND RISPERDAL ORAL SOLUTION 1MG/ML RISPERDAL is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.
BRU15081924P	Risperdal Tablet 2mg	RISPERDAL TABLET (1MG, 2MG & 3MG) AND RISPERDAL ORAL SOLUTION 1MG/ML RISPERDAL® is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERDAL® alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISPERDAL® is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISPERDAL is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders. RISPERDAL TABLETS (1MG) AND RISPERDAL ORAL SOLUTION 1MG/ML RISPERDAL is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.

BRU15091929P	Dilantin Capsule 30mg	Clinical evidence indicates phenytoin is effective in controlling epilepsy, particularly of the generalised tonic-clonic type (grand mal) and psychomotor seizures. It will prevent or greatly decrease the incidence and severity of convulsive seizures in a substantial percentage of cases, and patients exhibit little tendency to become resistant to treatment.
BRU15091931P	Klerimed 500mg Film-Coated Tablets	Klerimed is indicated for treatment of infections caused by one or more susceptible organisms. Indications inclue: - Lower respiratory tract infections for example, acute and chronic bronchitis, and pneumonia. - Upper respiratory tract infections for example, sinusitis and pharyngitis. Klerimed is appropriate for initial therapy in community acquired respiratory infections and has been shown to be active in vitro against common and atypical respiratory pathogens as listed in the microbiology section. Klerimed is also indicated in skin and soft tissue infections of mild to moderate severity. Klerimed in the presence of acid suppression effected by omeprazole is also indicated for the eradication of *H. Pylori* in patients with proven duodenal ulcers.
BRU15091932P	Gadovist Injection 1.0mmol/ml Prefilled Syringe 5.0ml	This medicinal product is for diagnostic use only. Gadovist is indicated in adults and children of all ages including full-term newborns: • Contrast enhancement in cranial and spinal magnetic resonance imaging (MRI). • Contrast enhanced MRI of liver or kidneys in patients with high suspicion or evidence of having focal lesions to classify these lesions as benign or malignant. • Contrast enhancement in Magnetic Resonance Angiography (CE-MRA). Gadovist can also be used for MR Imaging of pathologies of the whole body. It facilitates visualisation of abnormal structures or lesions and helps in the differentiation between healthy and pathological tissue.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU15091933P	Gadovist Injection 1.0mmol/ml	This medicinal product is for diagnostic use only. Gadovist is indicated in adults and children of all ages including full-term newborns: • Contrast enhancement in cranial and spinal magnetic resonance imaging (MRI). • Contrast enhanced MRI of liver or kidneys in patients with high suspicion or evidence of having focal lesions to classify these lesions as benign or malignant. • Contrast enhancement in Magnetic Resonance Angiography (CE-MRA). Gadovist can also be used for MR Imaging of pathologies of the whole body. It facilitates visualisation of abnormal structures or lesions and helps in the differentiation between healthy and pathological tissue.
BRU15101947P	Cetyrol 10mg Film-Coated Tablet	Adults and children of 6 years and above: symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticaria of allergic origin
BRU15111957P	Stivarga Tablet 40mg	Colorectal Cancer Stivarga is indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild type, an anti-EGFR therapy. Gastrointestinal Stromal Tumors Stivarga is indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate. Hepatocellular Carcinoma Stivarga is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.
BRU15111959P; BRU15111959PS2	Insugen-N (NPH)	Treatment of diabetes mellitus.
BRU15111961NP	Infusol® NS (Ampoule)	● Plasma isotonic fluid replacement ● Sodium and chloride depletion ● Hypochloremic alkalosis ● Vehicle solution for supplementary medication

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU15111966P	Freederm Gel	Once daily antifungal treatment for tinea and other fungal skin infections – athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis), Pityriasis versicolor and fungal nail infection (cutaneous candidiasis).
BRU15121972PS1; BRU15121972PS2	Varivax (Refrigerated)	Refrigerator-stable VARIVAX is indicated for vaccination against varicella in individuals 12 months of age and older.
BRU15121974P	Paracetamol Codeine Tablet	It is indicated for the symptomatic relief of pain, aches and pyresis.
BRU16011983P	Amlibon 5mg Tablet	<u>Hypertension</u> Amlodipine is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha-blocker, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme inhibitor. <u>Chronic Stable Angina</u> Amlodipine is indicated for the first line treatment of myocardial ischaemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but where vasospasm/vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or beta-blockers.
BRU16011987P	Zenalb 20, Human Albumin Solution 20%	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.
BRU16021998P; BRU16021998PS2	Insugen-R (Regular)	Treatment of diabetes mellitus.
BRU16022002NP	Noxworm Suspension (Chocolate) 400mg	Noxworm is indicated for the treatment of single or mixed intestinal helmintic infestations, including pinworm, whipworm, roundworm, hookworm, tapeworm, trichinosis and threadworm (strongyloides).
BRU16032015PS1; BRU16032015PS2	M-M-R II® Vaccine	M-M-R II is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU16032016P; BRU16032016PS2	Insugen-30/70 (Biphasic)	Treatment of diabetes mellitus.
BRU16032017P	Natrixam 1.5mg/10mg Modified-Release Tablet	Natrixam is indicated as substitution therapy for treatment of essential hypertension in patients already controlled with indapamide and amlodipine given concurrently at the same dose level.
BRU16032018P	Natrixam 1.5mg/5mg Modified-Release Tablet	Natrixam is indicated as substitution therapy for treatment of essential hypertension in patients already controlled with indapamide and amlodipine given concurrently at the same dose level.
BRU16032020NP	Mifuko Ointment	For ringworm, athlete's foot, eczema, psoriasis, seborrheic dermatitis, scabies, warts and corns.
BRU16042028P	Oratane 20mg Capsules	ORATANE is indicated for the treatment of severe forms of nodulo-cystic acne which are resistant to therapy, particularly cystic acne and acne conglobate, especially when the lesions involve the trunk. ORATANE should only be prescribed by physicians who are experienced in the use of systemic retinoids, preferably dermatologists, and understand the risk of teratogenicity if ORATANE is used during pregnancy.
BRU16042029P	Oratane 10mg Capsules	ORATANE is indicated for the treatment of severe forms of nodulo-cystic acne which are resistant to therapy, particularly cystic acne and acne conglobate, especially when the lesions involve the trunk. ORATANE should only be prescribed by physicians who are experienced in the use of systemic retinoids, preferably dermatologists, and understand the risk of teratogenicity if ORATANE is used during pregnancy.
BRU16052039NP	Noxworm Chewtab	For the treatment of single or mixed intestinal helmintic infestations, including roundworms, threadworms, hookworms, whipworms and tapeworms.
BRU16052044P; BRU16052044PS2	Zometa Solution For Infusion 4mg/100ml	• Treatment of osteolytic, osteoblastic, and mixed bone metastases of solid tumours and osteolytic lesions of multiple myeloma, in conjunction with standard antineoplastic therapy. • Treatment of hypercalcemia of malignancy (HCM).
BRU16062049P; BRU16062049PS2	Seebri Breezhaler 50mcg Inhalation Powder Hard Capsules	Seebri Breezhaler is indicated as a once-daily maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).
BRU16062052P	Tidact Injection 150mg/ml	For the treatment of serious infections due to susceptible strains of Staphylococci, Streptococci, Pneumococci, and anaerobic bacteria.

BRU16072060P	Pethidine-Hameln Solution For Injection 50mg/ml	Severe pain.
BRU16072062P	Prednisolone Syrup 5mg/5ml	Prednisolone is a synthetic corticosteroid with predominantly glucocorticoid activity. It allows for a greater margin of safety than more potent agents. It is indicated for treatment of various disorders in which corticosteroids are indicated, such as asthmatic cough. However, it is not indicated for adrenal deficiency state.
BRU16082064P	Axcel Lamivudine 100mg Tablet	To be used only for the treatment of Human Immunodeficiency Virus (HIV) infection
BRU16082065P	Calpo Suspension	For the treatment of single or mixed worm infestations, including threadworm, roundworm, whipworm and hookworm.
BRU16092069P; BRU16092069PS2	Sifrol Extended Release 0.375mg Tablet	Sifrol® extended-release tablet is indicated in the treatment of signs and symptoms of advanced idiopathic Parkinson's disease. It may be used as monotherapy or in combination with levodopa.
BRU16092070P; BRU16092070PS2	Sifrol Extended Release 1.5mg Tablet	Sifrol® extended-release tablet is indicated in the treatment of signs and symptoms of advanced idiopathic Parkinson's disease. It may be used as monotherapy or in combination with levodopa.
BRU16092071NP	Mentholatum Deep Heating Rub Extra Strength Cream	For the temporary relief of minor aches and pains of muscles, simple backache, strains, and sprains.
BRU16092075P	Amphotret For Injection U.S.P. 50mg	**AMPHOTRET®** (Amphotericin B for Injection U.S.P.) Intravenous should be administered primarily to patients with progressive, potentially life-threatening fungal infections. This potent drug should not be used to treat noninvasive fungal infections, such as oral thrush, vaginal candidiasis and esophageal candidiasis in patients with normal neutrophil counts. **AMPHOTRET®** (Amphotericin B for Injection U.S.P.) Intravenous is specifically intended to treat potentially lifethreatening fungal infections : aspergillosis, cryptococcosis (torulosis), North American blastomycosis, systemic candidiasis, coccidioidomycosis, histoplasmosis, zygomycosis including mucormycosis due to susceptible species of the genera Absidia, Mucor and Rhizopus, and infections due to related susceptible species of Conidiobolus and Basidiobolus, and sporotrichosis.
BRU16092076NP	Alumag Plus Tablet	As antacid in dyspepsia, peptic ulcer, gastritis; use in the relief of abdominal distension and treatment of flatulence, and oesophageal reflux with heartburn.

BRU16102079P	Baxter Chlorhexidine Acetate 0.1% w/v Antiseptic Solution	Chlorhexidine Acetate (0.1% antiseptic solution is used as a general antiseptic. It is used for the cleaning and disinfecting of wounds and the antiseptic treatment of burns.
BRU16102080P	Magurol 2mg Tablet	Magurol is indicated for the treatment of hypertension where it can be administered alone or in combination with other antihypertensive agents such as diuretics, beta-blockers, calcium antagonist or ACE inhibitors.
BRU16102081P	Magurol 4mg Tablet	Magurol is indicated for the treatment of hypertension where it can be administered alone or in combination with other antihypertensive agents such as diuretics, beta-blockers, calcium antagonist or ACE inhibitors.
BRU16102084P	Bilaxten 20mg Tablet	Symptomatic treatment of allergic rhino-conjunctivitis and urticaria.
BRU16102085P	Loxin Injection (5ml Amp)	Dopamine hydrochloride is indicated for the correction of haemodynamic imbalances present in the shock syndrome due to myocardial infarctions, trauma, endotoxic septicaemia, open heart surgery, renal failure and chronic cardiac decompensation as in congestive failure.
BRU16102087P	Vaxcel Fluconazole 2mg/ml IV Infusion	Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. 1. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g. pulmonary, cutaneous). Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. Fluconazole can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS. 2. Systemic candidiasis including candidemia, disseminated candidiasis & other forms of invasive candidal infection. These include infections of the peritoneum, endocardium, eye and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. 3. Mucosal candidiasis. These include oropharyngeal, non-invasive bronchopulmonary infections, candidura, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated. Prevention of relapse of orpharyngela candidiasis in patients with AIDS. 4. Genital candidiasis. Vaginal candidiasis, acute or recurrent; and prophylaxis to reduce the incidence or recurrent vaginal candidiasisi (3 or more episodes a year). Candida balanitis. 5. Prevention of fungal infections in patients malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy or radiotherapy. 6. Dermatomycosis including tinea pedis, tinea corporis, tinea cruris, tinea versicolor and dermal candida infections.
BRU16102088P	Sellon Shampoo	In the management of simple dandruff and seborrheic dermatitis of the scalp.

BRU16102090NP	Three Legs Cough Relief	As an expectorant for the symptomatic relief of cough due to colds.
BRU16112092P	Risperidone Orally Disintegrating Tablet 3mg	Risperidone orally disintegrating tablet is indicated for the treatment of schizophrenia. Risperidone orally disintegrating tablet is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders. Risperidone orally disintegrating tablet is indicated for the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. Risperidone orally disintegrating tablet is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.
BRU16112093P	Risperidone Orally Disintegrating Tablet 2mg	Risperidone orally disintegrating tablet is indicated for the treatment of schizophrenia. Risperidone orally disintegrating tablet is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders. Risperidone orally disintegrating tablet is indicated for the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. Risperidone orally disintegrating tablet is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.
BRU16112098NP	Calamine Lotion With Menthol	Antipruritic with cooling effect.
BRU16112099P	Toujeo 300 Units/ml Solution For Injection In Pre-Filled Pen	Treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.
BRU16112102NP	Three Legs White Balsem	For symptomatic relief of muscle pain, rheumatic pain and sprain.

BRU16112103NP	Three Legs Tinea Skin Solution	For ringworm, athletes foot and tinea versicolor.
BRU16112104NP	Three Legs Yellow Lotion	As an antiseptic for treatment of skin lesions, cuts, abrasions, infected wounds and burns.
BRU16112105P	Furosemide-Hameln 10mg/ml Injection	Furosemide is a potent diuretic with a rapid action. It is used in the treatment of: - Oedema associated with heart failure including pulmonary oedema, renal and hepatic disorder, nephritic syndrome and may be effective in patients unresponsive to thiazide diuretics. Furosemide is particularly useful when an agent with greater diuretic potential than that of the more commonly used agent is desired. - Hypertensive crises. - Acute or chronic renal failure.
BRU16112106NP	Three Legs Tolnaftate Cream	For the treatment of fungal infections including Ringworm, Athlete's Foot, Tinea Capitis, Tinea Corporis, Tinea Barbae, Tinea Versicolor and Tinea Cruris.
BRU16112107NP	Three Legs Medicinal Powder Aspirin 600mg/Sachet	For relief of headache, fever, toothache and minor pain.
BRU16112109NP	5% Dextrose In 0.9% Sodium Chloride Solution For Intravenous Infusion	1. For replacement or maintenance of fluid and electrolytes. 2. As a vehicle for compatible drugs used in therapy or in diagnostic procedures.
BRU16112110P	Zylovaa Tablet 100mg	• Hypertension Zylovaa is indicated for treatment of hypertension. • Hypertensive patients with left ventricular hypertrophy Zylovaa is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients. • Nephropathy in Type 2 Diabetic Patients Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio 300 mg/g or more) in patients with type 2 diabetes and a history of hypertension. In this population, Zylovaa reduces the rate of progression of nephropathy as measured by the occurrence of doubling the serum creatinine or end stage renal disease (need for dialysis or renal transplantation) or death.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU16122112P	Ziagen Tablets 300mg	*ZIAGEN* is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and children.
BRU16122113P	Apo-Alendronate 70mg Tablet	Apo-Alendronate is indicated for the treatment of osteoporosis in postmenopausal women.
BRU16122116P	Apo-Quetiapine 25mg Tablet	• Treatment of depressive episodes associated with bipolar disorder. • Treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct to lithium or divalproex. • Treatment of schizophrenia.
BRU16122117P	Apo-Quetiapine 100mg Tablet	• Treatment of depressive episodes associated with bipolar disorder. • Treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct to lithium or divalproex. • Treatment of schizophrenia.
BRU16122118P	Apo-Quetiapine 200mg Tablet	• Treatment of depressive episodes associated with bipolar disorder. • Treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct to lithium or divalproex. • Treatment of schizophrenia.
BRU16122119NP	Actimax 500 Tablet	For the relief of fever and mild to moderate pain including headache, migraine, symptoms of colds and flu, dental pain, period pain, back pain, muscular pain and osteoarthritis.
BRU16122121NP	Flanil Analgesic Cream	For temporary relief of minor ache and pains of muscle s and joints associated with arthritis, strains, sprains and rheumatism.
BRU16122124P	Ferriprox 500mg Tablet	Ferriprox is indicated for the treatment of iron overload in patients with thalassemia major when deferoxamine therapy is contra-indicated or inadequate.

BRU17012130PS2; BRU17012130PS3	Tarceva Tablet 100mg	**Non-small cell lung cancer**: Tarceva is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer with EGFR activating mutations. Tarceva is also indicated for switch maintenance treatment in patients with locally advanced or metastatic NSCLC with EGFR activating mutations and stable disease after first-line chemotherapy. Tarceva is also indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen. No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with Epidermal Growth Factor Receptor (EGFR)- negative tumours. **Pancreatic cancer**: Tarceva in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.
BRU17012131PS2; BRU17012131PS3	Tarceva Tablet 150mg	**Non-small cell lung cancer**: Tarceva is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer with EGFR activating mutations. Tarceva is also indicated for switch maintenance treatment in patients with locally advanced or metastatic NSCLC with EGFR activating mutations and stable disease after first-line chemotherapy. Tarceva is also indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen. No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with Epidermal Growth Factor Receptor (EGFR)- negative tumours. **Pancreatic cancer**: Tarceva in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.
BRU17012137P	Tussidex Forte Linctus	Tussidex Forte Linctus is indicated for the relief of resistant, dry and unproductive cough for adults and children. It is non-sedative and free of alcohol. As it does not contain sugar, it may be suitable for diabetic use.
BRU17012138P	Floctil 250mg Capsule	Azithromycin is indicated for the treatment of bronchitis, community-acquired pneumonia, sinusitis, pharyngitis/tonsillitis, otitis media, skin and soft tissue infections, and uncomplicated genital infections due to Chlamydia trachomatis. Considerations should be given to official guidance regarding the appropriate use of antibacterial agents.

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BRU17012141P	Dyna Metformin Tablet 500mg	Control of hyperglycaemic of maturity onset diabetes mellitus. It is used in non Insulin-dependant diabetes mellitus when diet control fails. It is sometimes given to patients no longer responding to the sulphonylureas.
BRU17022146P	Azarga Eye Drops Suspension	Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.
BRU17022147P	Pharmaniaga Dermasole Cream 0.1% w/w	Betamethasone is a potent topical corticosteroid indicated for adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These include the following: - Atopic dermatitis (including infantile atopic dermatitis) - Nummular dermatitis (discoid eczema) - Prurigo nodularis - Psoriasis (excluding widespread plaque psoriasis) - Lichen simplex chronicus (neurodermatitis) and lichen planus - Seborrhoeic dermatitis - Irritant or allergic contact dermatitis - Discoid lupus erythematosus - Adjunct to systemic steroid therapy in generalized erythroderma - Insect bite reactions - Miliara (prickly heat)

BRU17022148P; BRU17022148PS2	Jardiance 10mg Film-Coated Tablet	**Type 2 diabetes mellitus** ***Glycaemic control*** Jardiance is indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as: Monotherapy When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. Add-on combination therapy In combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. ***Prevention of cardiovascular death*** Jardiance is indicated in patients with type 2 diabetes mellitus and established cardiovascular disease to reduce the risk of cardiovascular death. To prevent cardiovascular deaths, Jardiance should be used in conjunction with other measures to reduce cardiovascular risk in line with the current standard of care. **Heart failure** Jardiance is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV).

BRU17022149P; BRU17022149PS2	Jardiance 25mg Film-Coated Tablet	**Type 2 diabetes mellitus** ***Glycaemic control*** Jardiance is indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as: Monotherapy When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. Add-on combination therapy In combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. ***Prevention of cardiovascular death*** Jardiance is indicated in patients with type 2 diabetes mellitus and established cardiovascular disease to reduce the risk of cardiovascular death. To prevent cardiovascular deaths, Jardiance should be used in conjunction with other measures to reduce cardiovascular risk in line with the current standard of care. **Heart failure** Jardiance is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV).
BRU17022154P	Targin Prolonged Release Tablets 10mg/5mg	The management of moderate to severe chronic pain unresponsive to non-narcotic analgesics. The opioid antagonist naloxone in the fixed combination is added to counteract and/or prevent opioid-induced constipation. Second line symptomatic treatment of patients with severe to very severe idiopathic Restless Legs Syndrome (RLS) after failure of dopaminergic therapy.
BRU17022157P	Pristine Shampoo 2% w/w	Pristine shampoo is used for the treatment and prophylaxis of infections such as pityriasis capitis (dandruff), seborrheic dermatitis and pityriasis versicolor (white spots).
BRU17022159P	Salmol Expectorant	It is used for prophylactic treatment and relief of asthma, chronic bronchitis, emphysema, and other bronchopulmonary disorders involving bronchospasm in adults and children 2 years of age and older. It may be useful for the symptomatic relief of respiratory conditions characterized and in the presence of mucus in the respiratory tract because of guaiphenesin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU17022164P	Cef-4 1G Injection	CEF-4® is used in the treatment of susceptible infections including:- -Lower Respiratory Tract Infections -Urinary Tract Infections -Skin and Soft Tissue Structure Infections -Bacterial Septicemia -Bone and Joint infections -Gynecological infections, including endometritis, pelvic cellulitis and other infections of the female genital tract -Intraabdominal infections -CNS infections -Severe and life-threatening infections
BRU17032165P	Asthator 4mg Chewable Tablet	For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 2 years of age and older. ASTHATOR is indicated in adults and pediatric patients 2 years of age and older for the relief day time and night time symptoms of allergic rhinitis.
BRU17032166P	Asthator 5mg Chewable Tablet	For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 2 years of age and older. ASTHATOR is indicated in adults and pediatric patients 2 years of age and older for the relief day time and night time symptoms of allergic rhinitis.
BRU17032167P	Asthator 10mg Tablet	For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 2 years of age and older. ASTHATOR is indicated in adults and pediatric patients 2 years of age and older for the relief day time and night time symptoms of allergic rhinitis.
BRU17032168NP	Oliclinomel N7-1000E Emulsion For Infusion	Parenteral nutrition for adults and children greater than two years of age, when oral or enteral nutrition is impossible, insufficient or contraindicated.
BRU17032169P	Pharmaniaga Ziconal Cream 2% w/w	Ketoconazole cream is indicated for the topical treatment of tinea corporis, tinea cruris and tinea pedis caused by Trichophyton rubrum, T. mentagrophytes and Epidermophyton floccosum; in the treatment of tinea versicolor caused by Malassezia furfur; in the treatment of cutaneous candidiasis caused by Candida spp. and the treatment of seborrheic dermatitis.
BRU17032170P	Zolennic Concentrate For Solution For IV Infusion	1) An adjunct to antineoplastic therapy for the treatment of bone metastases of solid tumors and osteolytic lesions of multiple myeloma. 2) Paget's disease of bone. 3) Hypercalcemia of malignancy (HCM).
BRU17032171P	Dynadryl Syrup	Irritating coughs, nasal stuffiness and bronchial congestion associated with common cold and allergy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU17032172P	Depo Geston Injection 50mg/ml	For contraception (ovulation suppression).
BRU17032173P	Axcel Valacyclovir-500 Tablet	Axcel Valacyclovir-500 is indicated for the treatment of herpes zoster (shingles). Axcel Valacyclovir-500 accelerates the resolution of pain; it reduces the duration, and the proportion of patients with zoster-associated pain, which includes acute and post-herpetic neuralgia. Axcel Valacyclovir-500 is indicated for the treatment of herpes simplex infections of the skin and mucous membranes, including initial and recurrent genital herpes. Axcel Valacyclovir-500 can prevent lesion development when taken at the first signs and symptoms of an HSV recurrence. Axcel Valacyclovir-500 is indicated for the prevention (suppression) of recurrent herpes simplex infections of the skin and mucous membranes, including genital herpes. Axcel Valacyclovir-500 can reduce transmission of genital herpes when taken as suppressive therapy and combined with safer sex practices (particularly the use of condoms).
BRU17032174P	Pharmaniaga Lidocaine Hydrochloride 2% w/v Injection	Lidocaine can be used for most major nerve blocks, e.g. sciatic and retrobulbar. Lidocaine can be used for local or regional anaesthesia and nerve block.
BRU17032175NP	Axcel Paracetamol-250 Suspension (Strawberry)	For the relief of fever, symptoms of cold and influenza, teething pain and headache.
BRU17042176NP	Oliclinomel N4-550E Emulsion For Infusion	Parenteral nutrition for adults and children greater than two years of age, when oral or enteral nutrition is impossible, insufficient or contraindicated.
BRU17042177NP	Huachi Enema	The product is indicated for the relief of constipation.
BRU17042179P	Glumet XR Tablet 500mg	Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate, glycaemic control. Glumet XR may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.
BRU17042181P	Zimmex 20 Tablet	Coronary Heart Disease: Reduce risk of death, coronary death & non-fatal Myocardial Infarction; Reduce risk of undergoing myocardial revascularization procedures (CABG & PTCA); slow progression of coronary atherosclerosis, including reducing development of new lesions & new total occlusions. Hyperlipidaemia: As an adjunct to diet to reduce elevated total-C, LDL-C, Apo B & TG, LDL-C/HDL-C & total-C/HDL-C ratios & to increase HDL-C in primary hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet & other nonpharmacological measures is inadequate.
BRU17042182P	KOP 2.5% Gel (Ketoprofen BP)	For inflammatory non-articular musculoskeletal conditions and mild trauma due to sport injuries, sprains, tendinitis, musculotendinous contusion and oedema.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU17042183P	Dextracin Eye/Ear Drops	**EYE** Treatment of inflammatory conditions of the anterior segment of the eye complicated by infection caused by organisms sensitive to neomycin. **EAR** Treatment of inflammatory conditions of the external ear complicated by infection caused by organisms sensitive to neomycin.
BRU17042185P	Triplixam 5mg/1.25mg/5mg Film-Coated Tablets	Triplixam indicated as substitution therapy for treatment of essential hypertension in patients already controlled with perindopril / indapamide fixed dose combination and amlodipine, taken at the same dose level.
BRU17042186P	Triplixam 5mg/1.25mg/10mg Film-Coated Tablets	Triplixam indicated as substitution therapy for treatment of essential hypertension in patients already controlled with perindopril / indapamide fixed dose combination and amlodipine, taken at the same dose level.
BRU17042187P	Triplixam 10mg/2.5mg/5mg Film-Coated Tablets	Triplixam indicated as substitution therapy for treatment of essential hypertension in patients already controlled with perindopril / indapamide fixed dose combination and amlodipine, taken at the same dose level.
BRU17042188P	Triplixam 10mg/2.5mg/10mg Film-Coated Tablets	Triplixam indicated as substitution therapy for treatment of essential hypertension in patients already controlled with perindopril / indapamide fixed dose combination and amlodipine, taken at the same dose level.
BRU17042189P	Cotren Vaginal Tablet 500mg	Vaginal infections caused by fungi-mainly candida and/or trichomonas.
BRU17042190P	Axcel Bromhexine Tablet	For the reduction of sputum viscosity.

BRU17042192P	Zocol 150mg Capsule	Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g., pulmonary, cutaneous). Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. Fluconazole can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS. Systemic candidiasis including candidemia, disseminated candidiasis and other forms of invasive candidal infection. These include infections of the peritoneum, endocardium and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. Mucosal candidiasis including oropharyngeal, esophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated. Prevention of relapse of oropharyngeal candidiasis in patients with AIDS. Genital candidiasis, vaginal candidiasis, acute or recurrent; and prophylaxis to reduce the incidence of recurrent vaginal candidiasis (=3 episodes a year). Candidal balanitis. Prevention of fungal infections in patients with malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy or radiotherapy. Dermatomycosis including tinea pedis, tinea corporis, tinea cruris, pityriasis versicolor and candida infections.
BRU17042193NP	Anucare Ointment	For the relief of itching, burning and soreness of haemorrhoids and minor rectal inflammations and irritations.
BRU17052195P	Pamorelin 3.75mg Powder For Suspension For Injection	Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg is indicated for the treatment of locally advanced or metastatic, hormone-dependent prostate cancer. Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg are indicated as concomitant to and following radiotherapy in patients with high-risk localized or locally advanced prostate cancer. Pamorelin 3.75 mg is indicated for the treatment of endometriosis. Pamorelin 3.75 mg is indicated for the pituitary down-regulation in the context of assisted reproduction technology. Pamorelin 3.75 mg is indicated as adjuvant treatment, in combination with tamoxifen or an aromatase inhibitor, of hormone receptor positive early stage breast cancer in women at high risk of recurrence who are confirmed as premenopausal after completion of chemotherapy. Pamorelin 22.5 mg is indicated for the treatment of central precocious puberty (CPP) in children of 2 years of age and older with an onset of CPP before 8 years in girls and 10 years in boys.
BRU17052196P	Pamorelin 11.25mg Powder For Suspension For Injection	Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg is indicated for the treatment of locally advanced or metastatic, hormone-dependent prostate cancer. Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg are indicated as concomitant to and following radiotherapy in patients with high-risk localized or locally advanced prostate cancer. Pamorelin 3.75 mg is indicated for the treatment of endometriosis. Pamorelin 3.75 mg is indicated for the pituitary down-regulation in the context of assisted reproduction technology. Pamorelin 3.75 mg is indicated as adjuvant treatment, in combination with tamoxifen or an aromatase inhibitor, of hormone receptor positive early stage breast cancer in women at high risk of recurrence who are confirmed as premenopausal after completion of chemotherapy. Pamorelin 22.5 mg is indicated for the treatment of central precocious puberty (CPP) in children of 2 years of age and older with an onset of CPP before 8 years in girls and 10 years in boys.

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BRU17052197P	Pamorelin 22.5mg Powder For Suspension For Injection	Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg is indicated for the treatment of locally advanced or metastatic, hormone-dependent prostate cancer. Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg are indicated as concomitant to and following radiotherapy in patients with high-risk localized or locally advanced prostate cancer. Pamorelin 3.75 mg is indicated for the treatment of endometriosis. Pamorelin 3.75 mg is indicated for the pituitary down-regulation in the context of assisted reproduction technology. Pamorelin 3.75 mg is indicated as adjuvant treatment, in combination with tamoxifen or an aromatase inhibitor, of hormone receptor positive early stage breast cancer in women at high risk of recurrence who are confirmed as premenopausal after completion of chemotherapy. Pamorelin 22.5 mg is indicated for the treatment of central precocious puberty (CPP) in children of 2 years of age and older with an onset of CPP before 8 years in girls and 10 years in boys.
BRU17052198NP	Weng Heng Tablet Paracetamol 500mg	For the relief of fever, headache, toothache and mild to moderate pain including dysmenorrhea, condicitons involving musculoskeletal pain, myalgias, neuralgias, analgesic after tooth extraction and in teething, and earache.
BRU17052199P	MST Continus 10mg Prolonged Release Tablets	Prolonged relief of severe pain.
BRU17052200P	MST Continus 30mg Prolonged Release Tablets	Prolonged relief of severe pain.
BRU17052204P	Oxair Chewable Tablet 5mg	1) For the prophylaxis and chronic treatment of asthma in adults and children ≥ 2 years of age. 2) It is indicated in adults ≥ 15 years of age for the relief of daytime and night-time symptoms of seasonal allergic rhinitis.
BRU17052205P	Anacaine Injection 1%	Local or regional anaesthetic solution for use in infiltration anaesthetia.
BRU17052206P	Anacaine Injection 2%	Local or regional anaesthetic solution for use in infiltration anaesthetia.
BRU17052207NP	Ferromed Tablet 200mg	Indicated in the prevention and treatment of iron deficiency anemia, which may result from inadequate diet, malabsorption, pregnancy, rapid growth during childhood, and/or blood loss. Iron deficiency may lead to defective erythropoiesis that may eventually result in a hypochromic anaemia (low haemoglobin concentrations); the red blood cells in iron-deficiency anaemia may be either normocytic (normal size) or microcytic (small in size). Note: Deficiency of iron may lead to fatigue, shortness of breath, decreased physical performance, impaired learning in children and adults, altered body temperature, and altered immune function.
BRU17052208NP	Calazite Lotion	A soothing and protecting lotion for the relief of skin irritations due to insect bites, prickly heat, sunburn, cosmetic, nappy rash and other minor skin irritation.

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BRU17052209P	Acipan Injection 1mg/ml (1ml Ampoule)	1) Pre-anaesthetic medication to inhibit excessive salivary and bronchial secretion and to diminish the risk of vagal inhibition of the heart. 2) Management of patients with acute myocardial infarction and sinus bradycardia who have associated hypotension and increased verticular irritability. 3) In conjunction with morphine or other drugs for the relief of biliary or renal colic. 4) Administered concurrently with anticholinesterase agents (eg. neostigmine, physostigmine) to block the adverse muscarinic effects of these latter agents when they are used after surgery to terminate curarization. 5) Concomitant with a cholinesterase reactivator (eg.: pralidoxime) to reverse muscarinic effects associated with toxic exposure to anticholinesterase compounds (eg.: organophosphate pesticides).
BRU17062211P	SW Hyoscine Butylbromide Tablets	It is indicated for gastrointestinal spasm hypermotility, biliary dyskinesia and spasm of the urinary tract, delayed relaxation of the lower uterine segment and dysmenorrhea.
BRU17062212NP	SMOFKABIVEN Emulsion For Infusion	Parenteral nutrition for adult patients when oral or enteral nutrition is impossible, insufficient or contraindicated.
BRU17062214P	Cosentyx 150mg Solution For Injection In Pre-Filled Syringe	**Plaque psoriasis** Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. **Psoriatic arthritis** Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **Axial spondyloarthritis (axSpA)** **Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)** Cosentyx is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. **Non-radiographic axial spondyloarthritis (nr-axSpA)** Cosentyx is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).

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BRU17062215P	Cosentyx 150mg Solution For Injection In Pre-Filled Pen	**Plaque psoriasis** Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. **Psoriatic arthritis** Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **Axial spondyloarthritis (axSpA)** **Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)** Cosentyx is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. **Non-radiographic axial spondyloarthritis (nr-axSpA)** Cosentyx is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).
BRU17062216P	Morphine-Hameln 10mg/ml Injection, 1mL	Analgesic for severe and very severe pain.
BRU17062217P	Xtandi Soft Capsules 40mg	Xtandi is indicated for : • the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC). • the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC). • the treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. • the treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy.
BRU17062218P	PRAXBIND Solution For Injection/Infusion 50mg/ml	Praxbind is a specific reversal agent for dabigatran and is indicated in patients treated with Pradaxa when rapid reversal of the anticoagulant effects of dabigatran is required: • For emergency surgery/ urgent procedures • In life-threatening or uncontrolled bleeding
BRU17062219NP	Zam-Buk Ointment	Indicated for temporary relief of pain and itch associated with minor wounds, burns, scalds, chapped hands, mosquitoes and insect bites.

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BRU17062220P	Axcel Sildenafil-100mg Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil to be effective, sexual stimulation is required.
BRU17072223P	Monoclox 500mg Powder For Solution For Injection Or Infusion	• Cloxacillin is indicated for the treatment of sensitive staphylococcal infections: respiratory infections, otorhinolaryngologic infections, urogenital infections, neuro-meningeal infection, bone and joint infections, endocarditis and treatment of skin infections caused by sensitive staphylococci and/or streptococci. • Cloxacilliln is also indicated as preventive treatment of postoperative infections in neurosurgery.
BRU17072225P	Gluvecron MR 30mg Tablet	Gluvecron MR is recommended in adults for non-insulin-dependent diabetes (type 2), in association with dietary measures and with physical exercise, when these measures alone are not sufficient to obtain normal blood glucose levels (levels of sugar in blood).
BRU17072226NP	Restors Oral Powder	Helps to restore fluid and electrolyte loss and prevent dehydration due to diarrhoea, vomiting and gastroenteritis.
BRU17072227P	Flumazenil-Hameln 0.1mg/ml Injection	Flumazenil-hameln 0.1mg/ml injection is indicated for the complete or partial reversal of the central sedative effects of benzodiazepines. It may therefore be used in anaesthesia and in intensive care in the following situations: In anaesthesia: -Termination of hyposedative effects in general anaesthesia induced and/or maintained with benzodiazepines in hospitalised patients. -Reversal of benzodiazepines sedation in short-term diagnostic and therapeutic procedures in ambulatory patients and hospitalised patients. In intensive care situations: -For diagnostic in intoxication with benzodiazepines or to rule out such intoxication. -As a diagnostic measure in unconsciousness of unknown origin to differentiate between involvement of benzodiazepines, other drugs or brain damage. -For specific reversal of the central effects of benzodiazepines in drug overdose (return to spontaneous respiration and consciousness in order to render intubation unnecessary or allow extubation)
BRU17082232P	Xeljanz Film-Coated Tablet 5mg	XELJANZ is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs). Limitations of Use: Use of XELJANZ in combination with biologic DMARDs or with potent immunosuppressants, such as azathioprine and cyclosporine is not recommended.

BRU17082233P	Amoxicap 250 Capsule	For treatment of: 1) Ear, nose and throat infections caused by streptococci, pneumococci, non-penicillinase-producing staphylococci and H.influenzae 2) Genitourinary tract infections caused by E.Coli, P.Mirabilis, S.Faecalis 3) Skin and soft-tissues infections caused by streptococci, non-penicillinase-producing staphylococci and E.Coli 4) Anogenital and urethral gonorrhoea caused by N.Gonorrhoea
BRU17082234P	Forxiga 5mg Film-Coated Tablet	**Type 2 diabetes mellitus** Forxiga is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as: **Monotherapy** When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. **Add-on combination therapy** In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations). **Initial Combination** Forxiga is indicated for use as initial combination therapy with metformin, as an adjunct to diet and exercise, to improve glycaemic control in patients with type 2 diabetes mellitus when diet and exercise have failed to provide adequate glycaemic control and there are poor prospects for response to metformin monotherapy (for example, high initial HbA1c levels). To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors. For study results with respect to combination of therapies, effects on glycaemic control, cardiovascular and renal events, and the populations studied, see sections 4.4, 4.5 and 5.1. **Heart failure** Forxiga is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction. **Chronic kidney disease** Forxiga is indicated in adults for the treatment of chronic kidney disease.

BRU17082235P	Forxiga 10mg Film-Coated Tablet	**Type 2 diabetes mellitus** Forxiga is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as: **Monotherapy** When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. **Add-on combination therapy** In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations). **Initial Combination** Forxiga is indicated for use as initial combination therapy with metformin, as an adjunct to diet and exercise, to improve glycaemic control in patients with type 2 diabetes mellitus when diet and exercise have failed to provide adequate glycaemic control and there are poor prospects for response to metformin monotherapy (for example, high initial HbA1c levels). To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors. For study results with respect to combination of therapies, effects on glycaemic control, cardiovascular and renal events, and the populations studied, see sections 4.4, 4.5 and 5.1. **Heart failure** Forxiga is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction. **Chronic kidney disease** Forxiga is indicated in adults for the treatment of chronic kidney disease.
BRU17082236P	Motigut Suspension 1mg/ml	Domperidone is indicated for the relief of the symptoms of nausea and vomiting. This includes: • Nausea and vomiting of functional, organic, infectious or dietary origin • Nausea and vomiting induced by: -Radiotherapy or drug therapy -Dopamine agonists (such as L-dopa and bromocriptine) used in the treatment of Parkinson's disease
BRU17082239P	Shrizine Injection 25mg/ml	Psychotic disorders including schizophrenia. It is not intended for use in non-psychotic disorders or for short term therapy.

BRU17082240P	Canesten HC Cream	Treatment of skin infections with co-existing symptoms of inflammation, eg. Itching, requiring rapid relief: - Dermatomycoses caused by dermatophytes (eg. Athlete's foot), yeasts (eg. Candida intertrigo), moulds and other fungi - Infections of the labia and adjacent areas caused by yeast fungi (candida vulvitis); inflammation of the glans and prepuce of the sexual partner caused by yeast fungi (candidal balanitis) - Skin diseases superinfected with organisms sensitive to clotrimazole
BRU17082242P; BRU17082242PS2	Losartan Hexal 50mg Film-Coated Tablets	• Losartan is indicated for the treatment of hypertension. • Losartan is indicated for the reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy (see 5.1. Pharmacodynamic properties, LIFE study). • Losartan is indicated for the treatment of renal disease in patients with type 2 diabetes with proteinuria and hypertension, as part of the anti-hypertensive therapy (see 5.1 Pharmacodynamic properties).
BRU17082243P; BRU17082243PS2	Losartan Hexal 100mg Film-Coated Tablets	• Losartan is indicated for the treatment of hypertension. • Losartan is indicated for the reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy (see 5.1. Pharmacodynamic properties, LIFE study). • Losartan is indicated for the treatment of renal disease in patients with type 2 diabetes with proteinuria and hypertension, as part of the anti-hypertensive therapy (see 5.1 Pharmacodynamic properties).
BRU17092244P	Relvar Ellipta 100/25 Micrograms Inhalation Powder, Pre-Dispensed	Asthma Relvar Ellipta is indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: • patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists. COPD (Chronic Obstructive Pulmonary Disease) Relvar Ellipta is indicated for the symptomatic treatment of adults with COPD with a FEV1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.
BRU17092245P	Relvar Ellipta 200/25 Micrograms Inhalation Powder, Pre-Dispensed	Asthma Relvar Ellipta is indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: • patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists. **Note: 200/25mcg strength is not indicated for COPD

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BRU17092246P	Hiprogin Injection 250mg/ml (1ml Ampoule)	1. Habitual abortion, when associated with proven progesterone-deficiency. 2. Primary and secondary amenorrhoea. 3. Infertility due to corpus luteum insufficiency, primary and secondary amenorrhoea.
BRU17092247P	Phebra Magnesium Sulfate Heptahydrate 50% 2.5g/5mL	•Treatment of acute hypomagnesaemia. •To prevent hypomagnesaemia in patients receiving total parenteral nutrition. •The prevention and treatment of life-threatening seizures in the treatment of toxaemias of pregnancy (pre-eclampsia and eclampsia). • For emergency treatment of some arrhythmias such as Torsade de Pointes and those associated with hypokalemia.
BRU17092249NP	Three Legs Yellow Balsem	For symptomatic relief of muscle pain, rheumatic pain and sprain
BRU17092251NP	ORS PLUS	For replacement of water and electrolytes lost during moderate to severe diarrhoea.
BRU17092252NP	Axe Brand Universal Oil	Provides temporary relief of headaches, colds and blocked noses, muscular and joint pains, stomach discomforts and wind, giddiness or travel sickness and soothes itching from insect bites.
BRU17092253NP	Vitabiotics Pregnacare Breast-Feeding Tablet/Capsule	For the prevention and correction of vitamin and mineral deficiency states.
BRU17092254P	Ravimed Tablet 5mg	1. Carcinoma: Palliative treatment of recurrent and or metastatic breast or renal cell cancer and of inoperable recurrent or metastatic endometrial carcinoma. 2. Endometriosis: For use in the treatment of visually proven (laparoscopy) endometriosis where the required end-point of treatment is pregnancy, or for the control of symptoms when surgery is contraindicated or has been unsuccessful. 3. Secondary amenorrhoea proven not due to pregnancy. In amenorrhoea associated with a poorly developed proliferative endometrium, conventional oestrogen therapy may be employed in conjunction with Medroxyprogesterone Acetate. 4. Abnormal uterine bleeding in the absence of organic pathology. 5. Adjunct to cyclic oestrogen therapy.
BRU17092255P	T.O. Prazosin 2mg Tablet	Prazosin tablet is indicated in the treatment of hypertension and left ventricular heart failure.
BRU17092256P	Vaxcel Acyclovir 250mg I.V. For Infusion	Vaxcel Acyclovir 250mg I.V. for Infusion is indicated: 1. For the treatment of Herpes simplex infections. 2. For the prophylaxis of Herpes simplex infections in immune-compromised patients. 3. In the treatment of Varicella zoster infections. 4. For the treatment of Herpes simplex infections in the neonate.

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BRU17112257P	Azithromycin Tablets 250mg	Azithromycin tablets can be applied in situations where micro-organisms sensitive to azithromycin have caused: - Upper respiratory tract infections: sinusitis, pharyngitis, tonsillitis - Acute otitis media - Lower respiratory tract infections: acute bronchitis and mild to moderately severe community acquired pneumonia - Skin and soft tissue infections - Uncomplicated Chlamydia trachomatis urethritis and cervicitis Considerations should be given to official guidance on the appropriate use of antibacterial agents.
BRU17112258P	Fybogel Orange Sachet	For relief of constipation including constipation in pregnancy and maintenance of regularity; for the management of bowel function in patients with colostomy, ileostomy haemorrhoids, anal fissure, chronic diarrhea associated with diverticular disease, irritable bowel syndrome and ulcerative colitis.
BRU17112259NP	Paracetamol Osteo-Tab Modified Release Tablets	Paracetamol osteo-tab s effective for the relief of fever and relief of mild to moderate pain including: headache, migraine, toothache, pain after dental procedures, neuralgia, muscular aches and joint pains, pain of osteoarthritis, rheumatic pain, period pain, pain after vaccination, sore throat and the discomfort from colds and influenza.
BRU17112260P	Phenadryl Syrup	Phenadryl syrup is indicated for control of cough and alleviation of nasal stuffiness, bronchial congestion and lachrymation.
BRU17112261P	Dermosone Cream 0.1%	For topical treatment of corticosteroid-responsive skin conditions. It provides symptomatic relief of itch, allergy and inflammation in eczema, dermatitis, psoriasis, neurodermatoses and pruritus.
BRU17112262P	Regpara® Tablets 25mg	Secondary hyperparathyroidism in patients undergoing maintenance dialysis.

BRU17112263PS1; BRU17112263PS2	Octagam 5%, Solution For Infusion	**Replacement therapy in adults, and children and adolescents (0-18 years) in**: • Primary immunodeficiency syndromes with impaired antibody production. • Hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia, in whom prophylactic antibiotics have failed. • Hypogammaglobulinaemia and recurrent bacterial infections in plateau phase multiple myeloma patients who have failed to respond to pneumococcal immunisation. • Hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation (HSCT). • Congenital AIDS with recurrent bacterial infections. **Immunomodulation in adults, and children and adolescents (0-18 years) in**: • Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count. • Guillain Barré syndrome • Kawasaki disease
BRU17122264P	Ceficad 1000mg Injection	Ceficad injection (Cefepime Hydrochloride) is indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms: Pneumonia (moderate to severe) caused bystreptococcus pneumoniae, including cases associated with concurrent bacteremia, pseudomonas aeruginosa, klebsiella pneumonia, or Enterobacter species. Empiric therapy for febrile neutropenic patients Cefepime as monotherapy is indicated for empiric treatment of febrile neutropenic patients. In patients at high risk for severe infection (including patients with a history of recent bone marrow transplantation, with hypotension at presentation, with an underlying hematologic malignancy, or with severe or prolonged neutropenia), antimicrobial monotherapy may not be appropriate. Insufficient data exist to support the efficacy of cefepime monotherapy in such patients. Urinary tract infections Uncomplicated and complicated Urinary Tract Infections (including pyelonephritis) caused by Escherichia coli, Klebsiella pneumonia, or Proteus mirabilis, when the infection is mild to moderate, including cases associated with concurrent bacteremia with these microorganisms. Skin and Skin Structure infections Uncomplicated Skin and Skin Structure infections caused by Staphylococcus aureus (methicillin susceptible strains only) or Streptococcus pyogenes. Intra-abdominal infections Complicated Intra-abdominal infections caused by Escherichia coli, pseudomonas aeruginosa or Bacteroides fragilis. To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefepime hydrochloride and other antibacterial drugs, cefepime hydrochloride should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

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BRU17122265P	Probitor Capsule 20mg	• Treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy; • Treatment of NSAIDs associated peptic and gastro-duodenal erosions • Prophylactic treatment in patients with an increased risk of NSAIDs associated peptic ulcer, gastro-duodenal erosions or dyspeptic symptoms • Helicobacter pylori associated peptic ulcer disease • Reflux oesophagitis • Zollinger-Ellison syndrome
BRU17122266P	Solbid Tablet 10mg	Isosorbide dinitrate is used prophylactically in the treatment of angina pectoris.
BRU17122268P; BRU17122268PS2	Converium 300mg Tablet	Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.
BRU17122269P	Salazine Enteric Coated Tablet 500mg	SALAZINE Tablets is indicated for the management of mild to moderate and severe ulcerative colitis, Crohn's Disease and rheumatoid arthritis.
BRU17122270P	Axcel Metronidazole-200 Tablet	Treatment of protozoal infection, intestinal and extra-intestinal amoebiasis, lambliasis, acute ulcerative gingivitis, urogenital trichomoniasis, glardiasis, and Vincent's infection.
BRU17122271NP	Dermorub Liniment Muscle & Joint	For the relief of aches and pains including rheumatism, arthritis, backache, bruises, sprains and strains due to sports injuries.

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BRU17122272P	Tenof 300mg Tablet	HIV-1 Infection Tenofovir is indicated in combination with other antiretroviral agents for the treatment of HIV-1infection in adults and pediatric patients 12 years of age and older. The following points should be considered when initiating therapy with tenofovir for the treatment of HiV-1 infection: • TENOF should not be used in combination with other products containing tenofovir disoproxil fumarate. Chronic Hepatitis B Tenofovir is indicated for the treatment of chronic hepatitis B in adults. The following points should be considered when initiating therapy with tenofovir for the treatment of HBV infections: • This indication is based primarily on data from treatment of subjects who were nucleoside-treatment-naïve and a smaller number of subjects who had previously received lamivudine or adefovir dipivoxil. Subjects were adult with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease. • Tenofovir was evaluated in a limited number of subjects with chronic hepatitis B and decompensated liver disease. • The numbers of subjects in clinical trials who had lamivudine- or adefovir associated substitutions at baseline were too small to reach conclusions of efficacy.
BRU17122273NP	Bisacodyl Tablets 5mg	Bisacodyl is used for the treatment of constipation for evacuation of the colon before radiological examination of the abdomen or endoscopy, and before or after surgical operations.
BRU17122274P	Alfutor ER Tablets 10mg	Treatment of the functional symptoms of benign prostatic hypertrophy (BPH). Adjuvant Treatment to a catheter in acute urinary retention related to benign prostatic hypertrophy.

BRU17122275P	Venlift ER 37.5mg Capsule	Venlift ER is indicated for the treatment of depression, including depression with associated anxiety, in hospitalized patients. Treatment of anxiety or Generalized Anxiety Disorder (GAD), including long-term treatment. For prevention of relapse of an episode of depression or for prevention of the recurrence of new depressive episodes. Venlift ER is indicated for the treatment of Social Anxiety Disorder, also known as Social Phobia, as defined in DSM-IV. Social Anxiety Disorder (DSM-IV) is characterised by a marked and persistent fear of 1 or more social or performance situations in which the person is exposed to unfamiliar people or to possible scrutiny by others. Exposure to the feared situation almost invariably provokes anxiety, which may approach the intensity of a panic attack. The feared situations are avoided or endured with intense anxiety or distress. The avoidance, anxious anticipation, or distress in the feared situation(s) interferes significantly with the person's normal routine, occupational or academic functioning, or social activities or relationships, or there is a marked distress about having the phobias. Lesser degrees of performance anxiety or shyness generally do not require psychopharmacological treatment. Panic disorder, including prevention of relapse.
BRU17122276P	Venlift ER 75mg Capsule	Venlift ER is indicated for the treatment of depression, including depression with associated anxiety, in hospitalized patients. Treatment of anxiety or Generalized Anxiety Disorder (GAD), including long-term treatment. For prevention of relapse of an episode of depression or for prevention of the recurrence of new depressive episodes. Venlift ER is indicated for the treatment of Social Anxiety Disorder, also known as Social Phobia, as defined in DSM-IV. Social Anxiety Disorder (DSM-IV) is characterised by a marked and persistent fear of 1 or more social or performance situations in which the person is exposed to unfamiliar people or to possible scrutiny by others. Exposure to the feared situation almost invariably provokes anxiety, which may approach the intensity of a panic attack. The feared situations are avoided or endured with intense anxiety or distress. The avoidance, anxious anticipation, or distress in the feared situation(s) interferes significantly with the person's normal routine, occupational or academic functioning, or social activities or relationships, or there is a marked distress about having the phobias. Lesser degrees of performance anxiety or shyness generally do not require psychopharmacological treatment. Panic disorder, including prevention of relapse.

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BRU17122277P	Venlift ER 150mg Capsule	Venlift ER is indicated for the treatment of depression, including depression with associated anxiety, in hospitalized patients. Treatment of anxiety or Generalized Anxiety Disorder (GAD), including long-term treatment. For prevention of relapse of an episode of depression or for prevention of the recurrence of new depressive episodes. Venlift ER is indicated for the treatment of Social Anxiety Disorder, also known as Social Phobia, as defined in DSM-IV. Social Anxiety Disorder (DSM-IV) is characterised by a marked and persistent fear of 1 or more social or performance situations in which the person is exposed to unfamiliar people or to possible scrutiny by others. Exposure to the feared situation almost invariably provokes anxiety, which may approach the intensity of a panic attack. The feared situations are avoided or endured with intense anxiety or distress. The avoidance, anxious anticipation, or distress in the feared situation(s) interferes significantly with the person's normal routine, occupational or academic functioning, or social activities or relationships, or there is a marked distress about having the phobias. Lesser degrees of performance anxiety or shyness generally do not require psychopharmacological treatment. Panic disorder, including prevention of relapse.
BRU17122279P; BRU17122279PS2	Medaxonum (Ceftriaxone) 1g Powder For Injection/Infusion	Medaxonum is indicated for the treatment of the following infections caused by susceptible organisms. For details of susceptible organisms, see Pharmacodynamics. Therapy may be initiated prior to the results of susceptibility testing being known. Bones, skin and soft tissue infection Gonorrhoea Infections in patients with impaired defence mechanisms Meningitis (bacterial), including meningococcal meningitis prophylaxos Pneumonia Septicaemia It is also indicated for use peri-operatively in the prophylaxis of infection associated with surgical procedures.
BRU17122281NP	Konsyl Original Formula Psyllium Fiber	For relief of occasional constipation and to induce regularity. This product generally produces bowel movements within 12-72 hours.

BRU17122282P	Vaxcel Cefobactam-1g Injection	**Monotherapy**: Sulbactam / cefoperazone is indicated for the treatment of the following infections when caused by susceptible organism: Respiratory tract infections (upper and lower) Urinary tract infections (upper and lower) Peritonitis, cholecystitis, cholangitis and other intra-abdominal infections Septicaemia Meningitis Skin and soft tissue infections Bone and joint infections Pelvic inflammatory disease, endometritis, gonorrhoea and other infections of the genital tract **Combination therapy**: Because of the broad spectrum of activity of sulbactam / cefoperazone, most infections can be treated adequately with this antibiotic alone. However, sulbactam / cefoperazone may be used concomitantly with other antibiotics if such combinations are indicated. If an aminoglycoside is used (see interaction with other medicaments) renal function should be monitored during the course of therapy (see Recommended Dose Use in Renal Function)
BRU17122283P	Ibuspan Tablet 200mg	Ibuprofen is used in the management of mild to moderate pain in conditions such as dysmenorrhoea, migraine, postoperative pain, ankylosing spondylitis, osteoarthritis, and rheumatoid including juvenile rheumatoid arthritis, and in other musculoskeletal and joint disorders such as sprains and strains.
BRU17122284NP	Three Legs Lemon Sweet Purgative	For the relief of constipation and difficulty in bowel movement due to hardened faeces.
BRU17122285P	Fucithalmic Eye Drops 1%	Bacterial eye infections caused by susceptible organisms in conjunctivitis, blepharitis, sty, keratitis, dacryocystitis and in connection with removal of foreign bodies.
BRU17122286NP	SM Calamine Lotion	Calamine is indicated for the topical relief of itching, pain and discomfort of minor skin irritations, such as those caused by eczemas, insect bites, prickly heat, sunburn and napkin rash.
BRU17122287P	Pivakan 0.5% w/v (Plain) Injection (20ml Vial)	It is indicated for the production of local or regional anaesthesia and analgesia in individuals as follows: Surgical anaesthesia: Epidural block for surgery, Field block (minor and major nerve blocks and infiltration). Analgesia: Continuous epidural infusion or intermittent bolus epidural administration for analgesia in postoperative pain or labour pain, Field block (minor nerve block and infiltration).
BRU18012288P	Irbesartan Tablets 150mg	• Treatment of essential hypertension. • Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.

BRU18012289P	Irbesartan Tablets 300mg	• Treatment of essential hypertension. • Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.
BRU18012291P	Spiolto Respimat Inhalation Solution 2.5µg/2.5µg Per Actuation	Spiolto Respimat is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).
BRU18012292P	Zykadia™ 150mg Hard Capsule	Zykadia as monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive-advanced non-small cell lung cancer (NSCLC). ZYKADIA as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.
BRU18012294NP	Ketosteril Film-Coated Tablet	Prevention and therapy of damages, due to faulty or deficient protein metabolism in chronic renal insufficiency in connection with limited protein in food of 40g per day (for adults) and less, i.e. generally in patients with glomerular filtration rate (GFR) between 5 and about 15 ml/minutes.
BRU18012295PS2	Kadcyla Powder For Concentrate For Solution For Infusion 100mg/Vial	**Breast Cancer** *Metastatic Breast Cancer (MBC)* Kadcyla, as a single agent, is indicated for the treatment of patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who have received prior treatment with trastuzumab and a taxane, separately or in combination. Patients should have either: - Received prior therapy for advanced or metastatic disease, or - Developed disease recurrence during or within six months of completing adjuvant therapy. *Early Breast Cancer (EBC)* Kadcyla, as a single agent, is indicated for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease, after neoadjuvant trastuzumab and taxane-based treatment.

BRU18012296PS2	Kadcyla Powder For Concentrate For Solution For Infusion 160mg/Vial	**Breast Cancer** Metastatic Breast Cancer (MBC) Kadcyla, as a single agent, is indicated for the treatment of patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who have received prior treatment with trastuzumab and a taxane, separately or in combination. Patients should have either: - Received prior therapy for advanced or metastatic disease, or - Developed disease recurrence during or within six months of completing adjuvant therapy. Early Breast Cancer (EBC) Kadcyla, as a single agent, is indicated for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease, after neoadjuvant trastuzumab and taxane-based treatment.
BRU18012297NP	5% Dextrose In Water Solution For Intravenous Infusion	1. For fluid and caloric maintenance. 2. As a vehicle for compatible drugs used in therapy or in diagnostic procedures.
BRU18012298NP	10% Dextrose In Water Solution For Intravenous Infusion	1. For fluid and caloric maintenance. As a vehicle for compatible drugs used in therapy or in diagnostic procedures.
BRU18012299P	Three Legs Tinea-Kare Anti-Fungal Cream 1% w/w	For treatment of fungal infections including ringworm, athletes foot, jock itch and white spot.
BRU18012301NP	Gascoal Tablet 50mg	For the relief of flatulence and gas expellation for (gastroscopic) gastrodiagraphic and X-ray examination.
BRU18012302NP	Vitabiotics Pregnacare Original Tablet	For the prevention and correction of vitamin and mineral deficiency states.
BRU18022303NP	Glycophos Concentrate For Solution For Infusion	Glycophos is indicated in adults patients as a supplement in intravenous nutrition to meet the requirements of phosphate.
BRU18022304NP	Nutrilite Daily Tablet	As dietary supplement.

BRU18022308P	Jakavi 10mg Tablet	Myelofibrosis (MF) Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. Polycythaemia vera (PV) Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea. Graft versus host disease (GvHD) Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).
BRU18022309P	Zycort Injection 100mg	Replacement therapy for adrenal-cortical failure or hypopituitarism. In patients with known or suspected adrenal insufficiency, intravenous or intra-muscular administration of a rapidly acting corticosteroid (such as hydrocortisone) is indicated prior to surgery, including dental surgery, or if shock, severe trauma, illness, or other stress conditions occur. Patients already receiving replacement therapy require supplemental pharmacologic doses; Congenital adrenal hyperplasia; Status asthmaticus; Allergic and anaphylactic reactions; Ulcerative colitis; Soft tissue or joint inflammation; Collagen diseases; Dermatological diseases; Hypercalcaemia associated with cancer.
BRU18022310PS2	Opsumit 10mg Film-Coated Tablet	Opsumit, as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU18022311P	Uractonum 25mg Tablet	Hepatic cirrhosis: Oedema in hepatic cirrhosis Hypertension: Congestive heart failure. Long-term treatment of primary aldosteronism Nephrotic syndrome
BRU18022312P	Perjeta Concentrate For Solution For Infusion 420mg/14ml	Metastatic Breast Cancer (MBC) Perjeta is indicated for use in combination with Herceptin and docetaxel for the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease. Early Breast Cancer Perjeta is indicated for use in combination with Herceptin and chemotherapy for the: • neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival. • adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence

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BRU18022318NP	Sangobion Capsule	Iron deficiency anaemia. Prophylaxis and therapy of anaemia due to deficiency or increased requirements of the active agents, e.g. in: haemorrhage of traumatic or endogenous origin, pregnancy, growth, convalescence and senility, poor nutrition and blood donation.
BRU18022319P	Talgesil Injection 0.1mg/2ml (Amp)	Short duration analgesia during pre-medication induction and maintenance of anaesthesia, and in the immediate post-operative period.
BRU18032320P	Norfox Tablet	Indicated for the oral treatment of adults with complicated and uncomplicated urinary tract infections that are caused by susceptible strains of microorganisms.
BRU18032321P	Domil Suspension 5mg/5ml	Domperidone is indicated for the relief of symptoms of nausea and vomiting. This includes: • Nausea and vomiting of functional, organic, infectious or dietary origin • Nausea and vomiting induced by: - Radiotherapy or drug therapy - Dopamine agonists (such as L-dopa and bromocriptine) used in the treatment of Parkinson's disease.
BRU18032322P	Latanostill 50mcg/ml Eye Drops Solution	Latanostill is indicated for the reduction of elevated intra-ocular pressure in patients suffering from open-angle glaucoma and from ocular hypertension.
BRU18032323P	Gardasil 9, Suspension For Injection	GARDASIL 9 is a vaccine indicated in girls and women from 9 through 45 years of age for the prevemtion of cervical, vulvar, vaginal, and anal cancer; premalignant genital lesions (cervical, vulvar and vaginal); premalignant anal lesions; HPV infections; cervical adenocarcinoma in situ (AIS); and external genital warts (condyloma acuminata) causally related to Human Paillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, and 58. GARDASIL 9 is indicate in boys and men from 9 through 45 years of age for the prevention of premalignant lesions and HPV infections caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58; anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58 and genital warts (condyloma acuminata) caused by HPV types 6 and 11.

BRU18032324P	Entresto 50mg Film-Coated Tablets	**Heart failure** Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. LVEF is a variable measure, so use clinical judgment in deciding whom to treat [see Clinical efficacy and safety (section 5.1)]. Entresto is administered in combination with other heart failure therapies (e.g. beta blockers, diuretics and mineralocorticoid antagonists) as appropriate, in place of an ACE inhibitor or ARB [see Clinical efficacy and safety (section 5.1)]. **Hypertension** Entresto is indicated for the treatment of essential hypertension. Entresto should not be used as a first-line drug for the treatment of hypertension because of the risk of excessive decrease in blood pressure.
BRU18032325P	Entresto 100mg Film-Coated Tablets	**Heart failure** Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. LVEF is a variable measure, so use clinical judgment in deciding whom to treat [see Clinical efficacy and safety (section 5.1)]. Entresto is administered in combination with other heart failure therapies (e.g. beta blockers, diuretics and mineralocorticoid antagonists) as appropriate, in place of an ACE inhibitor or ARB [see Clinical efficacy and safety (section 5.1)]. **Hypertension** Entresto is indicated for the treatment of essential hypertension. Entresto should not be used as a first-line drug for the treatment of hypertension because of the risk of excessive decrease in blood pressure.
BRU18032326P	Entresto 200mg Film-Coated Tablets	**Heart failure** Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. LVEF is a variable measure, so use clinical judgment in deciding whom to treat [see Clinical efficacy and safety (section 5.1)]. Entresto is administered in combination with other heart failure therapies (e.g. beta blockers, diuretics and mineralocorticoid antagonists) as appropriate, in place of an ACE inhibitor or ARB [see Clinical efficacy and safety (section 5.1)]. **Hypertension** Entresto is indicated for the treatment of essential hypertension. Entresto should not be used as a first-line drug for the treatment of hypertension because of the risk of excessive decrease in blood pressure.

BRU18032327P	Dyna Amoxycillin 125mg/5ml	Infections e.g. otitis media, sinusitis, pharyngitis, pneumonia, bronchitis caused by sensitive gram-positive organisms, including Streptococcus pneumonia, and other streptococci and Listeria monocytogenes. Gram-negative microorganism including some of strains of Bordetella pertussis, Haemophilus influenzae and some Enterobacteriaceae such as Escherichia coli, Proteus mirabilis, Salmonella and Shigella spp. ENT infections: otitis media, sinusitis, tonsillitis, pharyngitis, laryngitis, epiglottis. Lower respiratory tract infections: acute and chronic bronchitis, pneumonia, pleuritis. Urinary tract infections: acute and recurrent cystitis, acute and chronic pyelonephritis, asymptomatic bacteriuria, prostitis. Skin and soft tissue infections: erysipelas, impetigo
BRU18032328P	Winofen Suspension 2% w/v	Winofen suspension is indicated for its analgesic and anti-inflammatory effects in the treatment of juvenile rheumatoid arthritis and soft-tissue injuries such as sprains and strains. It is also indicated for its analgesic effect in the relief of mild to moderate pain such as dental pain and for symptomatic relief of headache. Winofen suspension is indicated in short-term use for the treatment of pyrexia in children over one year of age.
BRU18032329P	Wincort 1% Cream	Symptomatic relief of allergic disorders, localised itch and inflammatory conditions of the skin.
BRU18032330P	Acugesic Tablet 50mg	Severe acute and chronic pain.
BRU18032332P	Defuzin Cream 2% w/w	Defuzin Cream 2% w/w is indicated for treatment of skin infections caused by staphylococci, streptococci, Propionibacterium acnes, Corynebacterium minutissimum, and other organisms sensitive to fusidic acid. The most important indications are impetigo, infected wounds, folliculitis, boils, sycosis barbae, carbuncles, hidradenitis, paronychia and erythrasma.
BRU18032333P	Hydrochlorzide-50 Tablet	Hydrochlorzide is indicated for the treatment of oedema and hypertension.
BRU18032334P	SIMBRINZA* 10 mg/ml + 2 mg/ml Eye Drops, Suspension	SIMBRINZA* eye drops contains brinzolamide, a carbonic anhydrase (CA-II) inhibitor, and brimonidine tartrate, an alpha-2 adrenergic agonist. Decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.
BRU18032335NP	Hexidin Cream 1%	As a disinfectant cream. It can be used for disinfection or lubricating during gynaecological and obstetric procedures or childbirth.
BRU18032336NP	Three Legs Green Balsem	For symptomatic relief of muscular pain and joint pain.

BRU18042338P	Novatretin™ 25mg Capsules	Severe forms of psoriasis including - erythrodermic psoriasis; - local or generalized pustular psoriasis; Severe disorders of keratinization, such as - congenital ichthyosis; - pityriasis rubra pilaris; - Darier's disease; - other disorders of keratinization which may be resistant to other therapies
BRU18042339P	Novatretin™ 10mg Capsules	Severe forms of psoriasis including - erythrodermic psoriasis; - local or generalized pustular psoriasis; Severe disorders of keratinization, such as - congenital ichthyosis; - pityriasis rubra pilaris; - Darier's disease; - other disorders of keratinization which may be resistant to other therapies
BRU18042340P	Axcel Metoclopramide Tablet	<u>Adult population</u>: Axcel Metoclopramide Tablet is indicated in adults for: - Symptomatic treatment of nausea and vomiting, including acute migraine induced nausea and vomiting. - Prevention of delayed chemotherapy induced nausea and vomiting (CINV) - Prevention of radiotherapy induced nausea and vomiting (RINV) <u>Age 9-18 years patient</u>: Axcel Metoclopramide Tablet is indicated in patient (aged 9-18 years) for: Prevention of delayed chemotherapy induced nausea and vomiting (CINV) as a second line option.
BRU18042341P	TADIM Colistimethate Sodium 1 Million IU Powder For Nebuliser Solution Vial	Tadim powder for nebuliser solution is indicated for the treatment of colonisation and infections of the lung due to susceptible Pseudomonas aeruginosa in patients with cystic fibrosis. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

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BRU18042342P	Clovix 75mg Tablet	Clopidogrel is indicated in adults for the prevention of atherothrombotic events as follows: • Recent Myocardial Infarction, Recent Stroke or Established Peripheral Arterial Disease -patients suffering from Myocardial Infarction (from a few days until less than 35 days), Ischaemic Stroke (from 7 days until less than 6 months) or established peripheral arterial disease. • Acute Coronary Syndrome -Non-ST segment elevation acute coronary syndrome (unstable angina/non-Q-wave myocardial infarction), including patients undergoing a stent replacement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA). -ST segment elevation acute myocardial infarction, in combination with ASA in medically treated patients eligible for thrombolytic therapy.
BRU18042343P	Axcel Cetirizine Tablet	Adults and children of 3 years or above; symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticarial of allergic reaction.
BRU18042344P; BRU18042344PS2	Zarzio 30 MU/0.5ml Solution For Injection Or Infusion In Pre-Filled Syringe	- Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. - The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy. - Mobilisation of peripheral blood progenitor cells (PBPC). - In children and adults with severe congenital, cyclic or idiopathic neutropenia with an absolute neutrophil count (ANC) of ≤ 0.5 x 10^9/l, and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events. - Treatment of persistent neutropenia (ANC ≤ 1.0 x 10^9/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other therapeutic options are inappropriate.

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BRU18042345P	Ibrance Capsules 75mg	IBRANCE is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.
BRU18042346P	Ibrance Capsules 100mg	IBRANCE is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.
BRU18042347P	Ibrance Capsules 125mg	IBRANCE is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

BRU18042348P	Tulip® 40mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Fredrickson Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet Atorvastatin is also intended for the decrease of increased total or LDL cholesterol in patients suffering from homozygous familial hypercholesterolemia, when response to diet and other nonpharmacological measures are inadequate. Prevention of Cardiovascular Disease In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • reduce the risk of non-fatal myocardial infarction, • reduce the risk of fatal and non-fatal stroke, • reduce the risk for revascularization procedures, • reduce the risk of hospitalization for CHF, • reduce the risk of angina. Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains ≥ 190 mg/dL or b. LDL-C remains ≥ 160 mg/dL and: • there is a positive family history of premature cardiovascular disease or • two or more other CVD risk factors are present in the pediatric patient

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BRU18062349P	Victoza® 6mg/ml, Solution For Injection In Pre-Filled Pen	Victoza® is indicated for the treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes. Prevention of cardiovascular events Victoza is indicated as an adjunct to diet, exercise and standard care therapy to reduce the risk of major cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or nonfatal stroke) in patients with type 2 diabetes mellitus and established cardiovascular disease who have inadequate glycaemic control.
BRU18062350P	Axcel Clindamycin Topical Solution 1% w/v	Treatment of acne vulgaris.
BRU18062351P	Flucon Solution For IV Infusion 2mg/ml	FLUCON is indicated for the treatment of the following conditions: Use in Adults: 1. Cryptococcosis, including cryptococcal meningitis and infections of other sites (eg. pulmonary, cutaneous) Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. 2. Systemic candidiasis, including candidemia, disseminated candidiasis and other forms of invasive candidal infection. These include infections of the peritoneum, endocardium, eye and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. 3. Mucosal candidiasis These include oropharyngeal, esophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated.
BRU18062352P	Analpan Injection 75mg/3ml	1. Inflammatory and degenerative forms of rheumatism 2. Rheumatoid arthritis 3. Ankylosing spondylitis 4. Osteoarthritis, spondylarthritis 5. Non-articular rheumatism 6. Painful inflammatory conditions of non-rheumatic origin.
BRU18062353P	ELIGARD® Powder And Solvent For Solution For Injection 7.5mg	ELIGARD is indicated for the palliative treatment of hormone dependent advanced prostate cancer.

BRU18062354P	ELIGARD® Powder And Solvent For Solution For Injection 22.5mg	ELIGARD is indicated for the palliative treatment of hormone dependent advanced prostate cancer.
BRU18062355P	ELIGARD® Powder And Solvent For Solution For Injection 45mg	ELIGARD is indicated for the palliative treatment of hormone dependent advanced prostate cancer.
BRU18062356P	Three Legs Tinea-Kare Anti-Fungal Spray 1% w/v	- All dermatomycoses due to dermatophytes (Trichophyton species) e.g. athlete's foot (Tinea pedis), jock itch (Tinea cruris) and ringworm (Tinea corporis) - All dermatomycoses due to yeast (Candida species) e.g. Candida vulvitis, Candida balanitis - Dermatomycosis due to moulds and other fungi - Skin diseases showing secondary infection with these fungi.
BRU18062357NP	Potrelease TR Tablet 600mg	i. Hypokalaemia, (treatment) – Potassium supplements are indicated in patients with hypokalaemia with or without metabolic alkalosis, in digitalis intoxication, and in patients with hypokalaemic familial periodic paralysis. ii. Hypokalaemia (prophylaxis) - Potassium supplements are indicated to prevent hypokalaemia in patients whose dietary intake of potassium is inadequate and who are taking digitalis and diuretics. Potassium supplements are also indicated in patients who suffer from hepatic cirrhosis with ascites, aldosterone excess with normal renal function, severe diarrhoea, and potassium-losing nephropathy.
BRU18062359P	Encardil Tablet 10mg	Treatment of hypertension: Enalapril is indicated alone or in combination with a thiazide diuretic, in the treatment of hypertension. Also used for treatment of renovascular hypertension (except in patients with bilateral renal artery stenosis or renal artery stenosis in a solitary kidney). Treatment of congestive heart failure: Also indicated, in combination with diuretics and digitalis therapy, for treatment of congestive heart failure not responding to other measures. In patients with symptomatic heart failure, Enalapril is indicated to improve survival, retard the progression of heart failure and reduce hospitalization for heart failure. Prevention of symptomatic heart failure: In asymptomatic patients with left ventricular dysfunction, it is indicated to: - Retard the development of symptomatic heart failure - Reduce hospitalization for heart failure Prevention of Coronary Ischemic Events in Patients with Left Ventricular Dysfunction: Enalapril may reduce the incidence of myocardial infarction and reduce hospitalization for unstable angina pectoris.

BRU18062362P	Apo-Carvedilol 6.25mg Tablet	Hypertension: APO-CARVEDILOL (carvedilol) is indicated primarily for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents (e.g. calcium channel blockers, diuretics). Treatment of angina pectoris. Treatment of symptomatic chronic heart failure (CHF): APO-CARVEDILOL (carvedilol) is indicated for the treatment of symptomatic CHF to reduce mortality and cardiovascular hospitalizations, improve patient well-being and slow the progression of the disease. APO-CARVEDILOL may be used as adjunct of standard therapy, but may also be used in those patients unable to tolerate an ACE inhibitor, or those who are not receiving digitalis, hydralazine or nitrate therapy.
BRU18062363P	Apo-Carvedilol 25mg Tablet	Hypertension: APO-CARVEDILOL (carvedilol) is indicated primarily for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents (e.g. calcium channel blockers, diuretics). Treatment of angina pectoris. Treatment of symptomatic chronic heart failure (CHF): APO-CARVEDILOL (carvedilol) is indicated for the treatment of symptomatic CHF to reduce mortality and cardiovascular hospitalizations, improve patient well-being and slow the progression of the disease. APO-CARVEDILOL may be used as adjunct of standard therapy, but may also be used in those patients unable to tolerate an ACE inhibitor, or those who are not receiving digitalis, hydralazine or nitrate therapy.
BRU18062364P	Cef-3 Injection IM (500mg)	Ceftriaxone is used for treatment infections caused by susceptible bacteria. - Respiratory tract infections, pneumonia, otitis media - Renal and urinary tract infection - Septicemia - Meningitis in pediatric - Bone, joint and skin infection - Intra-abdominal infection - Uncomplicated gonorrhea infection

BRU18062365P	Simponi Solution For Injection 100mg/1.0ml	*Rheumatoid arthritis (RA):* SIMPONI, by SC administration, in combination with methotrexate (MTX), is indicated for: • the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate. • the treatment of severe, active, and progressive rheumatoid arthritis in adults not previously treated with MTX. SIMPONI, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function. *Psoriatic arthritis (PsA):* SIMPONI, by SC administration, alone or in combination with MTX, is indicated for: • the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate. SIMPONI has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Axial spondyloarthritis* *Ankylosing spondylitis (AS):* SIMPONI, by SC administration, is indicated for: • the treatment of severe, active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA):* SIMPONI, by SC administration, is indicated for: • the treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). *Ulcerative colitis (UC):* SIMPONI, by SC administration, is indicated for: • the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

BRU18062366P	Apo-Atorvastatin 20mg Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Frederickson levels type IV), and for patients with dysbetalipoproteinemia (Fredrickson type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia when response to diet and other non-pharmacological measures are inadequate. *Prevention of cardiovascular disease* In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • Reduce the risk of non-fatal myocardial infarction • Reduce the risk of fatal and non-fatal stroke • Reduce the risk for revascularization procedures • Reduce the risk of hospitalization for CHF • Reduce the risk of angina *Pediatric patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains more than 190mg/dl or b. LDL-C remains more than 160mg/dl and; • There is a positive family history or premature cardiovascular disease or • Two or more other CVD risk factors are present in the pediatric patient

BRU18062367P	Apo-Atorvastatin 40mg Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Frederickson levels type IV), and for patients with dysbetalipoproteinemia (Fredrickson type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia when response to diet and other non-pharmacological measures are inadequate. *Prevention of cardiovascular disease* In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • Reduce the risk of non-fatal myocardial infarction • Reduce the risk of fatal and non-fatal stroke • Reduce the risk for revascularization procedures • Reduce the risk of hospitalization for CHF • Reduce the risk of angina *Pediatric patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains more than 190mg/dl or b. LDL-C remains more than 160mg/dl and; • There is a positive family history or premature cardiovascular disease or • Two or more other CVD risk factors are present in the pediatric patient

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18062368NP	Sodium Chloride Parenteral Solution 0.9%	1. Parenteral Uses: • For volume and electrolyte replacement and maintenance • As vehicle/solvent for compatible drugs used in therapy or in diagnostic procedures 2. Non-Parenteral Uses: • As a surgical washing solution • For wound irrigation and moistening of wound dressings • As solution for nebulization
BRU18062369NP	Lactated Ringer's Solution	- For replacement of fluid and electrolytes. - Substitute for 5% Dextrose in Lactated Ringer's in cases where dextrose is not indicated.
BRU18062370NP	Optrex Refreshing Eye Drops	Soothe and revitalise tired, sore, uncomfortable eyes. For the relief of minor eye irritations caused by dusty or smoky atmospheres, driving or close work.
BRU18062371P	Codipront® Capsules	Symptomatic treatment of dry cough (non-productive cough) such as during bronchitis, influenza as well as inflammations of the respiratory tract due to allergic and infectious causes.
BRU18062372PS1; BRU18062372PS2; BRU18062372PS3	Mixtard® 30 Penfill® 100 IU/ml, 3ml Cartridge Suspension For Injection	To treat diabetes mellitus.
BRU18072375P	Dynalexin Dry Syrup 125mg/5ml	Cephalexin is a semi-synthetic cephalosporin antibiotic for oral administration. It is indicated in the treatment of the following infections due to susceptible microganisms: • Respiratory tract infections • Otitis media • Skin and soft tissue infections • Bone and joint infections • Genito-urinary tract infections, including acute prostatitis Dental infections
BRU18072376P	Aspira Tablet 10mg	For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older. Montelukast is indicated in adults and pediatric patients 2 years of age and older for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis. ***Note:*** *As the package insert for Aspira 10mg Tablet is shared with Aspira Chewable Tablet 4 mg and 5 mg as well as Aspira Oral Granules 4mg, general indication stated includes usage of montelukast on pediatric patients. However the use of Aspira 10mg Tablet in specific age group is stated under the Recommended Dosage.*

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18072377P	Terbin Cream 1%	Fungal infections of the skin and nails caused by dermatophytes, eg. Trichophyton (eg. T. rubrum, T.mentagrophytes, T.verrucosum, T.violaceum), Microsporum canis and Epidermophyton floccosum. Yeast infections of the skin caused by the genus Candida (eg. Candida albicans). Pityriasis (tinea) versicolor due to Pityrosporum orbiculare (also known as Malassezia furfur). Note: In contrast to topical Terfin, oral Terfin is not effective in Pityriasis versicolor.
BRU18072379P	Eye Glo Plus Eye Drops	Eye Glo Plus is an ophthalmic solution designed to comfort and cool eyes that are irritated and strained. Eye Glo Plus formula serves not only to cool eyes, but its mild antiseptic property means that it is suitable for the treatment of mild inflammatory conditions of the eye due to irritation and strain. Comforts strained and trained eyes.
BRU18072380NP	Crotocort Cream 10% w/w	i) Pruritis (itching) of varying origin. ii) Scabies (infestation of the skin by mites).
BRU18072381P	MabThera® Solution For Subcutaneous Injection 1400mg	***MabThera IV and MabThera SC*** **Non-Hodgkin's Lymphoma**: MabThera IV and MabThera SC are indicated for the treatment of: • patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma (DLCL) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) chemotherapy. • previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. MabThera IV and MabThera SC maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.
BRU18082382P	Tolanz ODT Tablets 5mg	Olanzapine is indicated for the treatment of schizophrenia. Olanzapine is effective in maintaining the clinical improvement during continuing therapy in patients who have shown initial treatment response. Olanzapine is indicated for short-term treatment of acute manic episode associated with Bipolar I Disorder. Olanzapine is indicated for preventing recurrence of manic, mixed or depressive episodes in Bipolar I Disorder.
BRU18082383P	Tolanz ODT Tablets 10mg	Olanzapine is indicated for the treatment of schizophrenia. Olanzapine is effective in maintaining the clinical improvement during continuing therapy in patients who have shown initial treatment response. Olanzapine is indicated for short-term treatment of acute manic episode associated with Bipolar I Disorder. Olanzapine is indicated for preventing recurrence of manic, mixed or depressive episodes in Bipolar I Disorder.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18082385P	Midazolam-Hameln 5mg/ml Injection, 1ml	Midazolam is a short-acting sleep-inducing drug that is indicated as follows: *In adults* • CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of anaesthesia - Induction of anaesthesia - As a sedative component in combined anaesthesia. • SEDATION IN INTENSIVE CARE UNITS *In Paediatrics* • CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of Anaesthesia • SEDATION IN INTENSIVE CARE UNITS
BRU18082386P	Optimol Eye Drops 0.5%	Timolol Opthalmic Drops is indicated in the reduction of elevated intraocular pressure. In clinical trials it has been shown to reduce intraocular pressure in: • Patients with ocular hypertension • Patients with chronic open-angle glaucoma • Aphakic patients with glaucoma
BRU18082387P	Niferin SR 30mg Tablet	1. Treatment of coronary heart disease -Chronic stable angina pectoris (angina of effort) 2. Treatment of hypertension
BRU18082388P	Pharmaniaga Pethidine Hydrochloride 50mg/1ml Injection	Moderate to severe pain, obstetric analgesia, pre-operative analgesia, enhancement of anaesthesia, for basal narcosis with Phenothiazines.
BRU18082389P	Pharmaniaga Pethidine Hydrochloride 100mg/2ml Injection	Moderate to severe pain, obstetric analgesia, pre-operative analgesia, enhancement of anaesthesia, for basal narcosis with Phenothiazines.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18082390P	Tagrisso 40mg Film-Coated Tablets	TAGRISSO (osimertinib) is indicated for: • the adjuvant therapy after tumour resection in adult patients with non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. • the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. • the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive (NSCLC) whose disease has progressed on or after EGFR TKI therapy.
BRU18082391P	Tagrisso 80mg Film-Coated Tablets	TAGRISSO (osimertinib) is indicated for: • the adjuvant therapy after tumour resection in adult patients with non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. • the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. • the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive (NSCLC) whose disease has progressed on or after EGFR TKI therapy.
BRU18082392P	Adezio Tablet 10mg	Adezio is indicated for the relief of symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis in adults and children over 2 years of age such as sneezing, rhinorrhea, postnasal discharge, nasal pruritis, ocular pruritis, tearing and redness of the eyes. Adezio is also indicated for the treatment of the uncomplicated skin manifestations of chronic urticarial in adults and children over 2 years of age. It significantly reduces the occurrence, severity and duration of hives and significantly reduces pruritis.
BRU18082393P	Enapril Tablet 20mg	Essential and renovascular hypertension; congestive heart failure; prevention of symptomatic heart failure and coronary ischemic events in patient with ledt ventricular dysfunction.
BRU18082394P	Xalkori 200mg Hard Capsules	**ALK- or ROS1-Positive Metastatic Non-Small Cell Lung Cancer** Crizotinib is indicated for the treatment of patients with advanced non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive.
BRU18082395P	Xalkori 250mg Hard Capsules	**ALK- or ROS1-Positive Metastatic Non-Small Cell Lung Cancer** Crizotinib is indicated for the treatment of patients with advanced non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive.
BRU18082396P	Normaten Tablet 100mg	Normaten is indicated for the control of hypertension and management of angina pectoris. It is also used as oral maintenance therapy for cardiac dysrhythmias after the acute attacks has been controlled by intravenous therapy and for long-term prophylaxis of myocardial infarction after recovery.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18082397P	Brilinta 60mg Film-Coated Tablet	**History of Myocardial Infarction (at least one year ago)** Brilinta, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events (cardiovascular death, myocardial infarction and stroke) in adult patients with a history of myocardial infarction (MI) (MI occurred at least one year ago), and a high risk of developing an atherothrombotic event. **Coronary Artery Disease, Type 2 Diabetes Mellitus and History of Percutaneous Coronary Intervention** Brilinta, co-administered with low-dose acetylsalicylic acid (ASA: 75-150mg), is indicated to reduce the risk of a first myocardial infarction or stroke in patients with Coronary Artery Disease (CAD), Type 2 Diabetes Mellitus (DM) and a history of percutaneous coronary intervention (PCI), who are also at high risk of developing an atherothrombotic events.
BRU18082400P	Normaten Tablet 50mg	Normaten is indicated for the control of hypertension and management of angina pectoris. It is also used as oral maintenance therapy for cardiac dysrhythmias after the acute attacks has been controlled by intravenous therapy and for long-term prophylaxis of myocardial infarction after recovery.
BRU18082401P	Adroten Tablet 5mg	• Treatment of high blood pressure (hypertension) • Treatment of coronary heart disease (angina pectoris). • Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.
BRU18092402P	Mapenem (1G Injection)	Mapenem 1gm is indicated for infections caused by pathogens sensitive to Meropenem including:- 1. Intra-abdominal infection 2. Skin and skin structure infection 3. Lower respiratory tract infections including bronchitis, pneumonia and Hospital-acquired pneumonia 4. Meningitis 5. Urinary tract infections 6. Gynaecological infections including endometritis and pelvic inflammatory disease 7. Bacterial septicemia 8. Empiric therapy in febrile neutropenia
BRU18092404P	Apo-Fluvoxamine 50mg Tablet	Major depressive episode, obsessive compulsive disorder.
BRU18092405P	Ultiva Injection 5mg	Ultiva is indicated as an analgesic agent for use during induction and/or maintenance of general anaesthesia during surgical procedures including cardiac surgery, and also for continuation of analgesia into the immediate post-operative period under close supervision, during transition to longer acting analgesia. Ultiva is indicated for provision of analgesia and sedation in mechanically ventilated intensive care patients.

BRU18092406P	Ultravist 300 Injection 300mg/ml	This medicinal product is for diagnostic use only. Ultravist 300: Contract enhancement in computerized tomography (CT), digital subtraction angiography (DSA), intravenous urography, phlebography of the extremities, venography, arteriography, visualization of body cavities (e.g. arthrography, hysterosalpingography, fistulography) with the exception of myelography, ventriculography, cisternography.
BRU18092407P	Ultravist 370 Injection 370mg/ml	This medicinal product is for diagnostic use only. Ultravist 370: Contract enhancement in computerized tomography (CT), digital subtraction angiography (DSA), intravenous urography, arteriography and especially angiocardiography, visualization of body cavities (e.g. arthrography, fistulography) with the exception of myelography, ventriculography, cisternography.
BRU18092408P	Halaven 0.5mg/ml Solution For Injection	<u>Breast cancer</u> HALAVEN® monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease (see CLINICAL STUDIES). Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments. HALAVEN® is indicated as monotherapy for the treatment of locally advanced or metastatic HER2 negative breast cancer after failure of one chemotherapeutic regimen for advanced disease. Patients should have received an anthracycline and a taxane unless these treatments were not suitable. <u>Soft Tissue Sarcoma (Liposarcoma)</u> HALAVEN® is indicated for the treatment of inoperable liposarcoma after progression following prior chemotherapy for advanced or metastatic disease in adults. Patients should have received two previous chemotherapy treatments, one of which should have included an anthracycline, unless this treatment is unsuitable.

BRU18092409P	Sivkort® Sterile Suspension For Injection 40mg/1ml	<u>Intramuscular</u> Where oral therapy is not feasible or is temporarily undesirable in the judgement of the physician, SIVKORT® INJECTION is indicated for intramuscular use as follows: 1. Endocrine disorders Nonsuppurative thyroiditis. 2. Rheumatic disorders As adjunctive therapy for short-term administration in: post-traumatic osteoarthritis; synovitis of osteoarthritis; rheumatoid arthritis; acute and subacute bursitis; epicondylitis; acute non-specific tenosynovitis; acute gouty arthritis; psoriatic arthritis; ankylosing spondylitis; juvenile rheumatoid arthritis. 3. Collagen diseases During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus; acute rheumatic carditis 4. Dermatologic diseases Pemphigus; severe erythema multiforme (Stevens-Johnson syndrome); exfoliative dermatitis; bullous dermatitis herpetiformis; severe seborrheic dermatitis; severe psoriasis. 5. Allergic states Control of severe incapacitating allergic conditions intractable to adequate trials of conventional treatment in bronchial asthma; contact dermatitis; atopic dermatitis; seasonal or perennial allergic rhinitis. 6. Ophthalmic diseases Severe chromic allergic, and inflammatory processes involving the eye; such as herpes zoster ophthalmicus; iritis; iridocyclitis; chorioretinitis: diffuse posterior uveitis and choroiditis; optic neuritis; sympathetic ophthalmia; anterior segment inflammation. 7. Gastrointestinal diseases Critical phase requiring systemic therapy in ulcerative colitis, regional enteritis 8. Respiratory diseases Symptomatic sarcoidosis; berylliosis; aspiration pneumonitis 9. Hematologic diseases Acquired (autoimmune) hemolytic anemia 10. Neoplastic disorders For palliative management of leukemias and lymphomas in adults; acute leukemia of childhood. 11. Edema To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus. <u>Intra-Articular</u> SIVKORT® INJECTION is indicated for intra-articular or intra-bursal administration, and for injections into tendon sheaths, as adjunctive therapy for short-term administration in the following conditions: Synovitis of osteoarthritis; rheumatoid arthritis; acute and subacute bursitis; acute gouty arthritis; epicondylitis; acute nonspecific tenosynovitis; posttraumatic osteoarthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18092410P	Dotarem 0.5 mmol/mL, Solution For Injection	This medicinal product is for diagnostic use only. Dotarem should be used only when diagnostic information is essential and not available with unenhanced magnetic resonance imaging (MRI). Magnetic resonance for: • cerebral and spinal disease, • diseases of the vertebral column, and other whole body pathologies (including angiography).
BRU18092411P	Polytet Eye Ointment	It is indicated for the treatment of superficial ocular infection involving the conjunctiva and/or cornea caused by Oxytetracycline with Polymyxin B Sulphate susceptible organisms. It may be administered topically alone, or as an adjunct to systemic therapy. It is effective in infections caused by susceptible strains of staphylococci, streptococci, pneumococci, *Haemophilus influenza* , *pseudomonas aeruginosa* , kochweeks bacillus, and Proteus.
BRU18092412P	IOPROST Latanoprost Eye Drops Solution 0.005% w/v	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma, chronic angle closure glaucoma and ocular hypertension.
BRU18092413NP	Eye Glo Relief Eye Drops 0.25% w/v	Eye Glo Relief is formulated to be used when your eyes are sore, swollen and watery eyes. The eye drops help to calm eyes that have become sore due to exposure to harsh conditions such as dust, strong wind, or when your eyes have been unprotected from chemicals like chlorine from swimming; or prolonged rubbing of the eyes.
BRU18092414NP	SW Aqueous Cream	It may be used as an emollient cream by itself or to serve as vehicle for other drugs.
BRU18092415P	Axcel Cefuroxime-125 For Oral Suspension (125mg/5ml)	Upper respiratory tract infections (for example: ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis). Lower respiratory tract infections (for example: pneumonia, acute bronchitis, and acute exacerbations of chronic bronchitis). Genito-urinary tract infections (for example: pyelonephritis, cystitis and urethritis). Gonorrhoea, acute uncomplicated gonococcal urethritis, and cervicitis. Skin and soft tissue infections (for example: furunculosis, pyoderma and impetigo). Treatment of early Lyme disease and subsequent prevention of late Lyme disease in adults and children over 12 years old.
BRU18092416P	Horf Lozenges	For the prophylaxis of stomatitis, gangrenous stomatitis, pharyngitis, laryngitis, tonsillitis, gingivitis, post-tonsillectomy and post tooth extraction secondary bacterial infections. For the temporary local relief of pain associated with dental conditions and sore throats.
BRU18092417NP; BRU18092417NPS2	Tiger Balm White Ointment	For the relief of headache, nasal congestion, insect bites, itchiness and flatulence.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18092418P	Prolia Solution For Injection 60mg/mL (Prefilled Syringe)	***Treatment of postmenopausal women with osteoporosis at high risk for fracture*** Prolia is indicated for the treatment of postmenopausal women with osteoporosis at high risk of fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures. ***Treatment of men with osteoporosis at high risk of fracture*** Prolia is indicated for the treatment of men with osteoporosis at high risk of fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other osteoporosis therapy. ***Treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer*** Prolia is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures. ***Treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer*** Prolia is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for nonmetastatic breast cancer. ***Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.***
BRU18102419PS1; BRU18102419PS2	Zient® 10mg Tablet	***Primary Hypercholesterolemia*** *ZIENT,* administered with an HMG-CoA reductase inhibitor (statin) or alone, is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C) and apolipoprotein B (Apo B) in patients with primary (heterozygous familial and non-familial) hypercholesterolemia. *ZIENT,* administered in combination with fenofibrate, is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B, and non-HDL-C in patients with mixed hyperlipidemia. ***Homozygous Familial Hypercholesterolemia (HoFH)*** *ZIENT* , administered with atorvastatin or simvastatin, is indicated for the reduction of elevated total-C and LDL-C levels in patients with HoFH, as an adjunct to other lipid-lowering treatments (eg. LDL apheresis) or if such treatments are unavailable. ***Homozygous Sitosterolemia (Phytosterolemia)*** *ZIENT* is indicated as adjunctive therapy to diet for the reduction of elevated sitosterol and campesterol levels in patients with homozygous familial sitosterolemia
BRU18102420P	Simulect Lyophilisate For Injection 20mg Per Vial	Simulect is indicated for the prophylaxisof acute organ rejection in de novo renal transplantation in combination with ciclosporin and corticosteroid-based immunosuppression (in adults and children), or in combination with long-term immunosuppressive triple therapy with ciclosporin, corticosteroids and either azathioprine or mycophenolate mofetil (adults only).
BRU18102421NP	SW Calcium Lactate Tablet 300mg	It is indicated as dietary calcium supplement in: a) Growing adolescents b) Pregnant women c) Post-menopausal women threatened with osteoporosis d) Elderly persons who are bedridden and thus facing slow calcium loss from the bones

BRU18102422P	Sulpin F.C. Tablets 200mg	For the treatment of acute and chronic schizophrenia.
BRU18102423P	Quetiapine Fumarate Tablets 25mg	Quetiapine tablet is indicated for the treatment of: Schizophrenia Bipolar disorder including: - manic episodes associated with bipolar disorder - major depressive episodes in bipolar disorder - preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment.
BRU18102424P	Quetiapine Fumarate Tablets 200mg	Quetiapine tablet is indicated for the treatment of: Schizophrenia Bipolar disorder including: - manic episodes associated with bipolar disorder - major depressive episodes in bipolar disorder - preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment.
BRU18102425P	Quetiapine Fumarate Tablets 100mg	Quetiapine tablet is indicated for the treatment of: Schizophrenia Bipolar disorder including: - manic episodes associated with bipolar disorder - major depressive episodes in bipolar disorder - preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment.
BRU18102426NP	Volulyte 6% Solution For Infusion	Treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient.
BRU18102427P	Hydrogen Peroxide Solution 6% w/v	It is used as a disinfectant, antiseptic and mouthwash.
BRU18102428P	Axcel Prednisolone-5mg EC Tablets	Rheumatic fever, rheumatoid arthritis, allergic diseases, nephritic syndrome, bronchial asthma and other corticosteroid-indicated conditions.
BRU18102433P	Udoxan Injection (1ml Amp)	Induction of labour; inadequate uterine effort; management of third stage of labour; post-partum haemorrhage.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18102435P	Ceftrex Injection 1g IV Ceftriaxone	CEFTREX is used for the treatment of infections caused by pathogens sensitive to ceftriaxone e.g.: • Lower respiratory tract infections • Skin and skin structure infections • Bone and joint infections • Intra-abdominal infections • Urinary tract infections • Meningitis, septicaemia and gonorrhoea caused by susceptible organisms
BRU18102437NP	Optrex Multi Action Eye Wash	Washes, soothes and cleanse to relieve tired, uncomfortable and irritated eyes.
BRU18102438NP	Optrex Rehydrating Eye Drops	Optrex Rehydrating Eye Drops: o Specially formulated to instantly rehydrate and lubricate dry eyes o Suitable for everyday use, even while using contact lenses
BRU18102439P	Candesartan Sandoz Tablet 8mg	Candesartan Sandoz Tablets 8mg are indicated for the: • Treatment of essential hypertension in adults • Treatment of adult patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction ≤ 40%) as add-on therapy to Angiotensin Converting Enzyme (ACE) inhibitors or when ACE-inhibitors are not tolerated

		Melanoma KEYTRUDA (pembrolizumab) is indicated for the treatment of patients with unresectable or metastatic melanoma. KEYTRUDA is indicated for the adjuvant treatment of patients with melanoma with lymph node involvement who have undergone complete resection. *Non-Small Cell Lung Carcinoma* KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic non-squamous non-small cell lung carcinoma (NSCLC), with no EGFR or ALK genomic tumor aberrations. KEYTRUDA, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of patients with metastatic squamous NSCLC. KEYTRUDA as monotherapy is indicated for the first-line treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 with a ≥1% tumor proportion score (TPS) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations. KEYTRUDA as monotherapy is indicated for the treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 with a ≥1% TPS as determined by a validated test and who have received platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have received prior therapy for these aberrations prior to receiving KEYTRUDA. *Head and Neck Cancer* KEYTRUDA, as monotherapy or in combination with platinum and 5-fluorouracil (5-FU) chemotherapy, is indicated for the first-line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC). KEYTRUDA, as monotherapy, is indicated for the treatment of patients with metastatic or unresectable recurrent HNSCC with disease progression on or after platinum-containing chemotherapy. *Classical Hodgkin Lymphoma* KEYTRUDA is indicated for the treatment of adult and pediatric patients with relapsed or refractory classical Hodgkin lymphoma (cHL).

BRU18102440P	Keytruda 25mg/mL	*Urothelial Carcinoma* KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by a validated test, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status. KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have received prior platinum-containing chemotherapy. KEYTRUDA is indicated for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in-situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy. *Esophageal Cancer* KEYTRUDA, in combination with platinum and fluoropyrimidine based chemotherapy, is indicated for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus or gastroesophageal junction. KEYTRUDA is indicated for the treatment of patients with recurrent locally advanced or metastatic esophageal cancer whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by a validated test, and who have received one prior line of systemic therapy. KEYTRUDA is indicated for the treatment of patients with recurrent locally advanced or metastatic esophageal cancer who have received two or more prior lines of systemic therapy. *Microsatellite Instability-High Cancer* KEYTRUDA is indicated for the treatment of patients with advanced microsatellite instability-high (MSI-H), including mismatch repair deficient (dMMR), cancer who have received prior therapy. *Colorectal Cancer* KEYTRUDA is indicated for the first-line treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC). *Renal Cell Carcinoma* KEYTRUDA, in combination with axitinib, is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC). KEYTRUDA, in combination with lenvatinib, is indicated for the first-line treatment of patients with advanced RCC. *Endometrial Carcinoma* KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma~~,~~ who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation. *Triple-Negative Breast Cancer* KEYTRUDA is indicated for the treatment of patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery. KEYTRUDA, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (CPS ≥10) as determined by a validated test.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18112441NP	African Sea Coconut Brand Cough MIxture	• Relieve cough due to o Cold o Flu o Tickling throat • Loosen phlegm • Soothes sore throat & irritated throat
BRU18112442P	Fresofol 2% MCT/LCT Emulsion For Injection Or Infusion	Fresofol 2% MCT/LCT is a short-acting intravenous general anaesthetic agent for - induction and maintenance of general anaesthesia - sedation of artificially ventilated patients in the Intensive Care Unit (ICU)
BRU18112443P	Fresofol 1% MCT/LCT Emulsion For Injection Or Infusion	Fresofol 1% MCT/LCT is a short-acting intravenous general anaesthetic agent for - induction and maintenance of general anaesthesia - sedation of artificially ventilated patients in the Intensive Care Unit (ICU)
BRU18112444NP	Surgical Spirit	As antiseptic and disinfectant of the skin before injections.
BRU18112445P	Androz 100 Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Sildenafil to be effective, sexual stimulation is required.
BRU18112446P	Androz 50 Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Sildenafil to be effective, sexual stimulation is required.
BRU18112447P	Verapime Powder For Solution For Injection 1g/Vial	Treatment of the following infections when caused by susceptible strains of bacteria: Lower respiratory tract infections (including pneumonia and bronchitis), urinary tract infections (both complicated, including pyelonephritis and uncomplicated infections), skin and skin structure infections; intra-abdominal infections (including peritonitis and biliary tract infections), gynecologic infections, septicemia, empiric treatment in febrile neutropenic patients. In pediatric patients for treatment of infections when caused by susceptible bacteria: Pneumonia, urinary tract infections (both complicated and uncomplicated, including pyelonephritis), skin and skin structure infections, septicemia, empiric treatment in febrile neutropenia.
BRU18112450PS1; BRU18112450PS2	Rebif Solution For Injection In Pre-Filled Cartridge 22mcg/0.5ml	Rebif is indicated for the treatment of relapsing multiple sclerosis. In clinical trials, this was characterised by two or more acute exacerbations in the previous two years. Efficacy has not been demonstrated in patients with secondary progressive multiple sclerosis without ongoing relapse activity.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18112451PS1; BRU18112451PS2	Rebif Solution For Injection In Pre-Filled Cartridge 44mcg/0.5ml	Rebif is indicated for the treatment of • patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing relapsing multiple sclerosis • patients with relapsing multiple sclerosis. In clinical trials, this was characterised by two or more acute exacerbations in the previous two years Efficacy has not been demonstrated in patients with secondary progressive multiple sclerosis without ongoing relapse activity.
BRU18112452P	Nelin 150mg/1.5mL Injection	NELIN injection is indicated in the treatment of infections caused by susceptible strains of the above microorganisms (refer to section of package insert under PHARMACODYNAMICS). Clinical studies have shown NELIN to be effective in: - Bacteremia, septicemia - Serious infections of the respiratory tract - Kidney and genitourinary tract infections - Skin, soft tissue infections - Bone, joint infections - Burns, wounds, peri-operative infections - Intra-abdominal infection (including peritonitis) - Infections of gastrointestinal tract NELIN injection is recommended as initial therapy in suspected or confirmed gram-negative infection. In serious infections when the causative organisms are unknown. NELIN injection may be administered as initial therapy in conjunction with a penicillin or cephalosporin type drug before, obtaining results of susceptibility testing. If anaerobic organisms are suspected suitable anti-microbial therapy in conjunction with NELIN injection should be given. Following identification of the organism and its susceptibility, NELIN injection or other appropriate antibiotic therapy should then be continued.
BRU18112453P	Midazolam-Hameln 5mg/ml Injection, 3ml	Midazolam is a short-acting sleep-inducing drug that is indicated as follows: *In adults* • CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of anaesthesia - Induction of anaesthesia - As a sedative component in combined anaesthesia. • SEDATION IN INTENSIVE CARE UNITS *In Paediatrics* • CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of Anaesthesia • SEDATION IN INTENSIVE CARE UNITS
BRU18112454P	Apo-Atenidone Tablets 100/25mg	Management of hypertension.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18112459P	Ificipro 250mg Tablets	Consideration should be given to available official guidance on the appropriate use of antibacterial agents. Uncomplicated and complicated infections caused by ciprofloxacin susceptible pathogens. Infections of the respiratory tract: Ciprofloxacin can be regarded as an advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, E.coli, Pseudomonas, Haemophilus, Moraxella, catarrhalis, Legionella and Staphylococcus. Infections of the middle ear (otitis media)*, of the paranasal sinuses (sinusitis)*, especially if these are caused by Gram-negative organisms including Pseudomonas aeruginosa or by staphylococci. Infections of the eyes Infections of the kidneys and/or the efferent urinary tract Infections of the genital organs, including adnexitis, gonorrhea, prostatitis Infections of the abdominal cavity (e.g. infections of the gastrointestinal tract or of the biliary tract, peritonitis) Infections of the skin and soft tissue Infections of the bones and joints Sepsis Infections or imminent risk of infection (prophlaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or have neutropenia) Selective intestinal decontamination in immunosuppressed patients *Ificipro 250/500 should be only used: When Pseudomonas is considered AND the patient is allergic to antipseudomonal penicillins/cephalosporins; For resistant organisms with no other alternative antibiotics available.

		Rheumatoid Arthritis Humira is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Humira is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with disease modifying anti-rheumatic drugs. **Axial Spondyloarthritis** **Ankylosing Spondylitis** Humira is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Non-radiographic Axial spondyloarthritis (Axial Spondyloarthritis without radiographic evidence of AS)** Humira is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. **Plaque Psoriasis** Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Crohn's Disease** Humira is indicated for the treatment of moderately to severely active Crohn's Disease in adult patients who have inadequate response to conventional therapy. Humira is also indicated for treatment in adult patients with moderately to severely active Crohn's Disease who have lost response to or are intolerant to infliximab.

BRU18112460P	Humira 40mg/0.4ml Solution For Injection	**Ulcerative colitis** Humira is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Hidradenitis Suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate. **<u>Paediatrics</u>** **Juvenile idiopathic arthritis** **Polyarticular Juvenile Idiopathic Arthritis** Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 2 years old who had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. **Enthesitis-Related Arthritis** Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

		Paediatric Crohn's Disease Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindication for such therapies. **Paediatric Plaque Psoriasis** Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. **Paediatric Uveitis** Humira is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. **Adolescent hidradenitis suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Ulcerative Colitis** Humira is indicated for inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.
BRU18112461P	Imach Injection 1ml	Allergy in acute urticaria, insect bites and stings, drug and serum reactions, desensitisation reactions, hay fever, vasometer rhinitis, pruritis
BRU18112462NP	Silverderm Cream	For prevention and treatment of infection in burn wounds. It has also been used as an aid to the short-term treatment in other skin conditions, such as leg ulcers where infections may prevent healing and as an aid to prophylaxis of infection in skin grafting.
BRU18112463P	Granisetron-AFT Solution For Injection 1mg/ml	GRANISETRON-AFT is indicated for the prevention or treatment of nausea and vomiting induced by cytostatic therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU18112464P	Lenvima 4mg Hard Capsule	LENVIMA is indicated for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hurthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI). LENVIMA is indicated in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy. LENVIMA is indicated as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy.
BRU18112465P	Lenvima 10mg Hard Capsule	LENVIMA is indicated for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hurthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI). LENVIMA is indicated in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy. LENVIMA is indicated as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy.
BRU18112466P	Kisqali 200mg Film-Coated Tablet	KISQALI is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine-based therapy in pre/perimenopausal or postmenopausal women or in men; or • fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.
BRU18112467P	Zylovaa Tablet 50mg	• Hypertension Zylovaa is indicated for the treatment of hypertension. • Hypertensive patients with left ventricular hypertrophy Zylovaa is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients. • Nephropathy in Type 2 Diabetic Patients Indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio 300mg/g or more) in patients with type 2 diabetes and a history of hypertension. In this population, Zylovaa reduces the rate of progression of nephropathy as measured by the occurrence of doubling the serum creatinine or end stage renal disease (need for dialysis or renal transplantation) or death.
BRU18122468P	Cloxabiotic Injection 500mg	Cloxacillin is indicated for the treatment of:- -Skin and soft tissue infections caused by pneumococci -Upper and lower respiratory tract infection

BRU18122469P	Losartan Potassium Tablet 50mg	Hypertension: Losartan is indicated for the treatment of hypertension. Reduction in the Risk of Cardiovascular Morbidity and Mortality in Hypertensive Patients with Left Ventricular Hypertrophy: Losartan is indicated to reduce the risk of cardiovascular morbidity and mortality as measured by the combined incidence of cardiovascular death, stroke, and myocardial infarction in hypertensive patients with left ventricular hypertrophy. Heart Failure: Losartan is indicated for the treatment of heart failure in patients who cannot tolerate an ACE inhibitor. Switching patients with heart failure who are stable on an ACE Inhibitor to Losartan is not recommended. Renal Protection in Type 2 Diabetic Patients with Proteinuria: Losartan is indicated to delay the progression of renal disease as measured by a reduction in the combined incidence of doubling of serum creatinine, end stage renal disease (need for dialysis or renal transplantation) or death; and to reduce proteinuria.
BRU18122470P	Losartan Potassium Tablet 100mg	Hypertension: Losartan is indicated for the treatment of hypertension. Reduction in the Risk of Cardiovascular Morbidity and Mortality in Hypertensive Patients with Left Ventricular Hypertrophy: Losartan is indicated to reduce the risk of cardiovascular morbidity and mortality as measured by the combined incidence of cardiovascular death, stroke, and myocardial infarction in hypertensive patients with left ventricular hypertrophy. Heart Failure: Losartan is indicated for the treatment of heart failure in patients who cannot tolerate an ACE inhibitor. Switching patients with heart failure who are stable on an ACE Inhibitor to Losartan is not recommended. Renal Protection in Type 2 Diabetic Patients with Proteinuria: Losartan is indicated to delay the progression of renal disease as measured by a reduction in the combined incidence of doubling of serum creatinine, end stage renal disease (need for dialysis or renal transplantation) or death; and to reduce proteinuria.
BRU18122471P	Injecsol LIG2 (Lignocaine Hydrochloride Injection 2% w/v)	Lignocaine is a local anaesthetic of the amide group. Lignocaine Hydrochloride Injection is for use in infiltration anaesthetic, intravenous regional anaesthesia and nerve blocks. Treatment or prophylaxis of life-threatening ventricular arrhythmias, including those associated with myocardial infarction, general anaesthesia in patients predisposed to ventricular arrhythmias, digitalis intoxication, or following resuscitation from cardiac arrest.
BRU18122472NP	Injecsol S20 (Sodium Chloride 20% w/v Injection BP)	Electrolyte rebalance when small supplementation of water is desired, in slow intravenous infusion. Sodium supplementation with reduced volume in solutions for parenteral nutrition.
BRU18122473NP	Dyna Ferrous Fumarate Tablet	For the treatment or prophylaxis of iron deficiency anaemia.
BRU18122474P	Oxynorm 5mg Capsules	The management of opioid responsive, moderate to severe pain.
BRU18122475P	Oxynorm 10mg Capsules	The management of opioid responsive, moderate to severe pain.

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BRU18122480PS1; BRU18122480PS2	Mucodin Tablet 375mg	Mucolytic agents for adjunctive therapy of respiratory disorders.
BRU18122482NP	Belcid Suspension	BELCID is used as an antacid, antiflatulent and demulcent in gastric hyperacidity, heartburn and used in the symptomatic relief of peptic and duodenal ulcer pains.
BRU18122484NP	Mifulin Lotion	For treatment of corns, warts and ringworm.
BRU18122485P	Ketazon Shampoo	Reduction of scaling due to dandruff, seborrheic dermatitis and pityriasis versicolor.
BRU18122486P	Duratocin® RTS 100 mcg/ml	Prevention of postpartum haemorrhage due to uterine atony.
BRU18122487NP	Alucid Suspension	Alucid Suspension can be used for relief of gastric pain, hyperacidity, flatulence and heartburn. Alucid Suspension will relieve and control pain in the symptomatic management of gastric and duodenal ulcers and reflux oesophagitis by neutralising hydrochloric acid in gastric secretion. Alucid Suspension is also suitable as a domestic remedy in conditions affecting the stomach which may not necessarily be related to hyperacidity.
BRU19012488P	Benzapen 2.4MIU Injection	Intramuscular Benzathine Benzylpenicillin is indicated in the treatment of infections due to penicillin-sensitive micro-organisms that are susceptible to the low and very prolonged serum levels common to this particular dosage form. The following infections will usually respond to adequate dosage of intramuscular Benzathine Benzylpenicllin: • Mild-to-moderate infections of the upper-respiratory tract due to susceptible streptococci • Venereal infections – Syphilis, yaws, bejel and pinta Medical conditions in which Penicillin G Benzathine Therapy is indicated as Prophylaxis: • Rheumatic fever and/or chorea – Prophylaxis with penicillin G benzathine has proven effective in preventing recurrence of these conditions • It has also been used as follow-up prophylactic therapy for rheumatic heart disease and acute glomerulonephritis.
BRU19012489NP	Vitbion Forte Tablet	It is used as a supplement in the treatment of polyneuritis, neuralgias, diabetic neuropathy, drug induced neuropathy.
BRU19012491P	Fentanyl-Hameln 50 mcg/ml Injection	Fentanyl is a short-acting opioid used: - as an intravenous analgesic agent in surgical procedures - as an adjunct in the maintenance of general anaesthesia - in combination with a neuroleptic agent in the technique of neuroleptanalgesia - as a respiratory depressant / analgesic in patients requiring prolonged assisted ventilation - for induction of anaesthesia

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BRU19012492P	Axinol Tablet 20mg	Axinol is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line antianginal therapies.
BRU19012493P	HCQS (Hydroxychloroquine Tablets BP 200mg)	Hydroxychloroquine is indicated for o Acute or chronic rheumatoid arthritis o Systemic and discoid lupus erythematosus
BRU19012494P	Vaxcel Cefepime 1g Injection	Adults: Vaxcel Cefepime 1g Injection is indicated in adults for the treatment of the following infections when caused by susceptible strains of bacteria: Lower respiratory tract infections (including pneumonia and bronchitis). Urinary tract infections (both complicated, including pyelonephritis and uncomplicated infections). Skin and skin structure infections. Intra-abdominal infections (including peritonitis and biliary tract infections). Gynecologic infections. Septicemia. Empiric treatment in febrile neutropenic patients. Peadiatrics: Vaxcel Cefepime 1g Injection is indicated in pediatric patients for treatment of infections when caused by susceptible bacteria: Pneumonia Urinary tract infections (both complicated and uncomplicated, including pyelonephritis) Skin and skin structure infections Septicemia Empiric treatment in febrile neutropenia Culture and susceptibility studies should be performed when appropriate to determine susceptibility of the causative organism(s) to cefepime. Empiric therapy with Vaxcel Cefepime may be instituted before results of susceptibility studies are known; however, once these results become available, the antibiotic treatment should be adjusted accordingly. Because of its broad spectrum of bactericidal activity against gram-positive and gram-negative bacteria, Vaxcel Cefepime can be used as monotherapy prior to identification of the causative organisms(s). In patients who are at risk of mixed aerobic-anaerobic infection, particularly if bacteria not susceptible to cefepime may be present, concurrent initial therapy with anti-anaerobic agent is recommended before the causative agents may or may not be necessary, depending on the susceptibility profile.
BRU19012495NP	Three Legs Povidone Iodine	For the treatment of wounds, cuts, abrasions and minor skin infections.
BRU19012496P	Altra™ Tablet 10mg	• Chronic and prophylaxis treatment of asthma in adults • Symptomatic relief of seasonal allergic rhinitis in adults

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BRU19012497P	Axcel Flemin Junior Expectorant	Relief of cough and alleviation of nasal and bronchial congestion.
BRU19012498NP	Visipaque 320mg I/ml, Solution For Injection	X-ray contrast medium for cardio angiography, cerebral angiography (conventional), peripheral arteriography (conventional), abdominal angiography (i.a.DSA), urography, venography, CT-enhancement. Lumbar, thoracic and cervical myelography.
BRU19012499PS1; BRU19012499PS2	Albunorm 20%, 200g/l, Solution For Infusion	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.
BRU19012500PS1; BRU19012500PS2	Albunorm 5%, 50g/l, Solution For Infusion	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.
BRU19012501PS1; BRU19012501PS2	Albunorm 25%, 250g/l, Solution For Infusion	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.
BRU19012502P	Vaxigrip Tetra Suspension For Injection In Pre-Filled Syringe	VaxigripTetra is indicated for active immunisation of adults and children from 6 months of age and older for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine.
BRU19012503NP	Regiocit Solution For Haemofiltration	Regiocit solution is indicated as replacement fluid before dialyzer for continuous renal replacement therapy (CRRT) using regional citrate anticoagulation. Citrate is particularly relevant when systemic anticoagulation with heparin is contraindicated, for example in patients with increased bleeding risks. In paediatric patients, Regiocit solution is indicated in all age groups provided that the equipment used is adapted to the weight of the child.
BRU19012504P	Pyronium Injection 200mcg/ml	1) To protect against the peripheral muscarinic actions of anticholinesterases such as neostigmine and pyridostigmine used to reverse residual neuromuscular blockade produced by non-depolarising muscle relaxants; 2) As a preoperative antimuscarinic agent to reduce salivary, tracheobronchial and pharyngeal secretions, and to reduce the acidity of the gastric contents; 3) As a preoperative or intraoperative antimuscarinic to attenuate or prevent intraoperative bradycardia associated with the use of suxamethonium or due to cardiac vagal reflexes.

BRU19012505P	Herceptin Solution For Injection 600mg/5ml	*Metastatic Breast Cancer (MBC)* Herceptin is indicated for the treatment of patients with metastatic breast cancer who have tumors that overexpress HER2: a) as monotherapy for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease b) in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease c) in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive metastatic breast cancer, not previously treated with trastuzumab. This indication is based on data from one Phase III trial which studied the use of Herceptin in combination with anastrozole. Experience with other aromatase inhibitors is limited. *Early Breast Cancer (EBC)* Herceptin is indicated for the treatment of patients with HER2 positive early breast cancer. - following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable). - following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel. - in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin. - in combination with neoadjuvant chemotherapy followed by adjuvant Herceptin therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter. Herceptin should only be used in patients whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay.
BRU19012506P	Ezetimibe Sandoz Tablet 10mg	Primary hypercholesterolaemia EZETIMIBE SANDOZ, co-administered with an HMG-CoA reductase inhibitor (statin) or alone is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C) and apolipoprotein B (Apo B) in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia. Homozygous Familial Hypercholesterolaemia (HoFH) EZETIMIBE SANDOZ co-administered with atorvastatin or simvastatin, is indicated for the reduction of elevated total-C and LDL-C levels in patients with HoFH as adjunctive therapy to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. A beneficial effect of EZETIMIBE SANDOZ on cardiovascular morbidity and mortality has not yet been demonstrated.
BRU19022507P	Apo-Fluconazole 100mg Tablets	APO-FLUCONAZOLE (Fluconazole) is indicated for the treatment of: 1. Oropharyngeal and esophageal candidiasis. APO-FLUCONAZOLE is also effective for the treatment of serious systemic candidal infections, including urinary tract infection, peritonitis, pneumonia. 2. Cryptococcal meningitis 3. Prevention of the recurrence of cryptococcal meningitis in patients with acquired immunodeficiency syndrome (AIDS). APO-FLUCONAZOLE is also indicated to decrease the incidence of candidiasis in patients undergoing bone marrow transplantation who receive cytotoxic chemotherapy and/or radiation therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19022508NP	Nutrilite Iron Folic Tablet	As dietary supplement.
BRU19022509P	Cefatum Injection 1g	Ceftazidime is indicated for the treatment of single and mixed infections caused by susceptible aerobic organisms with suspected resistance to other antimicrobials, but not to ceftazidime, as an alternative to aminoglycosides in pseudomonal infection in patients in whom aminoglycosides toxicity is a cause for concern and other pseudomonal antibiotics cannot be used. Indications include: Septicaemia including neonatal sepsis. Bacteraemia e.g. infected burns. Respiratory infections: pneumonia, broncho-pneumonia, infected pleurisy, infected bronchiectasis and bronchitis. Severe ear, nose and throat infections: otitis media, mastoiditis. Urinary tract infections: acute and chronic pyelonephritis, pyelitis, cystitis, urethritis (bacterial only) and infections associated with bladder and renal stones. Skin and soft tissue infections: erysipelas, abscesses, cellulitis, infected burns and wounds, mastitis. Gastro-intestinal and abdominal infections: intra-abdominal abscesses, enterocolitis. Bone and joint infections: osteitis, osteomyelitis, septic arthritis, infected bursitis.
BRU19022510NP	Hovid-Folic Acid Tablets 5mg	For the prevention and treatment of folate deficiency states, For the prevention of neural tube defect in the foetus.
BRU19022511P	Clopine 100mg Tablet	The use of clozapine is indicated in the treatment of resistant schizophrenic patients only, ie. Schizophrenic patients who are non-responsive to or intolerant of classical neuroleptics. Non-responsiveness is defined as lack of satisfactory clinical improvement despite the use of adequate doses of at least two marketed neuroleptics prescribed for adequate durations. Intolerance is defined as the impossibility of achieving adequate clinical benefit with classical neuroleptic drugs because of severe and untreatable neurological adverse reactions (extrapyramidal side effects or tardive dyskinesia). Clozapine is also indicated for reducing the risk of recurrent suicidal behavior in patients with schizoaffective disorder who are judged to be at chronic risk for re-experiencing suicidal behavior, based on history and recent clinical state.
BRU19022512P	Vaxcel Omeprazole 40mg Injection	Duodenal ulcer, gastric ulcer reflux oesophagitis and Zollinger-Ellison Syndrome.
BRU19022513NP	Medon 500 Capsule	For the relief of fever, headache and pain associated with common cold.
BRU19022515NP	Paracetamol-AFT Solution For Infusion 10mg/ml	Indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19022516P	Domi Injection 15mg (3ml Amp)	Intravenously as an agent for conscious sedation prior to short surgical, diagnostic, therapeutic or endoscopic procedures, such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography and cardiac characterisation, either alone or in conjunction with a narcotic. Intravenously for induction of anaesthesia, preliminary to administration of other anaesthetic agents. With the use of a narcotic premedicant, induction of anaesthesia can be attained with a narrower dose range and in shorter period of time. Sedation in intensive care units by intravenous intermittent administration or continuous infusion. Intramuscularly for preoperative sedation (induction of sleepiness or drowsiness and relief of apprehension) and to impair memory of perioperative events.
BRU19022519P	Chloroquine Tablets 250mg	Chloroquine is used for the suppression and treatment of malaria. It is especially active against the erythrocytic forms of malaria. It is not active against tissue forms of the malaria parasites.
BRU19022520P	Keno Oral Paste	Keno Oral Paste is indicated for the adjunctive treatment and for the temporary relief of symptoms associated with inflammatory or ulcerative lesions of oral mucosa resulting from trauma.
BRU19022521P	Atracurium-Hameln 10mg/ml Injection, 2.5ml	Intravenous use during surgical and other procedures and in intensive care. Atracurium besilate is used as an adjunct to general anaesthesia, to facilitate tracheal intubation and controlled ventilation.
BRU19022522NP	Kidz PCM 250 Suspension (Strawberry)	For the relief of fever and mild to moderate pain in children, including headache and toothache.
BRU19022523NP	Povil Antacid Tablet	For the relief of gastrointestinal conditions including gastric hyperacidity, peptic ulcer, heartburn, dyspepsia and flatulence.
BRU19022524P	Inlyta® 1mg Film-Coated Tablet	Axitinib is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.
BRU19022525P	Inlyta® 5mg Film-Coated Tablet	Axitinib is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.
BRU19022526P	Taflotan Ophthalmic Solution 0.0015%	Reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension.
BRU19022527NP	Paracil Suspension 250mg/5ml	1. Relief of fever and discomfort associated with common cold and flu 2. Relief of teething pain, toothache and earache
BRU19022528P	DTI For Injection 200mg	Metastatic malignant melanoma, Hodgkin's disease, soft-tissue sarcoma including leiomyosarcoma.

BRU19022529P	Sildegra 100mg Tablets	Sildenafil is indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Sildenafil to be effective, sexual stimulation is required.
BRU19032530P	Imexa Powder For Oral Suspension 200mg/5ml	Imexa is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present). In sexually transmitted diseases in men and women, Imexa is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated in the treatment of uncomplicated genital infection due to non-multiresistant *Neisseria gonorrhoea* , concurrent infection with Treponema pallidum should be excluded. Imexa is indicated, either alone or in combination with rifabutin, for prophylaxis against *Mycobacterium avium – Intracellulare complex* (MAC) infection, an opportunistic infection prevalent in patients with advanced human immunodeficiency virus (HIV).
BRU19032531P	Dysolvon Syrup (Raspberry)	Administered in bronchitis and other respiratory conditions to aid expectoration. Reduction of sputum-viscosity.
BRU19032532NP	Paracil Tablet 500mg	1) Relief of fever and discomfort associated with the common cold and flu. 2) Relief of teething pain, toothache and earache.
BRU19032533NP	Three Legs Ai Kan Shan Fever Powder Paracetamol 500mg/Sachet	For relief of fever, headache, toothache and mild to moderate pain.
BRU19032534NP	Dyna Calamine Lotion	Indicated in the relief of itchiness associated with prickly heat, acne, insect bites and sunburn.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19032535P	Gazyva Concentrate For Solution For Infusion	Chronic Lymphocytic Leukaemia Gazyva in combination with chlorambucil is indicated for the treatment of patients with previously untreated chronic lymphocytic leukaemia (CLL). Follicular Lymphoma GAZYVA in combination in chemotherapy, followed by GAZYVA maintenance in patients achieving a response, is indicated for the treatment of patients with previously untreated advanced follicular lymphoma. Gazyva in combination with bendamustine, followed by Gazyva maintenance is indicated for the treatment of patients with follicular lymphoma (FL) who did not respond to, or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen.
BRU19032536P	Pyrimine Tablet 60mg	Pyrimine Tablet 60mg is indicated in the treatment of Myasthenia Gravis.
BRU19032537P	Ceftriaxone-AFT Powder For Injection 1g	Infections caused by pathogens sensitive to Ceftriaxone e.g. - Sepsis - Meningitis - Abdominal infections (peritonitis, infections of the biliary and gastrointestinal tracts) - Infections of the bones, joints, soft tissue, skin and of wounds - Infections in patients with impaired defence mechanisms - Renal and urinary tract infections - Respiratory tract infections, particularly pneumonia, and ear, nose and throat infections - Genital infections, including gonorrhoea Perioperative prophylaxis of infections
BRU19032538NP	U-Lite Effervescent Granules	U-Lite Effervescent Granules is indicated to relieve the burning discomfort caused by mild urinary tract infections. It also helps to reduce the formation of uric acid and cystine calculi in chronic gout. It may enhance the action of certain antibiotics such as Sulphonamide and relieves symptoms associated with gastric hyperacidity.
BRU19032539P	Coldmax Suspension	Coldmax Suspension relieves common cold and flu symptoms including fever and pain, headache, body aches, nasal congestion and runny nose. It also relieves allergies symptoms such as sneezing, itching and watery eyes.
BRU19032540NP	Kidz PCM 250 Suspension (Orange)	For the relief of fever and mild to moderate pain in children, including headache and toothache.
BRU19032541NP	Uni-Ma Enema Solution	Relief of occasional constipation. Part of bowel cleansing regimen in preparing the colon for surgery, x-ray, or endoscopic examination.

BRU19032542P	Ciprocep Tablet 250mg	Ciprocep is indicated for infections caused by ciprofloxacin-sensitive pathogens: • The respiratory tract: In the treatment of outpatients with pneumonia due to Pneumococcus, Ciprocep should not be used as a first drug of choice. Ciprocep can be regarded as an advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, Pseudomonas, Haemophilus, Branhamella, Legionella and Staphylococcus. • Middle ear (otitis media) and paranasal sinuses (sinusitis), especially if these are caused by gram-negative organisms including Pseudomonas, or by Staphylococcus. • The eyes: kidney and/or the efferent urinary tract; genital organs, including gonorrhoea and chronic bacterial prostatitis; abdominal cavity (eg. Bacterial infections of the gastrointestinal tract or of the biliary tract, peritonitis); the skin and soft tissue; bones and joints • Sepsis • Prophylaxis in those patients whose immune system has been weakened (eg. Patients on immunosuppressant or in a state of neutropenia) • Selective intestinal decontamination in immunosuppressed patients • Inhalation anthrax (post-exposure): To reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis The following pathogens can be regarded as sensitive: E.coli, Shigella, Salmonella, Citrobacter, Klebsiella, Enterobacter, Serratia, Hafnia, Edwardsiella, Proteus (indole-positive and indole-negative), Providencia, Morganella, Yersinia, Vibrio, Aeromonas, Plesiomonas, Pasteurella, Haemophilus, Campylobacter, Pseudomonas, Legionella, Neisseria, Moraxella, Acinetobacter, Brucella, Staphylococcus, Listeria, Corynebacterium, Chlamydia. The following pathogens show varying degrees of sensitivity: Gardnerella, Flavobacterium, Alcaligenes, Streptococcus pyogenes, Enterococcus faecalis, Streptococcus agalactiae, Streptococcus pneumoniae, Mycoplasma hominis, and Mycobacterium. The following pathogens are usually resistant: Ureaplasma urealyticum, Clostridium difficile, Nocardia asteroides. Insufficient data are available on the efficacy of Ciprocep against Treponema pallidum.
BRU19032543P	Ferriprox 1000mg Film Coated Tablet	Ferriprox is indicated for the treatment of patients with transfusional iron overload due to thalassaemia syndromes when current chelation therapy is inadequate.
BRU19032544P	Octocaine 100	OCTOCAINE Solutions are indicated for the production of local anaesthesia for dental procedures by nerve block or infiltration techniques.
BRU19032545NP	Aniosgel 85 NPC	Thxotropic hydroalcoholic gel for hygienic treatment and surgical disinfection of hands by rubbing.
BRU19032546NP	Antiphlamine S Lotion	For the temporary relief of minor aches and pains of muscles, simple backaches, strains and sprains.
BRU19032547NP	Woods Peppermint Cough Syrup For Children	Woods' Peppermint Cough Syrup for Children provides relief of wet, productive cough. It helps loosen phlegm and thins bronchial secretions to rid bronchial passageways of bothersome mucus and makes cough more productive.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19032548NP	Xubil Oral Solution	• For the relief of occasional constipation • For use as part of a bowel cleansing regiment in preparing the patient for surgery or for preparing the colon or endoscopic examination
BRU19042549P	Oxytocin-Richter Solution For Injection 10 IU/1ml	Oxytocin is indicated for the initiation or improvement of uterine contractions. Antepartum uses: Induction of labour Induction of labour for medical reasons, e.g. in cases of postterm gestation, premature rupture of the membranes, pregnancy induced hypertension (preeclampsia). Augmentation of labour During the first and second stages of labour intravenous oxytocin infusion may be used to augment contractions if labour is prolonged or if dysfunctionall uterine inertia occurs. Early stages of pregnancy As adjunctive therapy for the management of incomplete, inevitable, or missed abortion. Postpartum uses: Prevention of postpartum uterine atony and haemorrhage for both vaginal and caesarean delivery (following the delivery of the child).
BRU19042550P	Vivic Tablet 100mg	Vivic is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil to be effective, sexual stimulation is required.
BRU19042551P	Requip PD 24 Hour Prolonged Release Tablet 4mg	• REQUIP PD 24 HOUR is indicated for the treatment of idiopathic Parkinson's disease • REQUIP PD 24 HOUR may be used alone (without Levodopa [L-Dopa]) in the treatment of idiopathic Parkinson's disease. • Addition of REQUIP PD 24 HOUR to levodopa may be used to control 'on-off' fluctuations and permit a reduction in the total daily dose of L-Dopa.
BRU19042552NP	Axcel Folic Acid Tablet 5mg	Folic acid is a member of the vitamin-B group. It is necessary for the normal production and maturation of red blood cells. Folic acid produces a haemopoietic response in nutritional macrocytic anaemia, megaloblastic anaemia of infancy, and the anaemias of pregnancy, pellagra, and sprue, and that following gastrectomy, and in pernicious anaemia.
BRU19042553P	Maxigesic Tablet 500mg/150mg	Maxigesic tablets are indicated for temporary relief of pain associated with: headache, migraine, backache, period pain, dental pain, muscular pain, cold and flu symptoms, sore throat and fever.

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BRU19042554P	Arnetin 50mg/2ml Solution For Injection/Infusion	Treatment of duodenal ulcer, benign gastric ulcer, post operative ulcer, oesophageal reflux disease and Zollinger-Ellison syndrome. In patients where the reduction of gastric secretion and acid output is desirable with the following conditions: Prophylaxis of gastric-intestinal haemorrhage from stress ulceration in seriously-ill patients Prophylaxis of recurrent haemorrhage in patients with bleeding peptic ulcers Prior to general anaesthesia in patients at risk from acid aspiration (Mendelson's syndrome) i.e. obstetric patients in labour.
BRU19042555P	Clavomax 625mg Tablet	Clavomax is indicated for the treatment of common bacterial infections where antibiotic therapy is indicated including: 1) Lower upper respiratory tract infections (including ENT) e.g. Sinusitis, tonsillitis, otitis media 2) Lower respiratory tract infections e.g. acute exacerbation of chronic bronchitis, lobar and bronchpneumonia 3) Skin and soft tissue infections e.g. boils/abcesses, cellulitis and would infections 4) Genito-urinary tract infections e.g. Cystitis, urethritis, pyelonephritis 5) Bone and joint infections e.g. osteomyelitis 6) Other infections: intra-abdominal sepsis
BRU19042556P	Chlorop Eye Ointment 1%	Indicated for the treatment of ocular infections involving the conjunctiva and/or cornea caused by chloramphenicol susceptible organisms. Chloramphenicol should be used only in serious infections for which less potent drugs are ineffective or contraindicated.
BRU19042557P	Akoset Injection 20mg/2ml	For the treatment of the oedema associated with congestive heart failure, cirrhosis of the liver and renal disease, including the nephrotic syndrome. Particularly useful when an agent with greater diuretic potential than that of the more commonly used agents is desired. Intravenous administration is indicated when a rapid onset of diuresis is desired, e.g. acute pulmonary oedema. Intramuscular or intravenous route is indicated if gastrointestinal absorption is impaired or oral medication is not practicable for any reason. Note: Parenteral administration should be reserved for patients with whom oral medication Is not practical.
BRU19042558P	Lipiodol Ultra Fluid 480mg I/ml, Solution For Injection	<u>In diagnostic radiology</u> Lymphography. Diagnosis of liver lesions. Diagnosis of the spread of malignant lesions, whether hepatic or not, by selective hepatic arterial injection. <u>In interventional radiology</u> Visualisation, localisation and vectorisation during Trans-Arterial Chemo-Embolisation (TACE) of hepatocellular carcinoma at intermediate stage, in adults. Embolization with surgical glues. In association with surgical glues during vascular embolizations. <u>In endocrinology</u> The use of Lipiodol in prevention of iodine deficiency disorders should exclusively be reserved to countries in which other methods of supplementation, particularly iodization of salt and/or drinking water, cannot be undertaken.

BRU19042559NP	Povil Antacid Mixture (Peppermint)	For the relief of gastric pain and discomforts of peptic ulcer, heartburn, dyspepsia (indigestion) and acid reflux
BRU19042560P	Betacort Cream 0.1% w/w	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses e.g. psoriasis, eczemas, pruritus, contact dermatitis, neurodermatitis, lichen planus.
BRU19042561P	Cravit Ophthalmic Solution 0.5%	The following infections caused by levofloxacin-susceptible strains of Staphylococcus sp., Streptococcus sp., Streptococcus pneumoniae, Micrococcus sp., Enterococcus sp., Corynebacterium sp., Pseudomonas sp.,Pseudomonas aeruginosa, Haemophilus sp. (H. influenzae, H. aegyptius [Koch-Weeks bacillus]), Moraxella (Branhamella) catarrhalis, Moraxella sp. (Morax-Axenfeld bacillus), Serratia sp., Klebsiella sp., Proteus sp., Acinetobacter sp., Enterobacter sp., Propionibacterium acnes: Blepharitis, hordeolum, dacryocystitis, conjunctivitis, tarsadenitis, keratitis, corneal ulcer, and postoperative infections.
BRU19042563P	Apo-Amilzide Tablet	Fixed-dose combination drugs are not indicated for initial therapy. Patients should be titrated on the individual drugs. If the fixed combination represents the dosage so determined, its use may be more convenient in patient management. If during maintenance therapy dosage adjustment is necessary, it is advisable to use the individual drugs. APO-Amilzide (hydrochlorothiazide and amiloride hydrochloride) is indicated in the maintenance therapy of patients with hepatic cirrhosis with ascites and oedema. Patients with oedema of cardiac origin or with arterial hypertension who are hypokalaemic or in whom maintenance of normal potassium levels is considered to be clinically important, i.e. digitalized patients, patients in whom adequate dietary intake of potassium is not feasible or patients with cardiac arrhythmias. <u>Use in Hepatic Cirrhosis with Ascites and Oedema</u>: Amiloride hydrochloride used alone may provide satisfactory diuresis with diminished potassium loss and with a reduced risk of metabolic alkalosis. In resistant cases, amiloride hydrochloride may be used with kaliuretic diuretic agents to help produce satisfactory diuretics, while maintaining a more balanced serum electrolyte pattern. As with all therapy for the ascites of hepatic cirrhosis, gradual weight loss and avoidance of electrolyte imbalance are the chief objectives.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19042564P	Tenof-EM Tablet	Emtricitabine and Tenofovir disoproxil fumarate is indicated in combination with other antiretroviral agents (such as non-nucleoside reverse transcriptase inhibitors or protease inhibitors) for the treatment of HIV-1 infection in adults. The following points should be considered when initiating therapy with Emtricitabine and Tenofovir disoproxil fumarate for the treatment of HIV-1 infection: • It is not recommended that Emtricitabine and Tenofovir disoproxil fumarate be used as a component of a triple nucleoside regimen. • Emtricitabine and Tenofovir disoproxil fumarate should not be co-administered with lamivudine+tenofovir DF+Efavirenz, emtricitabine, tenofovir DF or lamivudine-containing products. In treatment experienced patients, the use of Emtricitabine and Tenofovir disoproxil fumarate should be guided by laboratory testing and treatment history.
BRU19042565P	Freederm Lotion	Once daily antifungal treatment for tinea and other fungal skin infections – athlete's foot (tinea pedis), jock itch (tinea curis), ringworm (tinea corporis), Pityriasis versicolor and fungal nail infection (cutaneous candidiasis).
BRU19042566NP	Yellow Lotion 0.4%	Antiseptic for the treatment of infected wounds, cuts, burns or for skin disinfection.
BRU19042569P	Lamitor 50mg Tablet	LAMITOR is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalized seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome.
BRU19042570P	Onsia Tablet 8mg	• For the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy; • For the prevention of post-operative nausea and vomiting. For treatment of established post-operative nausea and vomiting, administration by injection is recommended.
BRU19042571P	Tivicay™ 50mg Film-Coated Tablets	Tivicay is indicated in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age.
BRU19042573P	Ursa 250mg Capsule	1. Dissolution of cholesterol gallstones; stones must be radiolucent, and in spite of gallbladder stones, the gallbladder must be functioning 2. As adjuvant medication for dissolution of gallstone fragments in conjunction with shock-wave lithotripsy treatment of patients with gallbladder stones 3. Biliary reflux gastritis 4. Cholestatic liver diseases (eg. PBC)

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BRU19042574P: BRU19042574PS2	Spiriva Respimat 2.5mcg Solution For Inhalation	COPD Tiotropium is indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD). Asthma Spiriva Respimat is indicated as an add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year.
BRU19042575P	Lavudin Standard F.C. Tablet 100mg	Lamivudine is indicated for the treatment of patients ≥ 16 years of age with chronic hepatitis B and evidence of hepatitis B virus (HBV) replication with one or more of the following conditions: - Elevated serum alanine aminotransferase (ALT) ≥ 2 times normal - Liver cirrhosis - Decompensated liver disease - Biopsy-proven necro-inflammatory liver disease - Immunocompromised state - Liver transplant
BRU19042576P	Faslodex Solution For Injection 250mg/5ml	Faslodex is indicated: • as monotherapy for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women: - who are human epidermal growth factor receptor 2 (HER2)-negative and not previously treated with endocrine therapy.~~, or~~ - with disease relapse on or after adjuvant endocrine therapy, or disease progression on endocrine therapy. • in combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have received prior endocrine therapy. In pre- or perimenopausal women, the combination treatment with palbociclib should be combined with a luteinizing hormone releasing hormone (LHRH) agonist.
BRU19042577NP	Multibic Potassium-Free Solution For Haemodialysis/Haemofiltration (Solution, Sterile)	multiBic® potassium-free is a solution for haemofiltration (removal of waste products from the body in people with kidney disease). It is used in patients with acute kidney failure. The type of solution you are given depends on the amount of potassium (a salt) in your blood. Your doctor will check your potassium levels regularly.
BRU19052578P	Pregeb Capsules 75mg	Neuropathic Pain: Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy: Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised Anxiety Disorder: Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. Fibromyalgia: Pregabalin is indicated for the management of fibromyalgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19052579NP	Omnipaque 300mg I/mL, Solution For Injection/Infusion	This medicinal product is for diagnostic use only. X-ray contrast medium for use in adults and children for angiography, urography, myelography, CT-enhancement and studies of the gastrointestinal tract. In adults only, phlebography, lumbar, thoracic, cervical myelography and computed tomography of the basal cisterns, following subarachnoid injection. Arthrography, endoscopic retrograde pancreatography (ERP), endoscopic retrograde cholangiopancreatography (ERCP), herniography, hysterosalpingography, sialography.
BRU19052580NP	Omnipaque 350mg I/mL, Solution For Injection/Infusion	This medicinal product is for diagnostic use only. X-ray contrast medium for use in adults and children for angiography, urography, myelography, CT-enhancement and studies of the gastrointestinal tract. In adults only, phlebography, lumbar, thoracic, cervical myelography and computed tomography of the basal cisterns, following subarachnoid injection. Arthrography, endoscopic retrograde pancreatography (ERP), endoscopic retrograde cholangiopancreatography (ERCP), herniography, hysterosalpingography, sialography.
BRU19052581P	Streptin Injection 1g	Tuberculosis, Plaque and tularaemia, Bacterial endocarditis (only used in combination with penicillin G or ampicillin), Brucellosis (in conjunction with a tetracycline), Granuloma inguinale.
BRU19052582P	Aricept Evess 5mg Orodispersible Tablet	Aricept Evess tablets are indicated for the treatment of mild, moderate and severe dementia in Alzheimer's Disease.
BRU19052583P	Aricept Evess 10mg Orodispersible Tablet	Aricept Evess tablets are indicated for the treatment of mild, moderate and severe dementia in Alzheimer's Disease.
BRU19052584P	Yucomy Shampoo 2% w/w	Treatment and prophylaxis of infections in which the yeast Pityrosporum is involved, e.g. pityriasis versicolor (localized), seborrhoeic dermatitis and pityriaysis capitis (dandruff).
BRU19052585P	Mapin 0.4mg/ml Injection	Naloxone is indicated for the complete or partial reversal of narcotic depression including respiratory depression induced by opioids including natural and synthetic narcotics, propoxyphene, methadone and the narcotic-antagonist analgesics nalbuphine, pentazocine and butorphanol. Naloxone is also indicated for the diagnosis of suspected acute opioid overdosage.
BRU19052586P	Apo-Warfarin 1mg Tablet	APO-WARFARIN (warfarin sodium) is indicated for the prophylaxis and/or treatment of venous thrombosis and its extension, pulmonary embolism, atrial fibrillation with embolization, and as an adjunct in the prophylaxis of systemic embolism after myocardial infarction, including stroke, reinfarction and death. The following are some of the more common clinical disorders which may be associated with or predispose patients to the above indications: 1. Thrombophlebitis 2. Congestive heart failure 3. Surgical procedure or trauma associated with a high risk of thromboembolism. 4. Myocardial infarction 5. Cerebral embolism and treatment of transient cerebral ischemic attacks due to intravascular clotting

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19052587PS1; BRU19052587PS2	Medovir 400mg Tablet	MEDOVIR Tablets are indicated: For the treatment of herpes simplex virus infections of the skin and mucous membranes including initial and recurrent genital herpes. For the suppression (prevention of recurrences) of recurrent herpes simplex infections in immune-competent patients. For the prophylaxis of herpes simplex infections in immune-compromised patients. For the treatment of herpes zoster infections.
BRU19052588P	Bisloc 2.5	Indicated for the treatment of: • Hypertension • Stable chronic angina • Stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides
BRU19052589P	Derzid Cream	Betamethasone valerate is a potent topical corticosteroid indicated for adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These include the following: o Atopic dermatitis (including infantile atopic dermatitis) o Nummular dermatitis (discoid eczema) o Prurigo nodularis o Psoriasis (excluding widespread plaque psoriasis) o Lichen simplex chronicus (neurodermatitis) and lichen planus o Seborrhoeic dermatitis o Irritant or allergic contact dermatitis o Discoid lupus erythematosus o Adjunct to systemic steroid therapy in generalized erythroderma o Insect bite reactions
BRU19052590P	Pentasa® Prolonged Release Tablet 500mg	Treatment of mild to moderate ulcerative colitis and Crohn's disease.
BRU19052594P	SW Bromhexine Elixir	It is indicated in bronchitis and other respiratory conditions as an aid to expectoration.
BRU19052595P	Allersin Syrup 4mg/5ml	It is indicated in allergic conditions responsive to antihistamines.

BRU19052596P	Quetiapine Sandoz 100mg Tablets	• Treatment of schizophrenia. • Treatment of acute manic episodes associated with bipolar I disorder. • Treatment of moderate to severe depressive episodes associated with bipolar disorder. • Preventing recurrence in maintenance treatment of bipolar I disorder (manic, mixed or depressive episode) as monotherapy or in combination with lithium or valproate.
BRU19052597P	Cifloxin Infusion (2mg/ml)	Ciprofloxacin solution for infusion is indicated for the treatment of the following infections. Special attention should be paid to available information on resistance to ciprofloxacin before commencing therapy. Consideration should be given to official guidance on the appropriate use of antibacterial agents. Adults • Lower respiratory tract infections due to Gram-negative bacteria - exacerbations of chronic obstructive pulmonary disease - broncho-pulmonary infections in cystic fibrosis or in bronchiectasis - pneumonia • Chronic suppurative otitis media • Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria • Urinary tract infections • Genital tract infections - epididymo-orchitis including cases due to susceptible Neisseria gonorrhoeae - pelvic inflammatory disease including cases due to susceptible Neisseria gonorrhoeae • Infections of the gastrointestinal tract (e.g. travellers` diarrhoea) • Intra-abdominal infections • Infections of the skin and soft tissue caused by Gram-negative bacteria • Malignant external otitis • Infections of the bones and joints • Inhalation anthrax (post-exposure prophylaxis and curative treatment) Ciprofloxacin may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection. Children and adolescents • Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa • Complicated urinary tract infections and pyelonephritis • Inhalation anthrax (post-exposure prophylaxis and curative treatment) Ciprofloxacin may also be used to treat severe infections in children and adolescents when this is considered to be necessary. Treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents
BRU19052598NP	Tiger Balm Soft	For relief of minor headaches due to muscle tension, itchiness from insect bites, muscular aches and pains of joints, backaches, arthritis and rheumatism.
BRU19052599P	Vizomet Cream 0.1% w/w	Vizomet is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19052600P	Vizomet Ointment 0.1% w/w	Vizomet is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.
BRU19052601P	Eperon Film Coated Tablets 2mg	Eperon is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. Eperon alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. Eperon is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Risperidone is indicated for the short-term treatment of persistent aggression in patients with moderate to severe dementia of the Alzheimer's type unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. Eperon is indicated for the treatment of behavioural disorders associated with autism (eg irritability, social withdrawal, stereotypic behaviour, hyperactivity and inappropriate speech) in children and adolescents. Eperon is also indicated for bipolar mania. Adjunctive therapy: Eperon is indicated as adjunctive therapy to mood stabilizers in the treatment of manic episodes associated with bipolar disorders. These episodes are characterized by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviors. Monotherapy: Eperon is indicated in the treatment of acute manic episodes associated with bipolar 1 disorder. The effectiveness of Eperon for more than 12 weeks of treatment of an acute episode, and for the prevention of new manic episodes has not been established. Eperon is indicated in the treatment of conduct and other disruptive behavior disorders in children (over 5 years), adolescents and adults with subaverage intellectual functioning or mental retardation in whom destructive behaviors (e.g. aggression, impulsivity and self-injurious behaviors) are prominent.
BRU19052602P	Quetiapine Sandoz 25mg Tablets	• Treatment of schizophrenia. • Treatment of acute manic episodes associated with bipolar I disorder. • Treatment of moderate to severe depressive episodes associated with bipolar disorder. • Preventing recurrence in maintenance treatment of bipolar I disorder (manic, mixed or depressive episode) as monotherapy or in combination with lithium or valproate.
BRU19072603P	Vectibix Concentrate For Solution For Infusion 100mg/Vial	Vectibix is indicated for the treatment of adult patients with wild-type RAS metastatic colorectal cancer (mCRC): ♦In first-line in combination with FOLFOX or FOLFIRI. ♦In second-line in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan) ♦As monotherapy after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens

BRU19072604P	Simponi I.V. Concentrate For Solution For Infusion 12.5mg/1ml	*Rheumatoid arthritis (RA):* SIMPONI, by IV administration, in combination with MTX, is indicated for: • the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease modifying anti rheumatic drug (DMARD) therapy including MTX has been inadequate. SIMPONI, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X ray and to improve physical function. *Ankylosing spondylitis (AS):* SIMPONI® by IV administration is indicated for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to conventional therapies. *Psoriatic arthritis (PsA):* SIMPONI, by IV administration, alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate.
BRU19072607NP	Thelban Suspension	Antihelmintic, which exhibit vermicidal, ovicidal and larvacidal activity in the treatment of Roundworm (Ascaris lumbriocides), Whipworm (Trichuris trichura), Pinworm or Threadworm (Enterobius vermicualris), Hookworm (Ancylostoma duodenale and Nectar americanus). Strongyloides stercoralis, Taenia sodium, Taenia saginata and Opisthorchis viverrini.
BRU19072608NP	Xenetix 300 Solution For Injection	This medicinal product is for diagnostic use only. Contrast agent for use in: • Intravenous urography • Computed tomography • Intravenous digital subtraction angiography • Arteriography • Angiocardiography • Arthrography • Hysterosalpingography
BRU19072609NP	Xenetix 350 Solution For Injection	This medicinal product is for diagnostic use only. Contrast agent for use in: • Intravenous urography • Computed tomography • Intravenous digital subtraction angiography • Arteriography • Angiocardiography

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19072610P	Fycompa 2mg Film-Coated Tablets	Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. Fycompa is indicated for the adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy
BRU19072611P	Fycompa 4mg Film-Coated Tablets	Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. Fycompa is indicated for the adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy
BRU19072612P	Fycompa 8mg Film-Coated Tablets	Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. Fycompa is indicated for the adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy
BRU19072614P	Tacarline Injection 1mg/ml	It is used in the emergency treatment of anaphylactic shock due to reaction from insect bites and drugs and for symptomatic relief of serum sickness, urticarial, pruritus, angioneurotic, oedema, respiratory distress due to bronchospasm, and relief of hypersensitivity reactions to drugs and other allergens.
BRU19072615P	Ranexa Prolonged-Release Tablet 375mg	Ranexa is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta- blockers and/or calcium antagonists).
BRU19072616P	Ranexa Prolonged-Release Tablet 500mg	Ranexa is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta- blockers and/or calcium antagonists).
BRU19072617P	Ranexa Prolonged-Release Tablet 750mg	Ranexa is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta- blockers and/or calcium antagonists).
BRU19072618P	SotaHexal 80mg Tablet	Oral administration of sotalol is indicated for: • Ventricular arrhythmias: Prevention of recurrence of life-threatening ventricular tachyarrhythmias; treatment of symptomatic non-sustained ventricular tachyarrhythmias. • Supraventricular arrhythmias: Prophylaxis of paroxysmal atrial tachycardia, paroxysmal atrial fibrillation, paroxysmal A-V nodal re-entrant tachycardia, paroxysmal A-V re-entrant tachycardia using accessory pathways, and paroxysmal supraventricular tachycardia after surgery; maintenance of normal sinus rhythm following conversion of atrial fibrillation or atrial flutter.

BRU19072619P	Zafibral 200mg Tablets Film Coated	BEZAFIBRATE is indicated for use in hyperlipidaemias of type IIa, IIb, III, IV and V. (Fredrickson Classification) which are illustrated below: Type Major Lipid Elevation IIa Cholesterol IIb Cholesterol and Triglycerides III Cholesterol and Triglycerides IV Triglycerides V Triglycerides (possibly cholesterol) BEZAFIBRATE is therefore indicated for use only in patients with a fully defined and diagnosed abnormality where diet alone is insufficient to correct the condition and in whom the long-term risks associated with the condition warrant treatment. The rationale for the use of BEZAFIBRATE to control abnormal elevations of serum lipids and lipoproteins is to reduce or prevent the long-term adverse effects which have been shown by many major epidemiological studies to be positively and strongly correlated with such dyslipidaemias. The possible beneficial and adverse long-term consequences of some drugs used in the hyperlipidaemias are still the subject of scientific discussion, however, and there is currently no clinical evidence to demonstrate that BEZAFIBRATE is effective in the prevention of heart disease.
BRU19072620P	Apo-Azathioprine 50mg Tablets	Used as an immunosuppressant antimetabolite either alone or, more commonly, in combination with other agents (usually corticosteroids) and procedures which influence the immune response. Therapeutic effect may be evident only after weeks or months and can include a steroidsparing effect, thereby reducing the toxicity associated with high dosage and prolonged usage of corticosteroids. Apo-Azathioprine, in combination with corticosteroids and/or other immunosuppressive agents and procedures, is indicated to enhance the survival of organ transplants, such as renal transplants, cardiac transplants, and hepatic transplants; and to reduce the corticosteroid requirements of renal transplant recipients. Apo-Azathioprine, either alone or more usually in combination with corticosteroids and/or other drugs and procedures, has been used with clinical benefit (which may include reduction of dosage or discontinuation of corticosteroids) in a proportion of patients suffering from the following: severe rheumatoid arthritis; systemic lupus erythematosus; dermatomyositis and polymyositis; auto-immune chronic active hepatitis; pemphigus vulgaris; polyarteritis nodosa; auto-immune haemolytic anaemia; chronic refractory idiopathic thrombocytopenic purpura
BRU19072621P	Pergoveris Powder And Solvent For Solution For Injection	Pergoveris is indicated for the stimulation of follicular development in adult women with severe LH and FSH deficiency. In clinical trials, these patients were defined by an endogenous serum LH level < 1.2IU/L.

BRU19072622P	Trustiva Tablet	TRUSTIVA is indicated for the treatment of HIV-1 infection in adults.
BRU19072624P	Pemirex Injection 100mg	1) Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naive patients with unresectable malignant pleural mesothelioma. 2) Pemetrexed in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. 3) Pemetrexed is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. 4) Pemetrexed is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.
BRU19072625P	Pemirex Injection 500mg	1) Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naive patients with unresectable malignant pleural mesothelioma. 2) Pemetrexed in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. 3) Pemetrexed is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. 4) Pemetrexed is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.
BRU19072626P	Tapcom-S Ophthalmic Solution	Reduction of intraocular pressure (IOP) in adult patients with open angle glaucoma or ocular hypertension who are insufficiently responsive to topical monotherapy with beta-blockers or prostaglandin analogues and require a combination therapy, and who would benefit from preservative free eye drops.

BRU19072627P	Cyramza 100mg/10ml Concentrate For Solution For Infusion	<u>Gastric cancer</u> Cyramza in combination with paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy. Cyramza monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate. <u>Colorectal cancer</u> Cyramza, in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine. <u>Non-small cell lung cancer</u> Cyramza in combination with erlotinib is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer with activating epidermal growth factor receptor (EGFR) mutations. Cyramza in combination with docetaxel is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with disease progression after platinum-based chemotherapy. <u>Hepatocellular carcinoma</u> Cyramza monotherapy is indicated for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma who have a serum alpha fetoprotein (AFP) of ≥ 400ng/ml and who have been previously treated with sorafenib.

BRU19072628P	Cyramza 500mg/50ml Concentrate For Solution For Infusion	<u>Gastric cancer</u> Cyramza in combination with paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy. Cyramza monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate. <u>Colorectal cancer</u> Cyramza, in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine. <u>Non-small cell lung cancer</u> Cyramza in combination with erlotinib is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer with activating epidermal growth factor receptor (EGFR) mutations. Cyramza in combination with docetaxel is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with disease progression after platinum-based chemotherapy. <u>Hepatocellular carcinoma</u> Cyramza monotherapy is indicated for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma who have a serum alpha fetoprotein (AFP) of ≥ 400ng/ml and who have been previously treated with sorafenib.
BRU19072629P	Hydrocortisone Cream 1% w/w	Hydrocortisone is a mild corticosteroid indicated for irritant contact dermatitis, allergic contact dermatitis and insect bites. Irritant dermatitis, may be caused by common household products such as detergents, bleaches, washing powders and various chemicals found in the workplace. Allergic contact dermatitis is caused by sensitisation to allergens in materials such as cosmetics, resins, rubber, adhesive plaster and plants. It may also be helpful in treating napkin rash if used under medical supervision.
BRU19072630NP	Microshield 4 Chlorhexidine Surgical Handwash	●Antimicrobial handwashing ●Surgical handwashing ●Body washing
BRU19072632NP	Betadine Sore Throat Spray 0.45% w/v	Betadine® Sore Throat Spray is used for relief of throat chapping, throat pain, throat swelling, throat discomfort and hoarseness caused by inflammation of the throat. Kelegaan untuk tekak kering dan gatal, sakit tekak, bengkak tekak, ketidakselesaan tekak dan serak disebabkan oleh radang tekak.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19072633P	Fludarabine Sandoz 50mg/2ml Concentrate For Solution For Injection Or Infusion	Treatment of B-cell chronic lymphocytic leukemia (CLL) in patients with sufficient bone marrow reserves. First line treatment in patients with advanced disease, Rai stages III/IV (Binet stages C), or Rai stages I/II (Binet stages A/B) where the patient has disease-related symptoms or evidence of progressive disease.
BRU19072634P	Platol (Cisplatin Concentrate For Solution For Infusion 50mg/50ml)	Cisplatin may be used single or in combination with other chemotherapeutic agents in the treatment of: Metastatic non-seminomatous germ cell carcinoma Advanced stage, refractory ovarian carcinoma Advanced stage, refractory bladder carcinoma Refractory squamous cell carcinoma of the head and neck
BRU19072635P	Doxorubicin 2mg/ml Concentrate For Solution For Infusion	Breast cancer, sarcoma, small-cell carcinoma of the lung, Hodgkin disease or non-Hodgkin lymphoma, acute leukaemia, cancer of the thyroid, bladder, ovaries, Paediatric tumours, such as neuroblastoma. Doxorubicin is frequently used in combination chemotherapy regimens with other cytotoxic drugs.
BRU19072636P	Montelukast Sandoz 10mg Film-Coated Tablet	For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older. Montelukast is indicated in adults and pediatric patients 2 years of age and older for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis.
BRU19072637P	Lakan Injection 1% (10ml Vial)	For local anaesthesia, peripheral nerve block, infiltration anaesthesia and diagnostic or therapeutic block.
BRU19072638P	Lakan Injection 2% (10ml Vial)	For local anaesthesia, peripheral nerve block, infiltration anaesthesia and diagnostic or therapeutic block.
BRU19072639P	Zosaar 50mg Tablets	1.Hypertension Zosaar is indicated for the treatment of hypertension. 2.Reduction in the risk of cardiovascular morbidity and mortality in hypertensive patients with left ventricular hypertrophy Indicated to reduce the risk of cardiovascular morbidity and mortality as measured by the combined incidence of cardiovascular death, stroke and myocardial infarction in hypertension patients with left ventricular hypertrophy. 3.Renal protection in Type 2 Diabetic patients with proteinuria Indicated to delay the progression of renal disease as measured by a reduction in the combined incidence of doubling of serum creatinine, end stage renal disease (need for dialysis or renal transplantation) or death and to reduce proteinuria.

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BRU19072640P; BRU19072640PS2	Converium 150mg Tablet	Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.
BRU19072642P	Clozole Cream 1%	Candidiasis, cutaneous (treatment) – Cutaneous candidiasis caused by Canadida albicans. Tinea corporis, Tinea cruris, Tinea pedis, Tinea versicolor.
BRU19072643NP	Thelban Tablet	Antihelmintic which exhibits vermicidal, ovicidal and larvicidal activityin the treatment of Roundworm (Ascaris lumbricoides), Whipworm (Trichuris trichura), Pinworm or Threadworm (Enterobius vermicularis), Hookworm (Ancylostoma duodenale and Nector americanus), Strongyloides stercoralis, Taenia solium, Taenia saginata and Opisthorchis viverrini.
BRU19072644P	Ribomustin 25mg/Vial Powder For Concentrate For Solution For Infusion	Ribomustin is indicated for monotherapy in patients with chronic lymphocytic leukaemia. Efficacy relative to first line therapies other than chlorambucil has not been established. Ribomustin is indicated for monotherapy in patients with indolent B-cell non-Hodgkin's lymphomas that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
BRU19072645P	Ribomustin 100mg/Vial Powder For Concentrate For Solution For Infusion	Ribomustin is indicated for monotherapy in patients with chronic lymphocytic leukaemia. Efficacy relative to first line therapies other than chlorambucil has not been established. Ribomustin is indicated for monotherapy in patients with indolent B-cell non-Hodgkin's lymphomas that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
BRU19072646P	Rydapt® 25mg Soft Capsules	Rydapt is indicated: ♦in combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for patients in complete response followed by Rydapt single agent maintenance therapy, for adult patients with newly diagnosed acute myeloid leukaemia (AML) who are FLT3 mutation-positive (see section Posology and method of administration); as monotherapy for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated haematological neoplasm (SM-AHN), or mast cell leukaemia (MCL).

BRU19072647P	Tecentriq Concentrate For Solution For Infusion 1200mg/20ml	**Non-small cell lung cancer** Tecentriq, in combination with Avastin, paclitaxel and carboplatin, is indicated for the treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) who had not received prior chemotherapy. Tecentriq as monotherapy is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have disease progression on approved therapy for these aberrations prior to receiving Tecentriq. Tecentriq, in combination with nab-paclitaxel and carboplatin, is indicated for first-line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumor aberrations. Tecentriq as monotherapy is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have a PD-L1 expression ≥ 50% tumor cells (TC) or ≥ 10% tumor-infiltrating immune cells (IC) and who do not have EGFR or ALK genomic tumor aberrations. **Small cell lung cancer** Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ESSCLC). **Triple-negative breast cancer** Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors have PD-L1 expression of ≥1% on IC, and who have not received prior chemotherapy for metastatic disease. **Hepatocellular carcinoma** Tecentriq, in combination with Avastin, is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.
BRU19072648NP	Tiger Balm Plaster - RD	Muscular pain, stiff neck and shoulders, contusion, sprain, backache and arthritic pain.
BRU19072649P	Carvedilol Sandoz 6.25mg	- Essential hypertension - Chronic stable angina pectoris - Adjunctive treatment of symptomatic chronic heart failure
BRU19072650P	Carvedilol Sandoz 25mg	- Essential hypertension - Chronic stable angina pectoris - Adjunctive treatment of symptomatic chronic heart failure
BRU19072651P	Betacylic Ointment	Relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses e.g., psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19072652NP	Woods Peppermint Cough Syrup	Woods' peppermint cough syrup provides relief of wet, productive cough. It helps loosen phlegm and thins bronchial secretions to rid bronchial passageways of bothersome mucus and makes coughs more productive.
BRU19072653P	Gabapentin Sandoz Capsules 300mg	<u>Epilepsy</u> Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above. <u>Treatment of peripheral neuropathic pain</u> Gabapentin is indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults. Safety and effectiveness in patients below the age of 18 years have not been established.
BRU19072654P	Aremed 1mg Tablet	Aremed is indicated for the treatment of hormone receptor-positive advanced breast cancer in postmenopausal women
BRU19072655P	Uniflex Cream 0.1% w/w	For the relief of the inflammatory manifestations of corticosteroid - responsive dermatoses such as in eczema, infantile eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, seborrhoeic dermatitis, neurodermatitis, some form of psoriasis and intertrigo.
BRU19072656P	Finil 8 Tablet	Indicated in the: Candesartan Cilexetil is indicated for the: -Treatment of essential hypertension in adults. -Treatment of hypertension in children and adolescents aged 6 to < 18 years. Treatment of adult patients with heart failure and impaired left ventricular systolic function (left ventricular ejection fraction ≤ 40%) when Angiotensin Converting Enzyme (ACE)-inhibitors are not tolerated or as add-on therapy to ACE-inhibitors in patients with symptomatic heart failure, despite optimal therapy, when mineralocorticoid receptor antagonists are not tolerated.
BRU19072657NP	Shine Cutie Chewable Tablet	As a dietary and nutritional supplement for children.
BRU19082658P	Motidone Tablet 10mg	Domperidone is indicated for the relief of the symptoms of nausea and vomiting. This includes: ♦Nausea and vomiting of functional, organic, infectious or dietary origin. ♦Nausea and vomiting induced by: -Radiotherapy or drug therapy. -Dopamine agonists (such as L-dopa and bromocriptine) used in the treatment of Parkinson's disease.
BRU19082659P	Hovid Alendronate 70mg Tablet	Hovid Alendronate Tablet 70 mg is indicated in adults for the treatment of postmenopausal osteoporosis. It reduces the risk of vertebral and hip fractures.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19082660P	Zobid Injection 3ml	Initial treatment of the following: Acute, severe pain caused by inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, spondylarthiritis Painful syndromes of the vertebral column. non-articular rheumatism, acute attacks of gout, renal colic and biliary colic. painful post- traumatic and post-operative inflammation and swelling.
BRU19082661P	Ceftriaxone-AFT Powder For Injection 500mg	Infections caused by pathogens sensitive to Ceftriaxone e.g. ♦Sepsis ♦Meningitis ♦Abdominal infections (peritonitis, infections of the biliary and gastrointestinal tracts) ♦Infections of the bones, joints, soft tissue, skin and of wounds ♦Infections in patients with impaired defence mechanisms ♦Renal and urinary tract infections ♦Respiratory tract infections, particularly pneumonia, and ear, nose and throat infections ♦Genital infections, including gonorrhoea Perioperative prophylaxis of infections
BRU19082662NP	Biphozyl Solution For Haemodialysis/Haemofiltration	Biphozyl solution is used as replacement solution and as dialysate for treatment of acute kidney injury during continuous renal replacement therapy (CRRT). Biphozyl solution is used in a post-acute phase after initiation of renal replacement therapy when pH, potassium and phosphate concentration have returned to normal. Biphozyl solution is also used when other buffer sources are available as well as during regional citrate anticoagulation. Moreover, Biphozyl solution is used in patients with hypercalcaemia. Biphozyl solution may also be used in cases of drug poisoning or intoxications when the substances are dialysable or filterable.
BRU19082663P	Exjade 90mg Film-Coated Tablet	Exjade film-coated tablet is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and pediatric patients (aged 2 years and over). Exjade film-coated tablets is also indicated for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes aged 10 years and over.
BRU19082665P	Exjade 360mg Film-Coated Tablet	Exjade film-coated tablet is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and pediatric patients (aged 2 years and over). Exjade film-coated tablets is also indicated for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes aged 10 years and over.

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BRU19082668P	Ondansetron-AFT Solution For Injection 2mg/ml	Adults: Ondansetron-AFT is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. Ondansetron-AFT is indicated for the prevention and treatment of post-operative nausea and vomiting (PONV). Paediatric Population: Ondansetron-AFT is indicated for the management of chemotherapy-induced nausea and vomiting (CINV) in children, and for the prevention and treatment of PONV in children.
BRU19082669P	Minirin Tablet 0.1mg	Central diabetes insipidus. The use of MINIRIN® in patients with an established diagnosis will result in a reduction in urinary output with concomitant increase in urine osmolality and decrease in plasma osmolality. This will result in decreased urinary frequency and decreased nocturia. Primary nocturnal enuresis in children aged 5 years or more. Symptomatic treatment of nocturia in adults, associated with nocturnal polyuria, i.e. nocturnal urine production exceeding bladder capacity.
BRU19082670P	Minirin Tablet 0.2mg	Central diabetes insipidus. The use of MINIRIN® in patients with an established diagnosis will result in a reduction in urinary output with concomitant increase in urine osmolality and decrease in plasma osmolality. This will result in decreased urinary frequency and decreased nocturia. Primary nocturnal enuresis in children aged 5 years or more. Symptomatic treatment of nocturia in adults, associated with nocturnal polyuria, i.e. nocturnal urine production exceeding bladder capacity.
BRU19082671NP	Dermoplex Antiseptic Cream	A topical antibacterial cream which helps prevent infections and assists in the healing of minor cuts and burns, nappy rashes, blisters, sunburn, insect bites and stings.
BRU19082672NP	Dias Glucosamine 500mg Capsule	Glucosamine supplementation.

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BRU19082673P	Atoris Film-Coated Tablet 40mg	Hypercholesterolemia Atoris is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atoris is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. Prevention of cardiovascular disease Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
BRU19082674P	Avorax Cream 5% w/w	Avorax Cream is indicated in the treatment of herpes simplex infections of the skin, including initial and recurrent labial and genital herpes simplex infections.
BRU19082675P	Letram OS (Levetiracetam Oral Solution 100mg/ml)	LEVETIRACETAM is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in patients from 16 years of age with newly diagnosed epilepsy. LEVETIRACETAM is indicated as adjunctive therapy: ♦In the treatment of partial onset seizures with or without secondary generalization in adults and children from4 years of age with epilepsy. ♦In the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. ♦In the treatment of primary generalized tonic-clonic seizures in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.
BRU19082676NP	Unilac Lactulose 3.35g/5ml Oral Solution USP	For constipation and the treatment of hepatic encephalopathy.
BRU19082677NP	Senna 7.5mg Tablet	Senna is indicated for the treatment of occasional constipation.

BRU19092678P	Flurocort Injection 40mg/ml	Where oral therapy is not feasible or is temporarily undesirable in the judgment of the physician, flurocort is indicated **for Intramuscular use as follows:** Endocrine disorder: Nonsuppurative thyroiditis Rheumatic disorder: As adjunctive therapy for short term administration (to tide the patient over an acute episode of exacerbation) in post-traumatic osteoarthritis; synovitis of osteoarthritis; rheumatoid arthritis; acute and subacute bursitis; epicondylitis; acute non-specific tenosynovitis; acute gouty arthritis, psoriatic arthritis; ankylosing spondylitis; juvenile rheumatoid arthritis. Collagen Diseases: During an exacerbation as maintenance therapy in selected cases of systemic lupus erythematosus: acute rheumatic carditis. Dermatologic Disease: Pemphigus, severe erythema multiforme (Steven-Johnson Syndrome), exfoliative dermatitis, bullous dermatitis herpetiformis, severe seborrheic dermatitis; severe psoriasis. Allergic states: Control of severe or incapacitating allergic condition intractable to adequate trials of conventional treatment in bronchial asthma; contact dermatitis; atopic dermatitis, seasonal or perennial allergic rhinitis. Ophthalmic Diseases: Severe chronic allergic and inflammatory process involving the eye, e.g herpes zoster ophthalmicus, iritis, indocyclitis, chorioretinitis; diffuse posterior uvertis and choroditis; optic neuritis; sympathetic ophthalmia; anterior segment inflammation. Gastrointestinal diseases: to tide to patient over a critical period of disease in ulcerative colitis (systemic therapy), regional anteritis (systemic therapy). Respiratory Diseases: Symptomatic sarcoidosis; berylliosis; aspiration pneumonitis. Hemolytic Disorders: Acquired (autoimmune) haemolytic anaemia. Neoplastic Diseases: For palliative management of leukaemia and lymphomas in adults and acute leukaemia of childhood. Edematous State: To include diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus. **Intra-Articular:** Flurocort IM is indicated for intra-articular administration and for injections into tendon sheaths, as adjunctive therapy for short-term administration (to tide the patient over an acute episodes or exacerbation) in synovitis of osteoarthritis, rheumatoid arthritis, acute and sub acute bursitis; acute gouty arthritis; epicondylitis, acute non specific tenosynovitis, post-traumatic osteoarthritis.
BRU19092679PS1; BRU19092679PS2	Imbruvica 140mg Capsule	IMBRUVICA as a single agent is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). IMBRUVICA as a single agent or in combination with rituximab or obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lympocytic leukaemia (CLL). IMBRUVICA as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. IMBRUVICA in combination with rituximab is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM). IMBRUVICA is indicated for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.
BRU19092680NP	Vitabiotics Pregnacare Plus Omega-3 Tablet/Capsule	For the prevention and correction of vitamin and mineral deficiency states.

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BRU19092681P	Flexin 20mg Capsule	Depression: Treatment of symptoms of depressive illness, with or without associated anxiety symptoms. Obsessive-compulsive disorder. Treatment of premenstrual dysphoric disorder (PMDD).
BRU19092685P	Curam 1000mg + 200mg Powder For Intravenous Solution	Curam 1000mg + 200mg of Powder for intravenous solution may be administered for the short-term treatment of primarily serious infections due to micro-organisms that are resistant to amoxicillin and other B-lactam antibiotics as a result of the formation of a clavulanic acid-susceptible β-lactamase, such as: • Upper respiratory tract infections (including ENT) e.g. recurrent tonsillitis, sinusitis, otitis media. • Lower respiratory tract infections e.g. acute exacerbation of chronic bronchitis, lobar and bronchopneumonia. • Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis. • Skin and soft tissue infections e.g. boils, abscesses, cellulites, wound infections. • Bone and joint infections e.g. osteomyelitis. • Other infections e.g. intra-abdominal sepsis. Curam 1000mg + 200mg Powder for intravenous solution can be used for prophylaxis against infections in major surgery such as gastrointestinal, pelvic, head and neck, cardiac, renal, joint replacement and biliary tract.
BRU19092687PS1; BRU19092687PS2; BRU19092687PS3	Insulatard Penfill 100IU/ml Suspension For Injection In Cartridge	To treat diabetes mellitus.
BRU19092688P	Maviret Film-Coated Tablets	Maviret is indicated for the treatment of adults and adolescents 12 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection.
BRU19092689P	Gemcitabine Sandoz Concentrate For Solution For Infusion 40mg/ml	<u>Non-small Cell Lung Cancer (NSCLC)</u> Gemcitabine, in combination with cisplatin, is indicated as first line treatment of patients with locally advanced (inoperable stage IIIA or IIIB) or metastatic (stage IV) non-small cell lung cancer (NSCLC). Gemcitabine is indicated for the palliative treatment of adult patients with locally advanced or metastatic NSCLC. <u>Pancreatic Cancer</u> Gemcitabine is indicated for the treatment of adult patients with locally advanced or metastatic adenocarcinoma of the pancreas. Gemcitabine is indicated for patients with 5-FU refractory pancreatic cancer. <u>Bladder Cancer</u> Gemcitabine is indicated for the treatment of advanced bladder cancer (muscle invasive Stage IV tumours with or without metastases) in combination with cisplatin therapy. <u>Breast Cancer</u> Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.

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BRU19092690NP	Flexijoint 3-in-1 Joint Care Powder	As adjuvant therapy for osteoarthritis.
BRU19092691P	Rexom Bromhexine Elixir 4mg/5ml	Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport.
BRU19092692P	Akynzeo (Netupitant/Palonosetron) 300mg/0.5mg Hard Capsules	Akynzeo (netupitant/ palonosetron) in combination with dexamethasone, is indicated for once-per-cycletreatment in adult patients for: - Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cancer chemotherapy. - Prevention of acute nausea and vomiting associated with moderately emetogenic cancer therapy that is uncontrolled by a 5-HT_3 receptor antagonist alone.
BRU19092693P	Aslene Capsule 120mg	Aslene is indicated in conjunction with a mildly hypocaloric diet for the treatment of obese patients with a body mass index (BMI) greater or equal to 30 kg/m^2, or overweight patients (BMI ≥ 28 kg/m^2) with risk factors associated with obesity. Aslene is effective in weight loss, weight maintenance and prevention of weight regains. Treatment with Aslene results in an improvement of risk factors and comorbidities associated with obesity, including hypercholesterolemia, noninsulin dependent diabetes mellitus (NIDDM), impaired glucose tolerance, hyperinsulinemia, hypertension and in a reduction of visceral fat. The use of Aslene in type 2 diabetic patients who are overweight (BMI ≥ 28 kg/m^2) or obese (BMI ≥ 30 kg/m^2), in conjunction with a mildly hypocaloric diet, provides additional glycemic control when used in combination with antidiabetic agents such as metformin, sulfonylurea and/or insulin. Treatment with Aslene should only be started if diet alone has previously produced a weight loss of at least 2.5kg over a period of 4 consecutive weeks. Treatment with Aslene should be discontinued after 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of therapy.
BRU19092694P	Lentronat (Letrozole Tablets USP, 2.5mg)	Letrozole is not indicated in hormone receptor negative disease. Letrozole is indicated in: • Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer. • Extended adjuvant treatment of invasive early breast cancer in post menopausal women who have received prior standard adjuvant tamoxifen therapy for five years. • First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer. • Treatment of advanced breast cancer after relapse or disease progression, in women with natural or artificially induced postmenopausal endocrine status, who have previously been treated with anti-oestrogens.

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BRU19092695P	Viagra 25mg Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil to be effective, sexual stimulation is required.
BRU19092696P	Vencid Enteric-Coated Tablet 40mg	• Moderate and severe cases of inflammation of the oesophagus (gastro-oesophageal reflux disease). • Duodenal and gastric ulcer. • Eradication of *Helicobacter pylori (H.pylori)* in combination with two appropriate antibiotics in patients with peptic ulcers with the objective of reducing the recurrence of duodenal and gastric ulcers caused by this microorganism. • Zollinger-Ellison Syndrome and other pathological hypersecretory conditions.
BRU19092697P	Breathnine Syrup 2mg/5ml	- Relief of bronchial asthma - Chronic bronchitis - Emphysema - Acute dyspnea
BRU19112699P	Beathorphan Tablets 15mg	Used for the relief of unproductive cough.
BRU19112701P	Taflotan®-S Ophthalmic Solution 0.0015%	Reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension.
BRU19112702P	Lartil Injection 12.5mg/ml (1ml Amp)	Nausea and vomiting due to various causes including migraine; vertigo due to Meniere's syndrome, labyrinthitis and other causes; minor mental and emotional disturbances.
BRU19112703NP	Phebra Calcium Chloride Dihydrate 10% 1g/10mL	Parenteral administration of calcium is indicated in the treatment of hypocalcaemia where a rapid increase in plasma calcium is required, such as in hypocalcaemic tetany and tetany due to parathyroid deficiency. Intravenous calcium is also indicated to antagonize the cardiotoxicity of hyperkalaemia.
BRU19112704PS1; BRU19112704PS2; BRU19112704PS3	Actrapid Penfill 100IU/ml, 3ml Cartridge Solution For Injection	Treatment of diabetes mellitus.

BRU19112705P	Uptravi 200mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112706P	Uptravi 400mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112707P	Uptravi 600mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112708P	Uptravi 800mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112709P	Uptravi 1000mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.

BRU19112710P	Uptravi 1200mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112711P	Uptravi 1400mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112712P	Uptravi 1600mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112713NP	Tiger Balm Plus Ointment	For relief of minor aches and pains of muscle and joints associated with simple backaches, arthritis pains, rheumatic pains sciatica and sprains.
BRU19112714NP	Tiger Balm Plaster	Muscular pain, stiff neck and shoulders, contusion, sprain, backache and arthritic pain.
BRU19112715NP	Microshield® Handrub	For rapid hand antisepsis. For skin antisepsis.
BRU19112716P; BRU19112716PS2	Glyxambi Film-Coated Tablet 10mg/5mg	GLYXAMBI is indicated to improve glycaemic control in adults with type 2 diabetes mellitus: ♦Instead of empagliflozin, when diet, exercise and treatment with empagliflozin ± metformin do not provide adequate glycaemic control ♦Instead of linagliptin, when diet, exercise and treatment with linagliptin ± metformin do not provide adequate glycaemic control GLYXAMBI can be used to replace the free combination of empagliflozin and linagliptin in adult patients with type 2 diabetes mellitus who are already being treated with this combination.

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BRU19112717P; BRU19112717PS2	Glyxambi Film-Coated Tablet 25mg/5mg	GLYXAMBI is indicated to improve glycaemic control in adults with type 2 diabetes mellitus: ♦Instead of empagliflozin, when diet, exercise and treatment with empagliflozin ± metformin do not provide adequate glycaemic control ♦Instead of linagliptin, when diet, exercise and treatment with linagliptin ± metformin do not provide adequate glycaemic control GLYXAMBI can be used to replace the free combination of empagliflozin and linagliptin in adult patients with type 2 diabetes mellitus who are already being treated with this combination.
BRU19112718NP	Shine Multivitamin and Mineral Capsule	Used as a health supplement.
BRU19112719P	Melicron Tablet 80mg	Melicron is indicated for the treatment of non-insulin-dependent Diabetes Mellitus. It is used to supplement treatment by dietary modification when such modification has proved insufficient.
BRU19112721NP	Tiger Balm Active Muscle Rub	Tiger Balm Active Muscle Rub is a specially formulated non-greasy cream. It provides temporary relief of aches and pains from sore muscles, sprains and strains for active people.
BRU19112722NP	Tiger Balm Active Muscle Gel	Tiger Balm Active Muscle Gel provides temporary pain relief from minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, and sprains.
BRU19112723P	Loraten Tablet 10mg	Indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. It is also indicated for relief of symptoms and signs of chronic urticarial and other allergic dermatologic disorders.
BRU19112724P	Irinotecan Hydrochloride 20mg/ml Concentrate For Solution For Infusion	Irinotecan is indicated for the treatment of patients with advanced colorectal cancer: ♦in combination with 5-fluorouracil and folinic acid in patients without prior chemotherapy for advanced disease, ♦as a single agent in patients who have failed an established 5-fluorouracil containing treatment regimen. Irinotecan in combination with cetuximab it is indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer, who had not received prior treatment for metastatic disease or after failure of irinotecan-including cytotoxic therapy. Irinotecan in combination with 5-fluorouracil, folinic acid and bevacizumab is indicated for first-line treatment of patients with metastatic carcinoma of the colon or rectum. Irinotecan in combination with capecitabine with or without bevacizumab it is indicated for first-line treatment of patients with metastatic colorectal carcinoma.

BRU19112725P	Torleva 500mg Tablet	TORLEVA is indicated as monotherapy in the treatment of partial seizure with or without secondary generalization in patients from 16 years of age with newly diagnosed epilepsy. TORLEVA is indicated as adjunctive therapy: ♦In the treatment of partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy ♦In the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy (JME) ♦In the treatment of primary generalized tonic-clonic seizures (PGTCS) in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.
BRU19112726P	Torleva 250mg Tablet	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in patients from 16 years newly diagnosed with epilepsy. Levetiracetam is indicated as adjunctive therapy ♦In the treatment of partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy ♦In the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy ♦In the treatment of primary generalized tonic-clonic seizures in adults and children from 12 years of age with Idiopathic Generalised Epilepsy.
BRU19112727P	Torleva 1000mg Tablet	TORLEVA is indicated as monotherapy in the treatment of partial seizure with or without secondary generalization in patients from 16 years of age with newly diagnosed epilepsy. TORLEVA is indicated as adjunctive therapy: ♦In the treatment of partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy ♦In the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy (JME) ♦In the treatment of primary generalized tonic-clonic seizures (PGTCS) in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.
BRU19112728P	Piperacillin/Tazobactam Sandoz Powder For Solution For Injection/Infusion 4.5g Vials	Piperacillin/Tazobactam is indicated for the treatment of the following systemic and/or local infections in which susceptible pathogens have been detected or are suspected: *Adults* In threatening situations therapy with Piperacillin/Tazobactam can be initiated, even before an antibiogram is available. In the case of treatment of neutropenic patients, Piperacillin/Tazobactam in the usual dose should be combined with an aminoglycoside. Lower respiratory tract infections; urinary tract infections (complicated and uncomplicated); intra-abdominal infections; skin and skin structure infections; bacterial septicaemia. *Children under 12 years of age* Piperacillin/Tazobactam is indicated for hospitalised children for the treatment of intra-abdominal infections and biliary infections. The efficacy and safety for children under 2 years old with these indications has not been investigated. Official recommendations on the appropriate use of antibiotics must be observed, in particular administration recommendations on the prevention of the increase in resistance to antibiotics.

BRU19112729P	Nexpro Tablet 40mg	Esomeprazole is indicated for the treatment of: Gastro-Oesophageal Reflux Disease (GERD) ♦Treatment of erosive reflux oesophagitis ♦Long-term management of patients with healed oesophagitis to prevent relapse ♦Symptomatic treatment of gastro-oesophageal reflux disease (GERD) In combination with an appropriate antibacterial therapeutic regimen for the eradication of Helicobacter pylori and ♦Healing of Helicobacter pylori associated with duodenal ulcer ♦Prevention of relapse of peptic ulcers in patients with Helicobacter pylori associated ulcers Patients requiring continued NSAID therapy ♦Healing of gastric ulcers associated with NSAID therapy ♦Prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk Prolonged treatment after IV induced prevention of rebleeding of peptic ulcers Treatment of Zollinger Ellison Syndrome
BRU19112731P	Xigduo XR (Dapagliflozin/Metformin HCl Extended-Release) Tablets 10mg/500mg	<u>Glycaemic control</u> Xigduo XR is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise, to improve glycaemic control when treatment with both dapagliflozin and metformin is appropriate. <u>Reduction in risk of hospitalization for heart failure</u> Dapagliflozin is indicated to reduce the risk of hospitalization for heart failure in adults with typ 2 diabetes mellitus and establishsed cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.
BRU19112732P	Xigduo XR (Dapagliflozin/Metformin HCl Extended-Release) Tablets 10mg/1000mg	<u>Glycaemic control</u> Xigduo XR is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise, to improve glycaemic control when treatment with both dapagliflozin and metformin is appropriate. <u>Reduction in risk of hospitalization for heart failure</u> Dapagliflozin is indicated to reduce the risk of hospitalization for heart failure in adults with typ 2 diabetes mellitus and establishsed cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.

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BRU19112733P	Onsia Injection	Adults: ♦Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy ♦Prevention and treatment of post-operative nausea and vomiting (PONV). Paediatric Population: Injection & Oral formulations: Management of chemotherapy-induced nausea and vomiting (CINV). No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of PONV; IV injection is recommended for this purpose.
BRU19112734P	Retorin Powder For Suspension 200mg/5ml	Genitourinary tract infections, Pneumonia, Diphteria, Erythrasma, Gonorrhoea, Legionnaires disease, Listeria infections, Pertussis, Pharyngitis, Respiratory tract infections – upper and lower, Rheumatic fever (prophylaxis) skin and soft tissue infections, and Syphilis.
BRU19112735P	Anastrozole Sandoz Film Coated Tablet 1mg	Treatment of hormone receptor-positive advanced breast cancer in postmenopausal women.
BRU19112736NP	Betadine Vaginal Gel 10% w/w With Applicator	a) Disinfection of the vagina before and after operations. b) In acute and chronic vaginal infections (vaginitis, vulvo-vaginitis): - Mixed infections and unspecific infections (bacterial vaginosis; Gardnerella vag.) - Fungal infections (Candida albicans) - Trichomonal infections. c) After antibiotic or steroid therapy in case of complications.
BRU19112737P	Elonza-50 Tablet	Indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.
BRU19112738P	Zenpro Capsule 20mg	Zenpro Capsule is indicated for: • Treatment of duodenal and benign gastric ulcers • Eradication of Helicobacter pylori in peptic ulcer disease • Treatment of reflux oesophagitis and symptomatic treatment of heartburn and regurgitation in gastro-oesophageal reflux disease (GORD) • Treatment of Pathological Hypersecretory Conditions (Zollinger-Ellison syndrome) • Prophylactic treatment in patients with an increased risk of NSAIDs associated peptic ulcer, gastro-duodenal erosion or dyspeptic symptoms • Treatment of NSAIDs induced peptic and gastro-duodenal erosion
BRU19112739P	Creobic Gold Cream 1% w/w	Treatment of topical fungal infections caused by dermatophytes such as *Epidermophyton floccosum, Microsporum canis, and Trichophyton* (e.g. T.rubrum, T.mentagrophytes, T.verrucosum, T.violaceum); yeast infections of the skin; pityriasis versicolor due to *Malassezia furfur* or *Pityrosporum orbiculare;* and cutaneous candidiasis.

BRU19122740P; BRU19122740PS2	Olvion 50mg Film-Coated Tablet	Treatment of men with erectile dysfunction, which is the inability to achieve or maintain penile erection sufficient for satisfactory sexual performance. In order for Olvion to be effective, sexual stimulation is required.
BRU19122741P	SKYCellflu Quadrivalent Pre-Filled Syringe	Active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine, for adults and children 3 years of age and older.
BRU19122742NP	Biotase Chewable Tablet	As an adjuvant in the treatment of indigestion as well as digestive disorder manifested by bloating, belching, flatulence, abdominal discomfort or feeling of fullness.
BRU19122745NP	Phoxilium 1.2 mmol/l Phosphate Solution For Haemodialysis/Haemofiltration	Phoxilium solution is used for CRRT (Continuous Renal Replacement Therapy) in critically ill patients with ARF (Acute Renal Failure) when pH and kalaemia have been restored to normal and when the patients need phosphate supplementation for loss of phosphate in the ultrafiltrate or to the dialysate during CRRT. Phoxilium may also be used in cases of drug poisoning or intoxications when the poisons ate dialyzable or pass through the membrane. Phoxilium solution is indicated for use in patients with normal kalaemia and normal or hypophosphataemia.
BRU19122746PS1; BRU19122746PS2	Bisohexal Tablet 5mg	Treatment of hypertension as well as treatment of coronary heart disease (angina pectoris). Treatment of stable chronic, moderate to severe heart failure with reduced systolic ventricular function (ejection fraction ≤ 35%, based on echocardiography) in addition to ACE inhibitors and diuretics, and optionally cardiac glycosides.
BRU19122747P	Azamun 50mg Tablet	**AZAMUN** is used as an immunosuppressant anti-metabolite either alone, or more commonly in combination with other agents (usually corticosteroids) and procedures that influence the immune response. The therapeutic effect of **AZAMUN** may be evident only after weeks or months and can include a steroid-sparing effect, thereby reducing the toxicity associated with high dosage and the prolonged use of corticosteroids. **AZAMUN**, in combination with corticosteroids and/or other immune-suppressive agents and procedures is indicated to enhance the survival or organ transplants, such as renal, cardiac and hepatic transplants; and to reduce the corticosteroid requirements of renal transplant recipients. **AZAMUN**, either alone or in combination with corticosteroids and/or other medicines and procedures has been used with clinical benefit (which may result in a dose reduction to/or the discontinuation of corticosteroid therapy) in a proportion of patients suffering from: severe rheumatoid arthritis; systemic lupus erythematosus; dermatomyositis and polymyositis; auto-immune chronic active hepatitis; pemphigus vulgaris; polyarteritis nodosa; auto-immune haemolytic anaemia and chronic refractory idiopathic thrombocytopenic purpura.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU19122748P	Candesartan Sandoz Tablet 16mg	Candesartan Sandoz Tablets 8mg and 16mg Tablets are indicated for the: - Treatment of essential hypertension in adults - The treatment of adult patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction ≤ 40%) as add-on therapy to Angiotensin Converting Enzyme (ACE) inhibitors or when ACE-inhibitors are not tolerated.
BRU19122749P	Concor AM 5mg / 10mg Tablet	Concor AM is indicated for the treatment of hypertension as substitution therapy in patients adequately controlled with the individual products given concurrently at the same doses level as in the combination, but as separate tablets.
BRU19122750P	Pregabalin Sandoz 75mg Capsules	• Neuropathic Pain: Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. • Epilepsy: As adjunctive therapy in adults with partial seizures with or without secondary generalization. • Generalised Anxiety Disorder: Treatment of Generalised Anxiety (GAD) in adults. • Fibromyalgia: Management of fibromyalgia.
BRU19122751P	Gentamicin-POS Eye Drops	Gentamicin-POS is indicated in infections of the anterior eye including conjunctivitis, keratitis, blepharitis, and hordeolum, caused by gentamicin-sensitive pathogens.
BRU19122753NP	Actimol Menstrual Tablet	For symptomatic relief of bloating, water-weight gain, backache, muscular aches, discomfort prior to pre-menstrual and during menstrual and also can be used for relief fever and headache.
BRU20012754NP	Eye Glo Regular Eye Drops	Cleans and soothes irritated eyes.
BRU20012755P	Axcel Ketotifen Syrup	Long-term prevention of bronchial asthma (all forms including mixed), allergic bronchitis, asthmatic symptoms associated with hay fever. Prevention and treatment of multisystem allergies, allergic rhinitis, allergic skin reactions and allergic conjunctivitis. Not effective in aborting established attacks of asthma.
BRU20012756P	Fusix Tablet 40mg	Frusemide is indicated in the treatment of edema associated with congestive heart failure, hepatic cirrhosis and renal disease (including nephrotic syndrome). It is also indicated in the treatment of mild to moderate hypertension, usually in combination with other antihypertensive agents.
BRU20012757P	Non-Preg Injection	It is a long-term contraceptive agent and treatment of endometriosis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20012758P	Bisloc 5 Tablet	indicated for the treatment of: - Hypertension - Stable chronic angina - Stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics and optionally cardiac glycosides
BRU20012759P	Comazole N Tablet	For the treatment of urinary tract infections (upper and lower), respiratory infections, genital tract infections, gastrointestinal tract infections, skin and wound infections, other bacterial infections caused by sensitive organisms, fungal skin infection; south America blastomycosis.
BRU20012760P	QUANTIA 25 Film Coated Tablet	Indicated for the treatment of: -Treatment of schizophrenia -Treatment of bipolar disorder: o For the treatment of moderate to severe manic episodes in bipolar disorder o For the treatment of major depressive episodes in bipolar disorder o For the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to Quetiapine treatment.
BRU20012761P	QUANTIA 100 Film Coated Tablet	Indicated for the treatment of: -Treatment of schizophrenia -Treatment of bipolar disorder: o For the treatment of moderate to severe manic episodes in bipolar disorder o For the treatment of major depressive episodes in bipolar disorder o For the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to Quetiapine treatment.
BRU20012762P	QUANTIA 200 Film Coated Tablet	Indicated for the treatment of: -Treatment of schizophrenia -Treatment of bipolar disorder: o For the treatment of moderate to severe manic episodes in bipolar disorder o For the treatment of major depressive episodes in bipolar disorder o For the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to Quetiapine treatment.
BRU20012763NP	IFIMOL IV (Paracetamol Solution For Intravenous Infusion 10mg/ml)	Paracetamol is indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

BRU20012764P	Sofilex Capsule 250mg	Cephalexin is administered by mouth for the treatment of susceptible infections including those of the respiratory, urinary tracts and of the skin. It is also indicated in upper respiratory infections including pharyngitis and tonsillitis (caused by *Streptococcus pyogenes*) and otitis media (caused by *Strep. Pneumoniae, H. Influenza, Staphlococci* and *S. pyogenes*).
BRU20012765P	Cavumox 1.2g Injection	**CAVUMOX® (1.2 G INJECTION)** is indicated for the treatment of the following infections in adults and children: • Severe infections of the ear, nose and throat (such as mastoiditis, peritonsillar infections, epiglottitis, and sinusitis when accompanied by severe systemic signs and symptoms) • Acute exacerbations of chronic bronchitis (adequately diagnosed) • Community acquired pneumonia • Cystitis • Pyelonephritis • Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis • Bone and joint infections, in particular osteomyelitis • Intra-abdominal infections • Female genital infections
BRU20012766P	Combiwave SF 125 (Salmeterol 25mcg/Actuation And Fluticasone Propionate 125mcg/Actuation Pressurised Inhalation)	Reversible Obstructive Airways Disease (ROAD): Salmeterol and Fluticasone Propionate Pressurized Inhalation is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: ♦Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. ♦Patients who are symptomatic on current inhaled corticosteroid therapy. ♦Patients on regular bronchodilator therapy who require inhaled corticosteroids. Chronic Obstructive Pulmonary Disease (COPD): Salmeterol and Fluticasone Propionate Pressurized Inhalation is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU20012767P	Combiwave SF 250 (Salmeterol 25mcg/Actuation And Fluticasone Propionate 250mcg/Actuation Pressurised Inhalation)	Reversible Obstructive Airways Disease (ROAD): Salmeterol and Fluticasone Propionate Pressurized Inhalation is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: ♦Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. ♦Patients who are symptomatic on current inhaled corticosteroid therapy. ♦Patients on regular bronchodilator therapy who require inhaled corticosteroids. Chronic Obstructive Pulmonary Disease (COPD): Salmeterol and Fluticasone Propionate Pressurized Inhalation is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20012769P	Covastin Tablet 20mg	Therapy with lipid-altering agents should be considered in those individuals at increased risk for atherosclerosis-related clinical events as a function of cholesterol level, the presence of congestive heart failure, or other risk factors. Covastin is used when the response to a saturated fat and cholesterol-restricted diet and other non-pharmacological measures alone has been inadequate. Coronary Heart Disease In patients with coronary heart disease and hypercholesterolemia, Covastin is indicated to: • Reduce the risk of total mortality by reducing coronary death. • Reduce the risk of non-fatal myocardial infarction. • Reduce the risk for undergoing myocardial revascularization procedures (coronary artery bypass grafting and percutaneous transluminal coronary angioplasty). •Slow the progression of coronary atherosclerosis, including reducing the development of new lesions and new total occlusions. Hyperlipidemia Covastin is indicated as an adjunct to diet for reduction of elevated total-cholesterol, LDL-C, apolipoprotein B (Apo B), and TG in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate. Covastin also raises HDL-C and therefore lowers the LDL/HDL and total cholesterol/HDL ratios.
BRU20012770NP	FlameX Suspension	FlameX Suspension is indicated in the relief of symptoms of gastroesophageal reflux such as acid regurgitation, heartburn and indigestion.
BRU20012771P	Letrozole Mevon Tablet 2.5mg	♦ Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer. ♦ Extended adjuvant treatment of early breast cancer in postmenopausal women who have received prior standard adjuvant tamoxifen therapy. ♦ First-line treatment in postmenopausal women with advanced hormone-dependent breast cancer. ♦ Treatment of advance breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antioestrogens.

BRU20012772P	Flucozole (Intravenous Infusion) 2mg/ml	**FLUCOZOLE (INTRAVENOUS INFUSION)** is indicated in adults for the treatment of: • Cryptococcal meningitis. • Coccidioidomycosis. • Invasive candidiasis. • Mucosal candidiasis including oropharyngeal, oesophageal candidiasis, candiduria and chronic mucocutaneous candidiasis. • Chronic oral atrophic candidiasis (denture sore mouth) if dental hygiene or topical treatment are insufficient. **FLUCOZOLE (INTRAVENOUS INFUSION)** is indicated in adults for the prophylaxis of: • Relapse of cryptococcal meningitis in patients with high risk of recurrence. • Relapse of oropharyngeal or oesophageal candidiasis in patients infected with HIV who are at high risk of experiencing relapse. • Prophylaxis of candidal infections in patients with prolonged neutropenia (such as patients with haematological malignancies receiving chemotherapy or patients receiving Hematopoietic Stem Cell Transplantation. **FLUCOZOLE (INTRAVENOUS INFUSION)** is indicated in term newborn infants, infants, toddlers, children and adolescents aged from 0 to 17 years old: **FLUCOZOLE (INTRAVENOUS INFUSION)** is used for the treatment of mucosal candidiasis (oropharyngeal, oesophageal), invasive candidiasis, cryptococcal meningitis and the prophylaxis of candidal infections in immunocompromised patients. **FLUCOZOLE (INTRAVENOUS INFUSION)** can be used as maintenance therapy to prevent relapse of cryptococcal meningitis in children with high risk of reoccurrence. Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. Consideration should be given to official guidance on the appropriate use of antifungals.
BRU20022773NP	Patent Blue V Sodium Guerbet 2.5%	This medicinal product is for diagnostic use only. Identification of lymph vessels and arterial territories. Identification of sentinel lymph nodes before biopsy in patients with operable breast cancer.
BRU20022774P	Micosten Cream 2%	For topical application in the treatment of tinea pedis (athlete's foot), tinea cruris, and tinea corporis caused by *Trichophyton rubrum, Trichophyton mentagrophytes,* and *Epidermophyton floccosum.* Also indicated in the treatment of cutaneous candidiasis (moniliasis) caused by *Candida albicans* . Topical miconazole nitrate is also indicated in the treatment of tinea versicolor caused by *Malassezia furfur.*
BRU20022775P	Mobitil Injection 20ml Vial	Dobutamine Hydrochloride is indicated in adults who require short-term treatment of cardiac failure secondary to acute myocardial infarction or cardiac surgery.

BRU20022776P	Fytosid Injection 20mg/ml	• Small cell lung cancer • Testicularcarcinoma Etoposide has demonstrated highly significant clinical activity against: • Malignant lymphomas of both Hodgkins and Non Hodgkins • Acute leukaemias
BRU20022777P	Fleming Oral Suspension (457mg/5ml)	Fleming is indicated for short-term treatment of bacterial infections at the following sites: Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media. Lower respiratory tract infections e.g. acute and acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis. Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections. Bone and joint infections e.g. osteomyelitis. Dental infections e.g. dentoalveolar abscess Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis.
BRU20022778P	Repatha Solution For Injection In Prefilled Syringe 140mg/ml	<u>Prevention of Cardiovascular Events</u> In adults with established cardiovascular disease, Repatha in combination with an optimally dosed statin and/or other lipid-lowering therapies is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularisation. <u>Primary Hypercholesterolaemia and Mixed Dyslipidaemia</u> Repatha is indicated as an adjunct to diet, for the treatment of adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, and paediatric patients aged 10 years and over with heterozygous familial hypercholesterolaemia to reduce low density lipoprotein cholesterol (LDL-C): • In combination with a statin or statin with other lipid-lowering therapies in patients who are unable to reach LDL-C goals with a statin or; • Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. <u>Homozygous Familial Hypercholesterolaemia</u> Repatha is indicated in adults and paediatric patients aged 10 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies.

BRU20022779P	Repatha Solution For Injection In Prefilled Autoinjector 140mg/ml	Prevention of Cardiovascular Events In adults with established cardiovascular disease, Repatha in combination with an optimally dosed statin and/or other lipid-lowering therapies is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularisation. Primary Hypercholesterolaemia and Mixed Dyslipidaemia Repatha is indicated as an adjunct to diet, for the treatment of adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, and paediatric patients aged 10 years and over with heterozygous familial hypercholesterolaemia to reduce low density lipoprotein cholesterol (LDL-C): • In combination with a statin or statin with other lipid-lowering therapies in patients who are unable to reach LDL-C goals with a statin or; • Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. Homozygous Familial Hypercholesterolaemia Repatha is indicated in adults and paediatric patients aged 10 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies.
BRU20022780P	Pemetrexed Seacross 500mg Powder For Concentrate For Solution For Infusion	Malignant pleural mesothelioma Pemetrexed Seacross in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. Non-small cell lung cancer Pemetrexed Seacross in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. Pemetrexed Seacross is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemetrexed Seacross is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

BRU20022781P	Pemetrexed Seacross 100mg Powder For Concentrate For Solution For Infusion	Malignant pleural mesothelioma Pemetrexed Seacross in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. Non-small cell lung cancer Pemetrexed Seacross in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. Pemetrexed Seacross is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemetrexed Seacross is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.
BRU20022783P	Momate Nasal Spray 50mcg	Mometasone Furoate Nasal Spray is indicated for use in adults, adolescents and children between the ages of 3 and 11 years to treat the symptoms of seasonal allergic or perennial rhinitis. In patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis, prophylactic treatment with Mometasone Furoate Nasal Spray is recommended two to four weeks prior to the anticipated start of the pollen season. Mometasone Furoate Nasal Spray is indicated for the treatment of nasal polyps in adults 18 years of age and older. Mometasone Furoate Nasal Spray is indicated for the treatment of symptoms associated with acute rhinosinusitis in patients 12 years of age and older without signs or symptoms of severe bacterial infection.
BRU20022784P	Somidem Tablet 10mg	Zolpidem is indicated for short-term treatment of insomnia. Hypnotics should generally be limited to 7 to 10 days of use, and re-evaluation of the patient is recommended if insomnia fails to remit after this period.
BRU20022785P	Ibicar 100 (Beclometasone Pressurised Inhalation BP 100µg/Actuation)	Ibicar is indicated in the prophylactic management of asthma.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20022786NP	Tonbien Solution Jen Sheng 150mg/ml	Tonbien Solution Jen Sheng is used for relieving constipation through external application via the anus. The medicine works quickly by stimulating the bowels as well as softening the excreata upon application for immediate relief. This contrasts sharply with oral medicines which have to be taken hours before any effect can be realized.
BRU20022788P	Azimax 250mg Tablet	Azithromycin is indicated for the treatment of the following infections when known or likely to be due to one or more susceptible microorganisms: • Bronchitis • Community-Acquired Pneumonia • Sinusitis • Pharyngitis/Tonsillitis • Otitis Media • Skin and soft tissue infections • Uncomplicated genital infections due to *Chlamydia trachomatis*
BRU20032789P	Kisan Injection 10mg/ml	Haemorrhage or threatened haemorrhage as a result of severe 'hypoprothrombinemia (ie. deficiency of coagulation factors II, VII, IX and X) due, for instance, to overdosage of anticoagulants of the dicoumaral type or their combination with phenylbutazone, or to other forms of hypovitaminosis K (eg. Obstructive jaundice, liver and intestinal disorders, or prolonged administration of antibiotics, sulfonamides or salicylates)
BRU20032790P	Basalog One Insulin Glargine Injection (rDNA origin) 100 IU/mL Prefilled Pen	For the treatment of adults, adolescents and children of 2 years or above with diabetes mellitus, where treatment with insulin is required.
BRU20032791P	Tasigna 50mg Capsule	Tasigna is indicated for: •the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).Clinical effectiveness of TASIGNA in adults with newly diagnosed Ph+ CML-CP is based on major molecular response rate at 12 months and complete cytogenetic response rate by 12 months. the treatment of paediatric patients 2 years of age and older with newly diagnosed Ph+ CML-CP.Clinical effectiveness of TASIGNA in paediatric patients with newly diagnosed Ph+CML-CP is based on major molecular response by 12 cycles and complete cytogenetic response at 12 cycles. •the treatment of chronic phase (CP) and accelerated phase (AP) Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib.Clinical effectiveness of TASIGNA in adults with imatinib-resistant or -intolerant Ph+CML-CP was based on the unconfirmed major cytogenetic and complete hematologic response rates. Clinical effectiveness of TASIGNA in imatinib-resistant or -intolerant Ph+ CML-AP for adult patients was based on the confirmed hematologic response rates and the unconfirmed major cytogenetic response rates. •the treatment of paediatric patients 2 years of age and older with Ph+ CML-CP with resistance or intolerance to prior therapy including imatinib. Clinical effectiveness of TASIGNA in paediatric patients with imatinib-resistant or intolerant Ph+ CML-CP was based on the MMR rate at 6 cycles. No overall survival benefit has been demonstrated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20032792P	Lochol 10mg Tablet	Simvastatin is used as an adjunctive therapy in the following indications: -Hypercholesterolaemia -Homozygous familial hypercholesterolaemia -Cardiovascular event prevention
BRU20032793P	Xgeva Solution For Injection 120mg/Vial	Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with multiple myeloma and in patients with bone metastases from solid tumours. Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.
BRU20032794P	Rekaxime Injection 1000mg	Infections of the respiratory tract, including throat and nose; of the ear; of the kidneys and urinary tract; of the skin and soft tissues; of the bones and joints; of the genital organs, including gonorrhoea; of the abdominal region. Septicaemia, bacterial endocarditis, meningitis; for perioperative prophylaxis in patients who are at increased risk from infection, and for the prophylaxis of infections in patients with reduced resistance.
BRU20032795P	Setisin Injection 2.5mg/ml (1ml Amp)	Reversal of the effects on nondepolarising neuromuscular blocking agents (e.g. tubocurarine, pancuronium, etc.). Prophylaxis and treatment of post-operative intestinal atony and urinary retention. Also treatment of myasthenia gravis.
BRU20032796P	Avarin Softgel Capsule	This medication is an antispasmodic that reduces intestinal gas. This medication is recommended for relieving painful digestion with stomach distension. It is indicated for use in the relief of smooth muscle spasm, in condition such as irritable bowel syndrome.
BRU20032797P	MENOPUR® Multidose 600IU Powder And Solvent For Solution For Injection	MENOPUR® is indicated for the treatment of infertility in the following clinical situations: Anovulation, including polycystic ovarian disease (PCOD), in women who have been unresponsive to treatment with clomiphene citrate. Controlled ovarian hyperstimulation to induce the development of multiple follicles for assisted reproductive technologies (ART) (e.g. in vitro fertilisation/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI).
BRU20032798P	Fleming Oral Suspension (228.5mg/5ml)	Fleming is indicated for short-term treatment of bacterial infections at the following sites: Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media. Lower respiratory tract infections e.g. acute and acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis. Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections. Bone and joint infections e.g. osteomyelitis. Dental infections e.g. dentoalveolar abscess Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis.

BRU20032800P	Vivocin (Vancomycin Hydrochloride For Injection USP 500mg/Vial)	Vancomycin is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (beta-lactam-resistant) staphylococci. It is indicated for penicillin-allergic patients, for patients who cannot receive or who have failed to respond to other drugs, including the penicillins or cephalosporins, and for infections caused by vancomycin-susceptible organisms that are resistant to other antimicrobial drugs. Vancomycin is indicated for initial therapy when methicillin-resistant staphylococci are suspected, but after susceptibility data are available, therapy should be adjusted accordingly. Vancomycin's effectiveness has been documented in other infections due to staphylococci, including septicemia, bone infections, lower respiratory tract infections, skin, and skin structure infections. When staphylococcal infections are localized and purulent, antibiotics are used as adjuncts to appropriate surgical measures. Specimens for bacteriologic cultures should be obtained in order to isolate and identify causative organisms and to determine their susceptibilities to vancomycin. To reduce the development of drug-resistant bacteria and maintain the effectiveness of vancomycin and other antibacterial drugs, vancomycin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

		Rheumatoid Arthritis Humira is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Humira is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with disease modifying anti-rheumatic drugs. **Axial Spondyloarthritis** **Ankylosing Spondylitis** Humira is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Non-radiographic Axial spondyloarthritis (Axial Spondyloarthritis without radiographic evidence of AS)** Humira is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. **Plaque Psoriasis** Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Crohn's Disease** Humira is indicated for the treatment of moderately to severely active Crohn's Disease in adult patients who have inadequate response to conventional therapy. Humira is also indicated for treatment in adult patients with moderately to severely active Crohn's Disease who have lost response to or are intolerant to infliximab.

BRU20032801P	Humira Solution For Injection In Pre-Filled Syringe 80mg/0.8ml	**Ulcerative colitis** Humira is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Hidradenitis Suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate. **<u>Paediatrics</u>** **Juvenile idiopathic arthritis** **Polyarticular Juvenile Idiopathic Arthritis** Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 2 years old who had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. **Enthesitis-Related Arthritis** Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

		Paediatric Crohn's Disease Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindication for such therapies. **Paediatric Plaque Psoriasis** Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. **Paediatric Uveitis** Humira is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. **Adolescent hidradenitis suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Ulcerative Colitis** Humira is indicated for inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

		Rheumatoid Arthritis Humira is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Humira is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with disease modifying anti-rheumatic drugs. **Axial Spondyloarthritis** **Ankylosing Spondylitis** Humira is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Non-radiographic Axial spondyloarthritis (Axial Spondyloarthritis without radiographic evidence of AS)** Humira is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. **Plaque Psoriasis** Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Crohn's Disease** Humira is indicated for the treatment of moderately to severely active Crohn's Disease in adult patients who have inadequate response to conventional therapy. Humira is also indicated for treatment in adult patients with moderately to severely active Crohn's Disease who have lost response to or are intolerant to infliximab.

BRU20032802P	Humira Solution For Injection In Pre-Filled Pen 80mg/0.8ml	**Ulcerative colitis** Humira is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Hidradenitis Suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate. **<u>Paediatrics</u>** **Juvenile idiopathic arthritis** **Polyarticular Juvenile Idiopathic Arthritis** Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 2 years old who had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. **Enthesitis-Related Arthritis** Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

		Paediatric Crohn's Disease Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindication for such therapies. **Paediatric Plaque Psoriasis** Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. **Paediatric Uveitis** Humira is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. **Adolescent hidradenitis suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Ulcerative Colitis** Humira is indicated for inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.
BRU20032803NP	Betadine Antiseptic Cream 5% w/w	Betadine Antiseptic Cream is indicated for: ♦Bacterial and mycotic (fungal) skin infections ♦Bed sore and leg ulcer ♦Minor burns, cuts and abrasions ♦ Herpes genitalis
BRU20032804P	Kytron Solution For Injection/Infusion 3mg/3ml	Kytron Solution for Injection/Infusion 3mg/3ml is indicated for the prevention and treatment (control) of a) acute and delayed nausea and vomiting associated with chemotherapy and radiotherapy b) post-operative nausea and vomiting

BRU20032806P	Penrazol Powder For Solution For Infusion 40mg/Vial	Omeprazole for intravenous use is indicated as an alternative to oral therapy for the following indications i.e. Adults • Treatment of duodenal ulcers • Prevention of relapse of duodenal ulcers • Treatment of gastric ulcers • Prevention of relapse of gastric ulcers • In combination with appropriate antibiotics, Helicobacter pylori (H. pylori) eradication in peptic ulcer disease • Treatment of NSAID-associated gastric and duodenal ulcers • Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk • Treatment of reflux esophagitis • Long-term management of patients with healed reflux esophagitis • Treatment of symptomatic gastro-esophageal reflux disease • Treatment of Zollinger-Ellison syndrome
BRU20032807P	Pospenem Powder For Solution For Injection 500mg	Pospenem is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem. ♦Pneumonias and Nosocomial pneumonias ♦Urinary Tract Infections ♦Intra-abdominal Infections ♦Gynaecological Infections, such as endometritis and pelvic inflammatory disease ♦Bacterial Meningitis ♦Septicaemia ♦Empiric treatment, for presumed infections in patients with febrile neutropenia, used as monotherapy or in combination with anti-viral or anti-fungal agents. Pospenem has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.
BRU20032808P	Pospenem Powder For Solution For Injection 1g	Pospenem is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem. ♦Pneumonias and Nosocomial pneumonias ♦Urinary Tract Infections ♦Intra-abdominal Infections ♦Gynaecological Infections, such as endometritis and pelvic inflammatory disease ♦Bacterial Meningitis ♦Septicaemia ♦Empiric treatment, for presumed infections in patients with febrile neutropenia, used as monotherapy or in combination with anti-viral or anti-fungal agents. Pospenem has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.

BRU20032809P	Ebetaxel Injection 6mg/ml	Ovarian Carcinoma First-line therapy in combination with platinum compound for the treatment of advanced metastatic carcinoma of the ovary. Second-line therapy for the treatment of advanced metastatic carcinoma of the ovary. Breast Carcinoma Adjuvant treatment of node-positive breast cancer administered sequentially to standard combination therapy. First-line therapy of advanced or metastatic breast cancer after relapse within 6 months of adjuvant therapy. Prior therapy should have included an anthracycline unless clinically contraindicated. First-line therapy of metastatic breast cancer in combination with trastuzumab in patients who overexpress HER-2 as determined by immunohistochemistry. First-line therapy of metastatic breast cancer in combination with anthracycline in patients for whom anthracycline therapy is not suitable. Second-line therapy of advanced or metastatic breast cancer after failure of combination chemotherapy for metastatic disease. Prior therapy should have included an anthracycline unless clinically contraindicated. Non-Small Cell Lung Carcinoma First-line therapy in combination with a platinum compound or as a single agent for the treatment of non small cell carcinoma of the lung in patients who are not candidates for potentially curative surgery and/or radiation therapy. Kaposi's Sarcoma • Second-line treatment of AIDS-related Kaposi's Sarcoma
BRU20032810P	Imarem 400mg Tablet	Imarem is indicated for the treatment of ♦adult and pediatric patients with newly diagnosed chronic myeloid leukemia (CML) as well as for the treatment of adult and pediatric patients with CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. ♦adult and pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy. ♦adult patients with relapsed or refractory Ph+ ALL as monotherapy. ♦adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. ♦adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα re-arrangement. ♦adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP). ♦adult patients with aggressive systemic mastocytosis (ASM) without the D816V cKit mutation or with c-Kit mutational status unknown. The effectiveness of Imarem is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on haematological response rates in HES/CEL and ASM and on objective response rates in adult patients with unresectable and/or metastatic DFSP. The experience with imatinib in patients with MDS/MPD associated with PDGFR gene rearrangements is very limited. Except in newly diagnosed chronic phase CML, there are no controlled trials demonstrating a clinical benefit or increased survival for these diseases.

BRU20032811P	Imarem 100mg Tablet	Imarem is indicated for the treatment of ♦adult and pediatric patients with newly diagnosed chronic myeloid leukemia (CML) as well as for the treatment of adult and pediatric patients with CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. ♦adult and pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy. ♦adult patients with relapsed or refractory Ph+ ALL as monotherapy. ♦adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. ♦adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα re-arrangement. ♦adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP). ♦adult patients with aggressive systemic mastocytosis (ASM) without the D816V cKit mutation or with c-Kit mutational status unknown. The effectiveness of Imarem is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on haematological response rates in HES/CEL and ASM and on objective response rates in adult patients with unresectable and/or metastatic DFSP. The experience with imatinib in patients with MDS/MPD associated with PDGFR gene rearrangements is very limited. Except in newly diagnosed chronic phase CML, there are no controlled trials demonstrating a clinical benefit or increased survival for these diseases.
BRU20032812P	Pharmidea Carbetocin 100mcg/ml	Pharmidea Carbetocin is indicated for the prevention of uterine atony and postpartum haemorrhage following elective caesarean section under epidural or spinal anaesthesia. Pharmidea Carbetocin has not been studied in cases involving emergency caesarean section, classical caesarean section, anaesthesia other than epidural or spinal, or in patients presenting significant heart disease, history of hypertension, known coagulopathy or evidence of liver, renal or endocrine disease (excluding gestational diabetes). Appropriate studies have not been undertaken and doses have not been established in women following labour or vaginal delivery.
BRU20032813P	Aurasert Tablet 50mg	Aurasert is indicated for the treatment of symptoms of depressive illness including accompanying symptoms of anxiety. It is also indicated in preventing relapse of the initial episode of depression or recurrence of further depressive episodes including accompanying symptoms of anxiety. Aurasert is indicated in the treatment of obsessions and compulsions in patients with obsessive compulsive disorder. Aurasert is indicated for the treatment of panic disorder with or without agoraphobia.
BRU20032814P	Aurasert Tablet 100mg	Aurasert is indicated for the treatment of symptoms of depressive illness including accompanying symptoms of anxiety. It is also indicated in preventing relapse of the initial episode of depression or recurrence of further depressive episodes including accompanying symptoms of anxiety. Aurasert is indicated in the treatment of obsessions and compulsions in patients with obsessive compulsive disorder. Aurasert is indicated for the treatment of panic disorder with or without agoraphobia.

BRU20032815NP	Septidin 10% Solution	Antiseptic Against Bacteria, Fungi, Viruses, Protozoa, Cysts & Spores For Minor Burns, Wounds & On Pre-Operative Preparation Of The Skin.
BRU20032816P	Prepenem 500mg Injection	TREATMENT The activity of PREPENEM against an unusually broad spectrum of pathogens makes it particularly useful in the treatment of polymicrobic and mixed aerobic/anaerobic infections, as well as initial therapy prior to the identification of the causative organisms. Prepenem is indicated for the treatment of the following infections due to susceptible organisms: - intra-abdominal infections -Lower respiratory tract infections -Gynecological infections -Septicemia -Genitourinary tract infections -Bone and joint infections -Skin and soft tissue infections -Endocarditis Prepenem is indicated for the treamtent of mixed infections caused by susceptible strains of aerobic and anaerobic bacteria. The majority of these mixed infections are associated with contaimination by fecal flora or flora orginating from the vagina, skin and mouth. In these mixed infections, Bacteroides fragilis is the most commonly encountered anaerobic pathogen and is usually resistant to aminoglycosides, cephalosporins and penicillins. However, Bacteroides fragillis is usually susceptible to Prepenem. Prepenem has demonstrated efficacy agaisnt many infections caused by aerobic and anaerobic gram-positive and gram-negative bacteria resistant to the cephalosporins, including cefazolin, cefoperazone, cephalothin, cefoxitin, cefotaxime, moxalactam, cefamandole, ceftazidime and ceftriaxone. Similarly, manay infections caused by organisms resistant to aminoglycosides (gentamicin, amikacin, tobramycin) and/or penicillins (ampicillin, carbenicillin, penicillin-G, ticarcillin, piperacillin, azlocillin, mezlocillin) responded to treatment with Prepenem. Prepenem is not indicated for the treatment of meningitis. PROPHYLAXIS Prepenem is also indicated for the prevention of certain post-operative infections in patients undergoing contaminated or potentially contaiminated surgical procedures or where the occurrence of post-operative infection could be especially serious.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20032819P	MYODEEN Adenosine Injection USP 3mg/ml	Rapid conversion to a normal sinus rhythm of paroxysmal supraventricular tachycardia, including those associated with accessory by-pass tracts (Wolff-Parkinson-White Syndrome). Diagnostic Indications Aid to diagnosis of broad or narrow complex supraventricular tachycardia. Although Adenosine will not convert atrial flutter, atrial fibrillation or ventricular tachycardia to sinus rhythm, the slowing of AV conduction helps diagnosis of atrial activity. Sensitization of intra-cavitary electrophysiological investigations.
BRU20032820P	Cravit Ophthalmic Solution 1.5% w/v	Indicated bacteria Susceptible strains of S*taphylococcus* sp.*, Streptococcus* sp.*, Streptococcus pneumoniae, Enterococcus* sp.*, Micrococcus* sp.*, Moraxella* sp.*, Corynebacterium* sp.*, Klebsiella* sp.*, Enterobacter* sp.*, Serratia* sp.*, Proteus* sp.*, Haemophilus influenzae, Haemophilus aegyptius [Koch-Weeks bacillus], Pseudomonas* sp.*, Pseudomonas aeruginosa, Acinetobacter* sp.*,* and *Propionibacterium acnes.* Indications Blepharitis, dacryocystitis, hordeolum, conjunctivitis, tarsadenitis, keratitis (including corneal ulcer), and postoperative infections.
BRU20032821P	Supirocin Ointment 2% w/w	Supirocin Ointment is indicated for the bacterial skin infections e.g.: impetigo, folliculitis and furunculitis.
BRU20032822NP	Minyak Urut GPU (Gosok-Pijat-Urut) - Minyak Jahe	Helps to relieve of muscular pains, joint pains, backache, sprains, bruises and helps blood circulation.
BRU20042823PS1; BRU20042823PS2	Darzalex 100mg/5ml (20mg/ml) Concentrate For Solution For Infusion	DARZALEX is indicated for the treatment of adult patients with multiple myeloma: • in combination with lenalidomide and dexamethasone - in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. - in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. • in combination with bortezomib, melphalan, prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. • in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant. • in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. • in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. • as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

BRU20042824PS1; BRU2004284PS2	Darzalex 400mg/20ml (20mg/ml) Concentrate For Solution For Infusion	DARZALEX is indicated for the treatment of adult patients with multiple myeloma: • in combination with lenalidomide and dexamethasone - in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. - in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. • in combination with bortezomib, melphalan, prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. • in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant. • in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. • in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. • as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.
BRU20042825P	Malon Injection 2ml Amp	Adult population: Malon Injection is indicated for use in adults in: •Prevention of post-operative nausea and vomiting, •Symptomatic treatment of nausea and vomiting, including nausea and vomiting induced by migraine attacks, •Prevention of radiotherapy-induced nausea and vomiting Pediatric population: Malon Injection is indicated in children aged 1 to 18 years for: •Prevention of delayed chemotherapy-induced nausea and vomiting as a second line option, •Prevention of post-operative nausea and vomiting as second-line option
BRU20042826P	GC FLU Pre-Filled Syringe Inj.	Prophylaxis against influenza
BRU20042827P	Thyrosit 100mcg Tablet	*Thyrosit 100mcg* is used in the treatment of hypothyroidism. It is used for replacement or substitution of diminished or absent thyroid function resulting from primary causes including functional deficiency, primary atrophy and partial or complete absence of the gland or from the effects of surgery, radiation of thyroid glands. *Thyrosit 100mcg* is also used for replacement or supplemental therapy in patients with secondary or tertiary hypothyroidism. It is considered the thyroid agent of choice for the treatment of congenital hypothyroidism (cretinism). It is used as replacement therapy in the management of simple goitre and chronic lymphocytic thyroiditis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20042828P	Lecetam 250 Tablet	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in adults and adolescents from 16 years of age with newly diagnosed epilepsy. Levetiracetam is indicated as adjunctive therapy in the treatment of: o partial onset seizures with or without secondary generalization in adults, adolescents, and children from 1 month of age with epilepsy. o myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. o primary generalized tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalized Epilepsy.
BRU20042829P	Pulmicort Respules 0.5mg/ml	PULMICORT RESPULES contain the potent non-halogenated corticosteroid budesonide for use in bronchial asthma in patients where use of a pressurized inhaler or dry powder formulation is unsatisfactory or inappropriate. PULMICORT RESPULES can be used for the treatment of acute laryngotracheobronchitis (croup) in infants and children. PULMICORT RESPULES can be used in patients with exacerbations of chronic obstructive pulmonary disease in persons without signs of acute respiratory insufficiency.
BRU20042830NP	Geliga Muscular Balm	Geliga Muscular Balm helps to relieve muscular and joint problems such as bruises, sprain and backaches. Geliga Muscular Balm is also good to be used as warming up balm for athletes.
BRU20042831NP	Minyak Urut GPU (Gosok-Pijat-Urut) - Minyak Sereh	Helps to relieve of muscular pains, joint pains, backache, sprains, bruises and promoting blood circulation.
BRU20042832P	Ceritec Syrup 1mg/ml	Adults and children ≥1 year: Cetirizine Hydrochloride is indicated for symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticaria of allergic origin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20042833P	Nexpro Tablets 20mg	Esomeprazole is indicated for the treatment of: Gastro-Oesophageal Reflux Disease (GERD) • Treatment of erosive reflux oesophagitis • Long-term management of patients with healed oesophagitis to prevent relapse • Symptomatic treatment of gastro-oesophageal reflux disease (GERD) In combination with an appropriate antibacterial therapeutic regimen for the eradication of *Helicobacter pylori* and • Healing of Helicobacter pylori associated with duodenal ulcer • Prevention of relapse of peptic ulcers in patients with *Helicobacter pylori* associated ulcers Patients requiring continued NSAID therapy • Healing of gastric ulcers associated with NSAID therapy • Prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk Prolonged treatment after IV induced prevention of rebleeding of peptic ulcers Treatment of Zollinger Ellison Syndrome
BRU20042834NP	Rexom Potassium Citrate Mixture	For the relief of the symptoms of cystitis and other mild urinary tract infections.

BRU20042835P	SVOZ (0.5% Ophthalmic Solution)	Moxifloxacin is indicated: • For the treatment of patients 1 year of age and older with bacterial conjunctivitis caused by susceptible strains of organisms listed below • Preoperative and postoperative sterilization (when prophylactic antibiotic treatment is required) Table 1 Gram-Positive Bacteria : • Corynebacterium species* • Microbacterium species • Micrococcus luteus* [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains] • Staphylococcus aureus [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline, and/or trimethoprim resistant strains] • Staphylococcus epidermidis [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline, and/or trimethoprim resistant strains] • Staphylococcus haemolyticus [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline, and/or trimethoprim resistant strains] • Staphylococcus hominis* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline, and/or trimethoprim resistant strains] • Staphylococcus warneri* [including erythromycin resistant strains] • Streptococcus mitis* [including penicillin, erythromycin, tetracycline, and/or trimethoprim resistant strains] • Streptococcus pneumonia [including penicillin, erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains] • Streptococcus viridans [including penicillin, erythromycin, tetracycline, and/or trimethoprim resistant strains] Gram-Negative Bacteria : • Acinetobacter species • Haemophilus “alconae” [including ampicillin resistant strains] •Haemophilus influenza [including ampicillin resistant strains] • Klebsiella pneumoniae* • Moraxella catarrhalis* • Pseudomonas aeruginosa* Other Microorganisms : • Chlamydia trachomatis Note: * indicates efficacy for this organism was studied in fewer than 10 infections

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20042836P	Disuf Ointment 2% w/w	DISUF OINTMENT is indicated for the treatment of skin infections caused by staphylococci, streptococci, corynebacterium minutissimum and other organisms sensitive to fusidic acid. The most important indications being: Impetigo, Boils, Carbuncles, Paronychia, Infected wounds, Sycosis barbae, Hidradenitis, Erythrasma, Folliculitis.
BRU20042837P	Hovid Allopurinol Tablet 100mg	For treatment or prevention of: •Chronic primary or secondary gout •Uric acid nephropathy •Uric acid stone formation •Problems associated with hyperuricemia (i.e. tissue urate deposition, renal calculi, or acute urate nephropathy) secondary to cancer chemotherapy or radiation therapy.
BRU20042838P	Virest 5% Cream	It is used for the treatment of herpes simplex viral infections of the skin including initial and recurrent genital herpes and herpes labialis.
BRU20052839P	Conpanzole Enteric Coated Tablet 20mg	1) In combination with two appropriate antibiotics for the eradication of Helicobacter pylori in patients with peptic ulcers with the objective of reducing the recurrence of duodenal and gastric ulcers caused by this microorganism 2) Duodenal ulcer 3) Gastric ulcer 4) Moderate and severe cases of inflammation of the esophagus (reflux esophagitis) 5) Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions
BRU20052840P	Conpanzole Enteric Coated Tablet 40mg	1) In combination with two appropriate antibiotics for the eradication of Helicobacter pylori in patients with peptic ulcers with the objective of reducing the recurrence of duodenal and gastric ulcers caused by this microorganism 2) Duodenal ulcer 3) Gastric ulcer 4) Moderate and severe cases of inflammation of the esophagus (reflux esophagitis) 5) Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions
BRU20052841P	Tensiber Film Coated Tablet 150mg	Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen.
BRU20052842P	Unitrexate Tablet 2.5mg	1) Acute lymphoblastic leukemia 2) Methotrexate is indicated for the treatment of trophoblastic neoplasms (choriocarcinoma, chorioadenoma destruens, and hydatiform mole). 3) Rheumatoid arthritis. 4) It is also used in the treatment of severe, uncontrolled psoriasis which is not responsive to other therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20052843NP	Hovid-Paracetamol Suspension 250mg/5ml (Sugar Free)	Indicated for the relief of fever, headache and symptoms of cold and flu, toothache, discomfort of teething and fever after vaccination.
BRU20052844P	A-Losartan 50mg Tablet	Treatment of hypertension.
BRU20052845P	A-Losartan 100mg Tablet	Treatment of hypertension.
BRU20052846P	Fustadin Cream 2% w/w	This cream is indicated for treatment of skin infections caused by staphylococci, streptococci, Propionibacterium acnes, Corynebacterium minutissimum and other organisms sensitive to fusidic acid. The most important indications being: •Impetigo •Infected wounds •Folliculitis •Boils •Sycosis barbae •Carbuncles •Hidradenitis •Paronychia •Erythrasma
BRU20052847P	Peace DM Syrup	Relief of dry irritating cough associated with common cold, upper respiratory tract infections and allergic rhinitis. Helps dry up running nose and opens congested bronchi to aid clear breathing.
BRU20052848NP	Wintinea Cream	Wintinea Cream is indicated for the treatment of superficial fungal infection of the skin including athlete's foot (tinea pedis), jock itch (tinea cruris), body ringworm (tinea corporis) and pityriasis versicolor.
BRU20052849P	Losartan + HCT Mevon Tablet 100/25mg	<u>Hypertension</u> Losartan + HCT Mevon film-coated tablets are indicated for the treatment of hypertension, for patients in whom combination therapy is appropriate. <u>Hypertensive patients with left ventricular hypertrophy</u> Losartan + HCT Mevon film-coated tablets is a combination of losartan and hydrochlorothiazide. In patients with hypertension and left ventricular hypertrophy, losartan, often in combination with hydrochlorothiazide, reduced the risk of stroke in hypertensive patients with left ventricular hypertrophy.
BRU20052850P	Bencodyl Linctus	For productive cough and complication associated with allergic disorders and allergic manifestation of respiratory illness e.g. common cold, flu and bronchitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20052851P	Defuzin-B Cream	Defuzin-B Cream is indicated for the inflammatory dermatoses where bacterial infection is present or likely to occur. Inflammatory dermatoses include atopic eczema, discoid eczema, stasis eczema, seborrheic dermatitis, contact dermatitis, lichen simplex chronicus, psoriasis, discoid lupus erythematosus
BRU20052852P	Pharmaniaga Simvastatin Tablet 20mg	Reductions in risk of coronary heart disease (CHD) mortality and cardiovascular events In patients at high risk of coronary events because of existing coronary heart disease, diabetes, peripheral vessel disease, history of stroke or other cerebrovascular disease, simvastatin is indicated to: • Reduce the risk of total mortality by reducing CHD deaths • Reduce the risk of non-fatal myocardial infarction and stroke • Reduce the need for coronary and non-coronary revascularization procedures. Hyperlipidaemia Simvastatin is indicated as an adjunct to diet to reduce elevated total plasma cholesterol (total-C), lowdensity lipoprotein (LDL-C), apolipoprotein B (Apo B), and triglycerides (TG) and to increase highdensity lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate. Simvastatin therefore, lowers the LDL-C/HDL-C and the total-C/HDL-C ratios. Pediatric patients with heterozygous familial hypercholesterolemia Simvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, TG, and Apo B levels in adolescent boys and girls who are at least one year post-menarche, 10-17 years of age, with heterozygous familial hypercholesterolemia (HeFH).
BRU20052853P	Torio 40 Tablet	Hypercholesterolemia – Treatment of primary hypercholesterolemia or mixed dyslipidemia, as an adjunct to diet, when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate. Treatment of homozygous familial hypercholesterolemia as an adjunct to diet and other lipid-lowering treatments (e.g. LOL apheresis) or if such treatments are not appropriate.
BRU20062854P	Basalog Insulin Glargine Injection (rDNA origin) 100IU/mL	For the treatment of adults, adolescents and children of 2 years or above with diabetes mellitus, where treatment with insulin is required.
BRU20062855P	Gilenya 0.25mg Hard Capsule	Gilenya is indicated for the treatment of adult patients and pediatric patients of 10 years of age and above with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20062856P	Zoledronic Acid 5mg/100ml Solution For Infusion	Treatment of osteoporosis • in post-menopausal women • in adult men at increased risk of fracture, including those with a recent low-trauma hip fracture. Treatment of osteoporosis associated with long-term systemic glucocorticoid therapy • in post-menopausal women • in adult men at increased risk of fracture. Treatment of Paget's disease of the bone in adults.
BRU20062857NP	Wellmex Atomic Enema	It is used for relieving constipation.
BRU20062858P	Vacodil 25mg Tablets	Hypertension - Vacodil is indicated primarily for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents (e.g. calcium channel blockers, diuretics). Treatment of angina pectoris Treatment of symptomatic chronic heart failure Vacodil is indicated for the treatment of symptomatic chronic heart failure (CHF) to reduce mortality and cardiovascular hospitalizations, improve patient well-being and slow the progression of the disease. Vacodil may be used as adjunct to standard therapy, but may also be used in those patients unable to tolerate an ACE inhibitor, or those who are not receiving digitalis, hydralazine or nitrate therapy.
BRU20062859P	Mementor Tablets 10mg	Treatment of patients with moderate to severe Alzheimer's disease.

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BRU20062860P	Covastin Tablet 40mg	Therapy with lipid-altering agents should be considered in those individuals at increased risk for atherosclerosis-related clinical events as a function of cholesterol level, the presence of congestive heart failure, or other risk factors. Covastin is used when the response to a saturated fat and cholesterol-restricted diet and other non-pharmacological measures alone has been inadequate. *Coronary Heart Disease* In patients with coronary heart disease and hypercholesterolemia, Covastin is indicated to: • Reduce the risk of total mortality by reducing coronary death. • Reduce the risk of non-fatal myocardial infarction. • Reduce the risk for undergoing myocardial revascularization procedures (coronary artery bypass grafting and percutaneous transluminal coronary angioplasty). •Slow the progression of coronary atherosclerosis, including reducing the development of new lesions and new total occlusions. *Hyperlipidemia* Covastin is indicated as an adjunct to diet for reduction of elevated total-cholesterol, LDL-C, apolipoprotein B (Apo B), and TG in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate. Covastin also raises HDL-C and therefore lowers the LDL/HDL and total cholesterol/HDL ratios.
BRU20062861P	Myborte 3.5mg (Bortezomib Powder For Solution For Injection 3.5mg/Vial)	Bortezomib is indicated for the treatment of patients with multiple myeloma. Bortezomib is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy
BRU20062863P	YSP Salbutamol Injection 0.5mg/ml	1) Relief of severe bronchospasm associated with asthma or bronchitis and for the treatment of status asthmaticus. 2) Management of uncomplicated premature labour in the last trimester of pregnancy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20062864P	YSP Bufencon Injection	This product is indicated for the treatment of acute and chronic corticosteroid-responsive disorders. Corticosteroid hormone therapy is an adjunct to, and not a replacement for, conventional therapy. Musculoskeletal and Soft Tissue Conditions: Rheumatoid arthritis; osteoarthritis; bursitis; ankylosing spondylitis; epicondylitis; radiculitis; coccydynia; sciatica; lumbago; torticollis; ganglion cyst; exostosis; fasciitis. Allergic Conditions: Chronic bronchial asthma (including adjunctive therapy for status asthmaticus); hay fever; angioneurotic edema; allergic bronchitis; seasonal or perennial allergic rhinitis; drug reactions; serum sickness; insect bites. Dermatologic Conditions: Atopic dermatitis (nummular eczema); neurodermatitis (circumscribed lichen simplex); contact dermatitis; severe solar dermatitis; urticaria; hypertrophic lichen planus; necrobiosis lipoidica diabeticorum; alopecia areata; discoid lupus erythematosus; psoriasis; keloids; pemphigus; dermatitis herpetiformis; cystic acne. Collagen Diseases: Disseminated lupus erythematosus; scleroderma; dermatomyositis; periarteritis nodosa. Neoplastic Diseases: For palliative management of leukaemias and lymphomas in adults; acute leukemia of childhood. Other Conditions: Adrenogenital syndrome; ulcerative colitis; regional ileitis; sprue; podiatric conditions (bursitis under heloma durum, hallux rigidus, digiti quinti varus); affections requiring subconjunctival injection; corticosteroid-responsive blood dyscrasias; nephritis, and nephritic syndrome. Primary and secondary adrenocortical insufficiency may be treated with this product but should be supplemented with mineralocorticoids, if applicable. This product is recommended for (1) Intramuscular injection in conditions responsive to systemic corticosteroids; (2) Injection directly into the affected soft tissues where indicated; (3) Intraarticular and periarticular injection in arthritides; (4) Intralesional injection in various dermatologic conditions; and (5) Local injection in certain inflammatory and cystic disorders of the foot.
BRU20062865P	Finil 16 Tablet	Indicated in the: • Treatment of essential hypertension in adults • Treatment of hypertension in children and adolescents aged 6 to < 18 years • Treatment of adult patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction ≤ 40%) when Angiotensin Converting Enzyme (ACE)-inhibitors are not tolerated or as add-on therapy to ACE-inhibitors in patients with symptomatic heart failure, despite optimal therapy, when mineralocorticoid receptor antagonists are not tolerated
BRU20062866NP	ActiMol Tablet 650mg	Relief of headache, backache, period pain, and aches due to cold and flu, pain related to mild arthritis and fever.

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BRU20062867NP	BAGES Cream	Indicated for temporary relief of minor aches and pains of muscle and joints associated with simple backache, arthritis, strains, etc.
BRU20062868P	Lorsedin Oral Solution 1mg/ml	Loratadine is indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. Nasal and ocular signs and symptoms are relieved rapidly after oral administration. Loratadine is also indicated for relief of symptoms and signs of chronic urticaria and other allergic dermatologic disorders.
BRU20052869P	Albumin (Human) U.S.P. Albutein 5%	Albutein 5% is indicated: a. For treatment of hypovolemic shock b. In conditions in which there is severe hypoalbuminemia. However, unless the pathologic condition responsible for the hypoalbuminemia can be corrected, administration of albumin can afford only symptomatic or supportive relief c. As an adjunct in hemodialysis and in cardiopulmonary bypass procedures In those conditions in which the colloid requirement is high and there is less need for fluid, albumin should be administered as a 25% solution. Pediatric Use: The pediatric use of Albutein 5% has not been clinically evaluated. Therefore, physicians should weigh the risks and benefits of the use of Albutein 5% in the pediatric population.
BRU20062870P	Mico Cream	Mico Cream is indicated for the topical treatment of the skin infections due to susceptible fungi (dermatophytes and yeasts) such as tinea pedis (athletes foot), tinea cruris, tinea corporis (ringworm), tinea versicolor (white spots) and candidiasis.
BRU20062871P	Sunvasc 5 Tablet	First-line treatment of hypertension and as the sole agent to control blood pressure in the majority of patients. Amlodipine has also been used successfully in combination with a thiazide diuretic, β-adrenoceptor-blocking agent or an angiotensin-converting enzyme inhibitor. Amlodipine is indicated for the 1st-line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used alone, as monotherapy or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of β-blockers.
BRU20062872P	Sensitamine Tablet	i) Symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis and allergic conjunctivitis due to inhalant allergens and foods. ii) Symptomatic treatment of pruritus associated with allergic reactions and of mild, uncomplicated allergic skin manifestation of urticaria and angioedema and in dermatographism. iii) May be used in combination with a decongestant (Pseudoephedrine) for the temporary relief of nasal and sinus congestion associated with the common cold and allergic rhinitis.

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BRU20062873P	Uniflex-N Cream	Uniflex-N Cream is indicated for the relief of corticosteroid-responsive inflammatory dermatoses, especially when secondary bacterial infection is present or likely to be present. It is indicated for the treatment of eczema, psoriasis, lichen planus, sebborrhoeic dermatitis, intertrigo, contact sensitivity reactions, discoid lupus, erythematosus, generalised erythroderma. Uniflex-N Cream can be used for the relief of insect bites and stings.
BRU20062874P	Orata 0.5 Film Coated Tablet	Entecavir is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with: • Compensated liver disease and evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis. • Decompensated liver disease For both compensated and decompensated liver disease, this indication is based on clinical trial data in nucleoside naive patients with HBeAg positive and HBeAg negative HBV infection.With respect to patients with Lamivudine-refractory hepatitis B. Entecavir is also indicated for the treatment of chronic HBV infection in nucleoside naive pediatric patients from 2 to < 18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis. With respect to the decision to initiate treatment in pediatric patients.
BRU20062875NP	INFUSOL D5 Intravenous Infusion	Indication: - Energy supply - Hypertonic dehydration - Vehicle solution for supplementary medication - Hypoglycaemia
BRU20062876P	Podoxred (Pemetrexed) Powder For Concentrate For Solution For Infusion 100mg	Malignant pleural mesothelioma: Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. Non-small cell lung cancer: Pemetrexed in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. Pemetrexed is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemetrexed is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

BRU20062877P	Podoxred (Pemetrexed) Powder For Concentrate For Solution For Infusion 500mg	Malignant pleural mesothelioma: Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. Non-small cell lung cancer: Pemetrexed in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. Pemetrexed is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemetrexed is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.
BRU20072878NP	Kwan Loong Minyak Angin	For effective relief of dizziness, headaches, travel sickness, stuffy nose, stomachache, insect bites, aches and pains of muscles and joints, backaches, bruises, sprains and strains, pains associated with arthritis.
BRU20072879P	Nifecard XL Tablet 30mg	Treatment of: Hypertension Coronary disease: • Stable angina pectoris • Vasospastic angina pectoris
BRU20072881P	Alecensa 150mg Hard Capsule	Alecensa is indicated for the first-line treatment of patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC). Alecensa is indicated for the treatment of patients with ALK-positive, locally advanced or metastatic NSCLC who have progressed on or are intolerant to crizotinib
BRU20072882NP	Dermoplex Burn-Aid Cream	Antiseptic creams for burns. Also for minor cuts, wounds, insect bites, sores, rashes and abrasions.
BRU20072883P	Avoxred (Azacitidine) Powder For Suspension For injection 100mg/Vial	Azacitidine is indicated for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with: • Intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS), • Chronic myelomonocytic leukaemia (CMML) with 10-29 % marrow blasts without myeloproliferative disorder, • Acute myeloid leukaemia (AML) with 20-30 % blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification

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BRU20072884P	Redtibin (Decitabine) Powder For Injection 50mg/Vial	Decitabine is indicated for treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British (FAB) subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and Intermediate-1, Intermediate-2, and High-Risk International Prognostic Scoring System (IPSS) groups. For the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.
BRU20072885P	Stelara 130mg/26ml Concentrate For Solution For Infusion	**Crohn's Disease** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies. **Ulcerative Colitis** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies (see Pharmacodynamic Properties).
BRU20072886P	Besomid 100mcg/Actuation HFA-Metered Dose Inhaler	It is indicated for the prophylactic management of asthma.
BRU20072887P	Timo-COMOD 0.5% Eye Drops	Timo-COMOD® 0.5% is indicated in elevated intraocular pressure, chronic open-angle glaucoma, aphakic glaucoma, congenital glaucoma, if other therapeutic regimens are not sufficient.
BRU20072888P	Granisetron Kabi 1mg/ml Concentrate Solution Injection/Infusion	Indicated for the prevention and treatment (control) of a) Acute and delayed nausea and vomiting associated with chemotherapy and radiotherapy b) Post-operative nausea and vomiting
BRU20072889NP	Unidine Povidone Iodine Solution 10% w/v	Disinfectant and antiseptic for the treatment of contaminated wounds, cuts and burns and also for the pre-operative preparation of the skin and mucous membrane.
BRU20072890P	Ikervis 1mg/ml Eye Drops, Emulsion	Treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes.
BRU20072891P	Dezor Plus Shampoo	Dezor Plus Shampoo is indicated for use in the treatment of Dandruff and Seborrhoeic Dermatitis of scalp.

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BRU20072892P	Atorvin 40 Film-Coated Tablet	*Hypercholesterolaemia* Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. *Prevention of cardiovascular disease* Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event as an adjunct to correction of other risk factors.
BRU20072893P	Vitraq Film-Coated Tablet 75mg	For the prevention of atherothrombotic events in: •Peripheral arterial disease, myocardial infarction, ischemic stroke •Acute coronary syndrome -Non-ST segment elevation (unstable angina or non-Q-wave myocardial infarction) that including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA). -ST-segment elevation acute myocardial infarction in combination with ASA in medically treated patients eligible for thrombolytic therapy.
BRU20072894P	Abiratred Abiraterone Acetate Tablets 250mg	Abiraterone is indicated with prednisone or prednisolone for: •The treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed after a docetaxel-based chemotherapy regimen. •The treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.
BRU20072895P	A-Lices Lotion 1% w/w	For the topical treatment of head lice.
BRU20072896P	Fusidasol Cream	Inflammatory dermatoses, psoriasis where bacterial infection caused by staphylococcus and streptococcus are present or likely to occur.
BRU20072897NP; BRU20072897PS2	Actimol Tablet 500mg	For the relief from fever For the relief from mild to moderate pain including: headache, migraine, backache, musculoskeletal pain, myalgia and neuralgia, dysmenorrhea, pain of osteoarthritis, toothache, pain after dental procedures/tooth extraction, pain after vaccination and the discomfort from colds, influenza and sore throats.
BRU20072898P	Proglutrol G2 Sustained Release Tablet 2/500mg	Proglutrol G2 is indicated as an adjunct to diet and exercise in non-insulin dependent diabetes mellitus (NIDDM) (Type 2) patients who are unable to achieve sufficient glycaemic control with monotherapy of metformin or glimepiride alone or who are already treated with combination of metformin and glimepiride as separate tablets.

BRU20082899P	Vacodil Tablets 6.25mg	Hypertension Vacodil is indicated primarily for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents (e.g. calcium channel blockers, diuretics) Treatment of angina pectoris Treatment of symptomatic chronic heart failure Vacodil is indicated for the treatment of symptomatic chronic heart failure (CHF) to reduce mortality and cardiovascular hospitalizations, improve patient well-being and slow the progression of the disease. Vacodil may be used as adjunct to standard therapy, but may also be used in those patients unable to tolerate an ACE inhibitor, or those who are not receiving digitalis, hydralazine or nitrate therapy.
BRU20082900P	Viranz 600 (Efavirenz Tablets USP 600mg)	Viranz 600 are indicated in antiretroviral combination treatment of HIV-1 infected adults, adolescents and children.
BRU20082901NP	Ubat Minyak Geliga	Known in its properties as counter-irritant and for temporary relief of minor aches, pains of muscles and joints
BRU20082906P	Erysol For Oral Suspension 200mg/5ml	Erysol is indicated for the treatment of infections due to susceptible organisms such as in upper and lower respiratory infections, soft tissue infections, skin infections, clostridial infections urethritis. It is also indicated as an alternative to penicillin in patients who are hypersensitive to penicillin.
BRU20082907P	Raloxon 60mg Film-Coated Tablets	Raloxifene is indicated for the treatment and prevention of osteoporosis in postmenopausal women. A significant reduction in the incidence of vertebral, but not hip fractures has been demonstrated. For those postmenopausal women taking raloxifene for osteoporosis treatment, raloxifene has been shown to reduce the risk of invasive breast cancer. When determining the choice of raloxifene or other therapies, including oestrogens, for an individual postmenopausal woman, consideration should be given to menopausal symptoms, effects on uterine and breast tissues, and cardiovascular risks and benefits.
BRU20082908NP	Throatsil (Menthol Flavour)	For relief of mouth and throat infections
BRU20082909NP	Throatsil (Prune Flavour)	For relief of mouth and throat infections
BRU20082910NP	Throatsil (Orange Flavour)	For relief of mouth and throat infections
BRU20082911NP	Throatsil (Wild Berries Flavour)	For relief of mouth and throat infections

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BRU20082912P	Univate Cream	Univate is indicated for the treatment of severe inflammatory skin disorders such as eczema, discoid lupus erythematosus, psoriasis, lichen planus and other conditions or in patients which do not respond to less potent corticosteroids.
BRU20082913P	Univate Ointment	Univate is indicated for the treatment of severe inflammatory skin disorders such as eczema, discoid lupus erythematosus, psoriasis, lichen planus and other conditions or in patients which do not respond to less potent corticosteroids.
BRU20082914P	Leflunomide Mevon Film-Coated Tablets 20mg	Leflunomide is indicated for the treatment of adult patients with: •active rheumatoid arthritis as a "disease-modifying antirheumatic drug" (DMARD), •active psoriatic arthritis. Recent or concurrent treatment with hepatotoxic or haematotoxic DMARDs (e.g. methotrexate) may result in an increased risk of serious adverse reactions; therefore, the initiation of leflunomide treatment has to be carefully considered regarding these benefit/risk aspects. Moreover, switching from leflunomide to another DMARD without following the washout procedure may also increase the risk of serious adverse reactions even for a long time after the switching.
BRU20082915P	Celxib 200 Capsule	Celecoxib is indicated in adults for the symptomatic relief in the treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The decision to prescribe a selective cyclooxygenase-2 (COX-2) inhibitor should be based on an assessment of the individual patient's overall risks.
BRU20082916P	Rexom Salbutamol Elixir 2mg/5ml	Salbutamol is used as a bronchodilator in the management of reversible airways obstruction, as in asthma and in some patients with chronic obstructive pulmonary disease.
BRU20082917P	Remafen Enteric-Coated Tablet 50mg	Treatment of: -Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism. -Acute attacks of gout -Painful post-traumatic and post-operative inflammation and swelling -Primary dysmenorrhoea
BRU20082918P	Peace Syrup	Symptomatic relief of sneezing, stuffy nose, and rhinorrhea caused by seasonal, allergic and vasomotor rhinitis.
BRU20082919NP	Addaven Concentrate For Solution For Infusion	To meet basal to moderately increased requirements of trace elements in intravenous nutrition.

BRU20082920P	Matenol MR Tablet	Indicated in adults as an add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line antianginal therapies.
BRU20082921P	Lamoga-50 Tablet	Epilepsy ***Adults and adolescents aged 13 years and above*** -Adjunctive or monotherapy treatment of partial seizures and generalised seizures, including tonic-clonic seizures -Seizures associated with Lennox-Gastaut syndrome. Lamotrigine tablet is given as adjunctive therapy but may be the initial antiepileptic drug (AED) to start with in Lennox-Gastaut syndrome ***Children and adolescents aged 2 to 12 years*** -Adjunctive treatment of partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome -Monotherapy of typical absence seizures Bipolar disorder ***Adults aged 18 years and above*** -Prevention of depressive episodes in patients with bipolar I disorder who experience predominantly depressive episodes Lamotrigine tablet is not indicated for the acute treatment of manic or depressive episodes.
BRU20082922P	Lamoga-100 Tablet	Epilepsy ***Adults and adolescents aged 13 years and above*** -Adjunctive or monotherapy treatment of partial seizures and generalised seizures, including tonic-clonic seizures -Seizures associated with Lennox-Gastaut syndrome. Lamotrigine tablet is given as adjunctive therapy but may be the initial antiepileptic drug (AED) to start with in Lennox-Gastaut syndrome ***Children and adolescents aged 2 to 12 years*** -Adjunctive treatment of partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome -Monotherapy of typical absence seizures Bipolar disorder ***Adults aged 18 years and above*** -Prevention of depressive episodes in patients with bipolar I disorder who experience predominantly depressive episodes Lamotrigine tablet is not indicated for the acute treatment of manic or depressive episodes.

BRU20082923P	Ultracet Tablet	ULTRACET is indicated for the management of moderate to severe pain.
BRU20092924NP	Dermoplex Calamine Lotion	Soothes and relieves minor skin irritations, insect bites, sunburn, prickly heat and nappy rashes.
BRU20092925P	Tremfya 100mg/ml Solution For Injection	**Plaque psoriasis** TREMFYA is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis** TREMFYA, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.
BRU20092926NP	Breacol Expectorant For Adults	Breacol Expectorant for Adults is used as an expectorant for symptomatic relief of coughs due to colds and upper respiratory tract infections.
BRU20092927P	Skyrizi 75mg Solution For Injection In Pre-Filled Syringe	**Plaque Psoriasis** Skyrizi is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **Psoriatic Arthritis** Skyrizi, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).
BRU20092928NP	Hydrosil Tablet	Hydrosil is used for the relief of pain in gastric ulcer, gastric pain or discomfort due to excessive acid secretion in the stomach (dyspepsia) and in reflux oesophagitis (heartburn).
BRU20092929P	Tolmide 500mg Tablet	Tolbutamide reduces blood sugar in non-insulin dependent cases of diabetes mellitus in adjunct to diet. It may use in cases which do not respond to other sulphonylurea agents.
BRU20092930P	Edyfil Film Coated Tablet 50mg	Sildenafil is indicated for treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Sildenafil to be effective, sexual stimulation is required.
BRU20092931P	Edyfil Film Coated Tablet 100mg	Sildenafil is indicated for treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Sildenafil to be effective, sexual stimulation is required.
BRU20092932P	Rhinitin Tablet	Indicated for relief of symptoms associated with allergic rhinitis as well as ocular itching and burning, chronic urticaria and other allergic dermatologic disorders.

BRU20092933P	Bisocor Tablet 2.5mg	Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.
BRU20092934P	Bisocor Tablet 5mg	Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.
BRU20092935P	Letara 2.5mg Tablet	•Adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. •Adjuvant treatment of postmenopausal women with early breast cancer (positive or unknown oestrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy (extended adjuvant therapy). •First-line treatment in postmenopausal women with hormone- dependent advanced breast cancer. •Treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antioestrogens.

		Rheumatoid Arthritis Humira is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Humira is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with disease modifying anti-rheumatic drugs. **Axial Spondyloarthritis** **Ankylosing Spondylitis** Humira is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Non-radiographic Axial spondyloarthritis (Axial Spondyloarthritis without radiographic evidence of AS)** Humira is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. **Plaque Psoriasis** Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Crohn's Disease** Humira is indicated for the treatment of moderately to severely active Crohn's Disease in adult patients who have inadequate response to conventional therapy. Humira is also indicated for treatment in adult patients with moderately to severely active Crohn's Disease who have lost response to or are intolerant to infliximab.

BRU20102936P	HUMIRA Solution For Injection In Pre-Filled Syringe 20mg/0.2ml	**Ulcerative colitis** Humira is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Hidradenitis Suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate. **<u>Paediatrics</u>** **Juvenile idiopathic arthritis** **Polyarticular Juvenile Idiopathic Arthritis** Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 2 years old who had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. **Enthesitis-Related Arthritis** Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

		Paediatric Crohn's Disease Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindication for such therapies. **Paediatric Plaque Psoriasis** Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. **Paediatric Uveitis** Humira is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. **Adolescent hidradenitis suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Ulcerative Colitis** Humira is indicated for inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.
BRU20102937P	Venclexta Film-Coated Tablets 10mg	VENCLEXTA in combination with rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. VENCLEXTA in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated CLL. VENCLEXTA (venetoclax) monotherapy is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other available treatment options. VENCLEXTA is indicated, in combination with azacitidine, or decitabine, or low- dose cytarabine for the treatment of newly diagnosed acute myeloid leukaemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

BRU20102938P	Venclexta Film-Coated Tablets 50mg	VENCLEXTA in combination with rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. VENCLEXTA in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated CLL. VENCLEXTA (venetoclax) monotherapy is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other available treatment options. VENCLEXTA is indicated, in combination with azacitidine, or decitabine, or low- dose cytarabine for the treatment of newly diagnosed acute myeloid leukaemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
BRU20102939P	Venclexta Film-Coated Tablets 100mg	VENCLEXTA in combination with rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. VENCLEXTA in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated CLL. VENCLEXTA (venetoclax) monotherapy is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other available treatment options. VENCLEXTA is indicated, in combination with azacitidine, or decitabine, or low- dose cytarabine for the treatment of newly diagnosed acute myeloid leukaemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
BRU20102940P	Mementor Tablets 20mg	Treatment of patients with moderate to severe Alzheimer's disease.
BRU20102941P	Menelat 30mg Tablets	Episode of major depression
BRU20102942NP	Uphalyte Salts	For replacement of water and electrolyte loss associated with diarrhoea and vomiting.
BRU20102943NP	Uphalyte Oral Rehydration Salts (Orange)	For replacement of water and electrolyte loss associated with diarrhoea and vomiting.
BRU20102944P	Zytiga 500mg Film-Coated Tablets	ZYTIGA is indicated with prednisone or prednisolone for • the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. • the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. ZYTIGA is also indicated in combination with prednisone or prednisolone and androgen deprivation therapy (ADT) for the treatment of patients with newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) who may have received up to 3 months of prior ADT.

BRU20102945PS1; BRU20102945PS2	Imfinzi (Durvalumab) Concentrate For Solution For Intravenous Infusion 50mg/ml	**Non-Small Cell Lung Cancer** IMFINZI is indicated for the treatment of patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. **Small Cell Lung Cancer (SCLC)** IMFINZI in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). **Biliary Tract Cancers (BTC)** IMFINZI in combination with gemcitabine-based chemotherapy is indicated for the treatment of patients with locally advanced or metastatic biliary tract cancer (BTC).
BRU20102946NP	CNI Fire-Sens Mentholated Rub	Provides symptomatic relief of muscle and joint pain, rheumatism, backache and sprains.
BRU20102947NP	UTIpure Effervescent Granules	INDICATIONS: • For relieving discomfort in mild urinary tract infections (UTI). • For symptomatic relief of dysuria (painful or difficult urination). • To enhance the action of certain antibiotics, especially sulphonamides. • For prevention of urates crystallization in gout therapy.
BRU20102948P	Defuzin Ointment 2% w/w	Defuzin is indicated for treatment of skin infections caused by staphylococci, streptococci, Propionibacterium acnes, Corynebacterium minutissimum and other organisms sensitive to Fusidic acid/Sodium Fusidate. The most important indications are impetigo, infected wounds, folliculitis, boils, sycosis barbae, carbuncles, hidradenitis, paronychia and erythrasma.
BRU20102949P	Cotren Vaginal Tablets 100mg	Vaginal infections caused by fungi-mainly candida and/or trichomonas.

BRU20102950P	Paclitaxel 6mg/ml Concentrate For Solution For Infusion	Paclitaxel 6 mg/ml concentrate for solution for infusion is indicated in adults. **Ovarian carcinoma**: in the first-line chemotherapy of ovarian cancer, paclitaxel is indicated for the treatment of patients with advanced carcinoma of the ovary or with residual disease (> 1 cm) after initial laparotomy, in combination with cisplatin. In the second-line chemotherapy of ovarian cancer, Paclitaxel is indicated for the treatment of metastatic carcinoma of the ovary after failure of standard, platinum containing therapy. **Breast carcinoma**: In the adjuvant setting, Paclitaxel is indicated for the treatment of patients with node-positive breast carcinoma following anthracycline and cyclophosphamide (AC) therapy. Adjuvant treatment with Paclitaxel should be regarded as an alternative to extended AC therapy. Paclitaxel is indicated for the initial treatment of locally advanced or metastatic breast cancer either in combination with an anthracycline in patients for whom anthracycline therapy is suitable, or in combination with trastuzumab, in patients who over-express HER-2 at a 3+level as determined by immunohistochemistry and for whom an anthracycline is not suitable (see section 4.4 and 5.1). As a single agent, Paclitaxel is indicated for the treatment of metastatic carcinoma of the breast in patients who have failed, or are not candidates for standard, anthracycline containing therapy. **Advanced non-small cell lung carcinoma**: Paclitaxel, in combination with cisplatin, is indicated for the treatment of non-small cell lung carcinoma (NSCLC) in patients who are not candidates for potentially curative surgery and/or radiation therapy. **AIDS-related Kaposi's sarcoma**: Paclitaxel is indicated for the treatment of patients with advanced AIDS-related Kaposi's sarcoma (KS) who have failed prior liposomal anthracycline therapy. Limited efficacy data supports this indication; a summary of the relevant studies is shown in section 5.1.
BRU20102951P	Bezartan Tablet 150mg	Treatment of essential hypertension. Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (>300 mg/day) in patients with type 2 diabetes and hypertension. In this population, Bezartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).
BRU20102952P	Bezartan Tablet 300mg	Treatment of essential hypertension. Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (>300 mg/day) in patients with type 2 diabetes and hypertension. In this population, Bezartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).
BRU20102953NP	Rexom Wina Calamine Lotion	For the relief of minor skin rashes and irritation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20102954P	Eberil 60 Film-Coated Tablet	Etoricoxib is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis. Etoricoxib is indicated in adults and adolescents 16 years of age and older for the short-term treatment of moderate pain associated with dental surgery. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.
BRU20102955P	Eberil 90 Film-Coated Tablet	Etoricoxib is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis. Etoricoxib is indicated in adults and adolescents 16 years of age and older for the short-term treatment of moderate pain associated with dental surgery. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.
BRU20102956P	Eberil 120 Film-Coated Tablet	Etoricoxib is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis. Etoricoxib is indicated in adults and adolescents 16 years of age and older for the short-term treatment of moderate pain associated with dental surgery. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.
BRU20122957P	Salbutamol 100mcg/Actuation HFA Metered Dose Inhaler	Salbutamol inhaler is indicated in the treatment and prophylaxis of bronchospasm in bronchial asthma, chronic bronchitis and emphysema.
BRU20122959P	Dimax MR 30mg Tablet	Gliclazide is indicated for the treatment of non-insulin dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose.

BRU20122960P	Imipenem/Cilastin Kabi 500mg/500mg Powder For Solution For Infusion	The activity of Imipenem/Cilastatin Kabi against an unusual broad spectrum of pathogens makes it particularly useful in the treatment of polymicrobic and mixed aerobic/anaroebic infections, as well as initial therapy prior to the identification of the causative organisms. Imipenem/Cilastatin Kabi is indicated for the treatment of the following infections due to susceptible organisms: •Intra-abdominal infections •Lower respiratory tract infections •Gynaecological infections •Septicaemia •Genitourinary tract infections •Bone and join infections •Skin and soft tissue infections •Endocarditis Imipenem/Cilastatin Kabi is indicated for the treatment of mixed infections caused by susceptible strains of aerobic and anaerobic bacteria. The majority of these mixed infections are associated with contamination by faecal flora and fauna originating from the vagina, skin and mouth. In these mixed infections, Bacteroides fragilis is the most commonly encountered anaerobic pathogen and is usually resistant to aminoglycosides, cephalosporins and penicillins. However, Bacteroides fragilis is usually susceptible to Imipenem/Cilastatin Kabi. Imipenem/Cilastatin Kabi has demonstrated efficacy against many infections caused by aerobic and anaroebic gram-positive and gram-negative bacteria resistant to the cephalosporins, including cefazolin, cefoperazone, cephalothin, cefoxitin, cefotaxime, moxalactam, cefamandole, ceftazidime and cefrioxone. Similarly, many infactions caused by organisms resistant to aminoglycosides (gentamicin, amikacin, tobramycin) and/or penicillin (ampicillin, carbenicillin, penicillin-G, ticarcillin, piperacillin, azlocillin, mezlocillin) responded to treatment with Imipenem/Cilastatin Kabi. Imipenem/Cilastatin Kabi is not indicated for the treatment of meningitis. Prophylaxis: Imipenem/Cilastatin Kabi is also indicated for the prevention of certain post-operative infections in patients undergoing contaminated or potentially contaminated surgical procedures or where the occurrence of post-operative infection could be especially serious.
BRU20122961NP	Actal Tablet	ACTAL Tablet is used for the relief of stomach discomfort such as indigestion, heartburn due to gastric hyperacidity (excessive acid) and peptic ulcer (an ulcer of the stomach, duodenum or lower end of esophagus).

BRU20122962P	Risperidone Mevon 1mg Tablet	RISPERIDONE is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERIDONE alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISPERIDONE is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISPERIDONE is indicated for the short-term treatment of persistent aggression in patients with moderate to severe dementia of the Alzheimer's type unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. RISPERIDONE is indicated for the treatment of behavioural disorders associated with autism (eg irritability, social withdrawal, stereotypic behaviour, hyperactivity and inappropriate speech) in children and adolescents. RISPERIDONE is also indicated for bipolar mania. Adjunctive therapy: RISPERIDONE is indicated as adjunctive therapy to mood stabilizers in the treatment of manic episodes associated with bipolar disorders. These episodes are characterized by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviors. Monotherapy: RISPERIDONE is indicated in the treatment of acute manic episodes associated with bipolar 1 disorder. The effectiveness of RISPERIDONE for more than 12 weeks of treatment of an acute episode, and for the prevention of new manic episodes has not been established. RISPERIDONE is indicated in the treatment of conduct and other disruptive behavior disorders in children (over 5 years), adolescents and adults with subaverage intellectual functioning or mental retardation in whom destructive behaviors (e.g. aggression, impulsivity and self-injurious behaviors) are prominent. As with all symptomatic treatments, the continued use of RISPERIDONE must be evaluated and justified on an ongoing basis.

BRU20122963P	Risperidone Mevon 2mg Tablet	RISPERIDONE is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERIDONE alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISPERIDONE is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISPERIDONE is indicated for the short-term treatment of persistent aggression in patients with moderate to severe dementia of the Alzheimer's type unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. RISPERIDONE is indicated for the treatment of behavioural disorders associated with autism (eg irritability, social withdrawal, stereotypic behaviour, hyperactivity and inappropriate speech) in children and adolescents. RISPERIDONE is also indicated for bipolar mania. Adjunctive therapy: RISPERIDONE is indicated as adjunctive therapy to mood stabilizers in the treatment of manic episodes associated with bipolar disorders. These episodes are characterized by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviors. Monotherapy: RISPERIDONE is indicated in the treatment of acute manic episodes associated with bipolar 1 disorder. The effectiveness of RISPERIDONE for more than 12 weeks of treatment of an acute episode, and for the prevention of new manic episodes has not been established. RISPERIDONE is indicated in the treatment of conduct and other disruptive behavior disorders in children (over 5 years), adolescents and adults with subaverage intellectual functioning or mental retardation in whom destructive behaviors (e.g. aggression, impulsivity and self-injurious behaviors) are prominent. As with all symptomatic treatments, the continued use of RISPERIDONE must be evaluated and justified on an ongoing basis.
BRU20122964P	Ator 20mg Film Coated Tablet	Hypercholesterolaemia: Ator is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Ator is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. Prevention of cardiovascular disease: Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20122965P	Onsia 4mg Tablet	•For the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. •For the prevention of post-operative nausea and vomiting; for treatment of established post-operative nausea and vomiting, administration by injection is recommended.
BRU20122966P	Piqray 200mg Film Coated Tablets	PIQRAY is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.
BRU20122967P	Piqray 250mg (200mg + 50mg) Film Coated Tablets	PIQRAY is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.
BRU20122968P	Piqray 300mg (150mg + 150mg) Film Coated Tablets	PIQRAY is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.
BRU20122969P	Siagran 50mg Tablet	Sumatriptan are indicated for the acute relief of migraine attacks with or without aura, including the acute treatment of migraine attacks associated with the menstrual period in women.
BRU20122970P	Vifas 60mg Tablet	VIFAS (60 MG TABLET) is indicated for relief of symptoms associated with allergic rhinitis in adult and children 6 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes. VIFAS (60 MG TABLET) is indicated for relief of symptoms associated with chronic idiopathic urticaria in adults and children 6 years of age and older.
BRU20122971P; BRU20122971PS2	Intacape Film Coated Tablet 500mg	Breast Cancer: INTACAPE in combination with docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. INTACAPE is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of a taxane and an anthracycline-containing chemotherapy regimen or for whom further anthracycline therapy is not indicated. Colorectal cancer: INTACAPE is indicated for the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. INTACAPE is indicated for the treatment of metastatic colorectal carcinoma. Gastric Cancer INTACAPE is indicated for first-line treatment of advanced gastric cancer in combination with a platinum-based regimen.

BRU20122972P; BRU20122972PS2	Intacape Film Coated Tablet 150mg	Breast Cancer: INTACAPE in combination with docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. INTACAPE is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of a taxane and an anthracycline-containing chemotherapy regimen or for whom further anthracycline therapy is not indicated. Colorectal cancer: INTACAPE is indicated for the adjuvant treatment of patients following surgery of stage III (Dukes' stage K2977:K2988C) colon cancer. INTACAPE is indicated for the treatment of metastatic colorectal carcinoma. Gastric Cancer INTACAPE is indicated for first-line treatment of advanced gastric cancer in combination with a platinum-based regimen.
BRU20122973P	Calcelar 25 Film Coated Tablet	Indicated for secondary hyperparathyroidism patients undergoing maintenance dialysis.
BRU20122974NP	Vemizol Suspension 200mg/5ml	Single or mixed infestations of intestinal parasites. Albendazole is effective in the treatment of Ascaris lumbricoides (roundworm), Trichuris trichiura (whipworm), Enterobius vermicularis (pinworm/threadworm), Ancylostoma duodenale and Necator americanus (hookworm), H. nana and Taenia sp (tapeworm), Strongyloides stercoralis and Opisthorchis viverrini and Opisthorchis sinensis.
BRU20122975NP	Actal Plus Tablet	ACTAL PLUS Tablet is used for the relief of pain and flatulence (wind) associated with gastric hyperacidity (excessive acid), heartburn, peptic ulcer (an ulcer of the stomach, duodenum or lower end of esophagus) and indigestion.
BRU20122976NP	Betadine PVP-I Antiseptic Liquid 10% w/v	Cuts and bruises. •Wounds and burns. •Bacterial and Mycotic (fungal) skin infections e.g. at groins, feet. Cold sores. •Herpes simplex, Herpes genitalis. •Disinfection of perineal wounds and skin. •Pre and post-operative disinfection and preparing of the skin.
BRU20122977P	Pregabalin Sandoz 150mg Capsules	•Neuropathic Pain: Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. •Epilepsy: As adjunctive therapy in adults with partial seizures with or without secondary generalisation. •Generalised Anxiety Disorder: Treatment of Generalised Anxiety Disorder (GAD) in adults. •Fibromyalgia: Management of fibromyalgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU20122978P	Levet 250mg Film-Coated Tablet	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy. Levetiracetam is indicated as adjunctive therapy in the treatment of: •Partial onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy. •Myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. •Primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy.
BRU20122979P	Levet 500mg Film-Coated Tablet	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy. Levetiracetam is indicated as adjunctive therapy in the treatment of: •Partial onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy. •Myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. •Primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy.
BRU20122980P	Siamik Injection 500mg	Amikacin is indicated in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, including Pseudomonas species. Although amikacin is not the drug of choice for infections due to staphylococci, at times it may be indicated for the treatment of known or suspected staphylococcal disease. These situations include: the initiation of therapy for severe infections when the organisms suspected are either Gram-negative or staphylococci, patients allergic to other antibiotics, and mixed staphylococcal/Gram-negative infections. Therapy with amikacin may be administered prior to obtaining the results of sensitivity testing. Surgical procedures should be performed where indicated. Consideration should be given to official guidance on the appropriate use of antibacterial agents.
BRU20122981P	Bonair HFA Inhaler 100mcg/Actuation	Bonair HFA inhaler provides short-acting (4 to 6 hour) bronchodilation with fast onset (within 5 minutes) in reversible airways obstruction. It is particularly suitable for the relief & prevention of asthma symptoms. It should be used to relieve symptoms when they occur, & to prevent them in circumstances recognized by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure). Bonair HFA inhaler is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction & use of regular inhaled corticosteroid therapy.
BRU20122982NP	Betadine Gargle & Mouth Wash	For minor irritation of the mouth and throat. Relief and prevention of painful infection as in pharyngitis, oral moniliasis, tonsillitis, aphthous ulcers, stomatitis, gingivitis, inflammatory conditions of the mouth & pharynx. Routine use to promote oral hygiene.

BRU20122983P	Invega Trinza 175mg/0.875ml Prolonged-Release Suspension For Intramuscular Injection	INVEGA TRINZA, a 3-month injection, is indicated for the maintenance treatment of schizophrenia in adult patients who have been adequately treated with the 1-month paliperidone palmitate injectable product for at least four months.
BRU20122984P	Invega Trinza 263mg/1.315ml Prolonged-Release Suspension For Intramuscular Injection	INVEGA TRINZA, a 3-month injection, is indicated for the maintenance treatment of schizophrenia in adult patients who have been adequately treated with the 1-month paliperidone palmitate injectable product for at least four months.
BRU20122985P	Invega Trinza 350mg/1.750ml Prolonged-Release Suspension For Intramuscular Injection	INVEGA TRINZA, a 3-month injection, is indicated for the maintenance treatment of schizophrenia in adult patients who have been adequately treated with the 1-month paliperidone palmitate injectable product for at least four months.
BRU20122986P	Invega Trinza 525mg/2.625ml Prolonged-Release Suspension For Intramuscular Injection	INVEGA TRINZA, a 3-month injection, is indicated for the maintenance treatment of schizophrenia in adult patients who have been adequately treated with the 1-month paliperidone palmitate injectable product for at least four months.
BRU20122987NP	Difflam AB Sore Throat Lozenges (Lemon)	For the symptomatic relief of mouth and throat infections
BRU20122988NP	Difflam AB Sore Throat Lozenges (Blackcurrant)	For the symptomatic relief of mouth and throat infections
BRU20122989NP	Difflam AB Sore Throat Lozenges (Orange)	For the symptomatic relief of mouth and throat infections
BRU20122990P	Oxitan Injection 5mg/ml	Oxaliplatin in combination with 5-fluorouracil (5-FU) and folinic acid (FA) is indicated for: • Adjuvant treatment of stage III (Dude's C) colon cancer after complete resection of primary tumor. • Treatment of metastatic colorectal cancer.
BRU20122991P	Bactricin Ointment 2% w/w	Treatment of bacterial skin infections, e.g. impetigo, folliculitis and furunculosis.
BRU21012992NP	Dermoplex Antifungal Cream	Treatment of fungal infections such as athlete's foot, ringworm, tinea versicolor (white spot) and jock (groin) itch. (Infections due to Trichophyton rubrum may relapse and a second course of treatment may be required).

BRU21012993P	Lipez Tablets 10mg	Primary Hypercholesterolemia LIPEZ, administered with an HMG-CoA reductase inhibitor (statin) or alone, is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C) and apolipoprotein B (Apo B) in patients with primary (heterozygous familial and non-familial) hypercholesterolemia. Homozygous Familial Hypercholesterolemia (HoFH) LIPEZ, administered with atorvastatin or simvastatin, is indicated for the reduction of elevated total-C and LDL-C levels in patients with HoFH, as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. Homozygous Sitosterolemia (Phytosterolemia) LIPEZ, is indicated as adjunctive therapy to diet for the reduction of elevated sitosterol and campesterol levels in patients with homozygous familial sitosterolemia.
BRU21012994NP	Avofer Injection 100mg/5ml	Avofer is indicated in the treatment of iron deficiency in the following indications: • Where there is a clinical need for a rapid iron supply • In patients who cannot tolerate oral iron therapy or who are non-compliant • Where oral iron preparations are ineffective (e.g., in active inflammatory bowel disease). Avofer should only be administered where the indication is confirmed by appropriate investigations.
BRU21012995P	Oxyla 10IU/ml Injection	Induction of labour for medical reasons (e.g. postmaturity, pre-mature rupture of the membranes, preeclampsia). Caesarean section following delivery of the infant. Prevention and treatment of postpartum haemorrhage associated with uterine atony.
BRU21012996P	Beclate-100 Inhaler (CFC Free)	Beclate CFC free inhaler is indicated in the maintenance treatment of asthma as prophylactic therapy. It is also indicated for asthma patients who require systemic corticosteroid administration, where adding Beclate CFC free inhaler may reduce or eliminate the need for the systemic corticosteroids. Beclate is NOT indicated for the relief of acute bronchospasm.
BRU21012997P	Azadine Azacitidine For Injection 100mg/vial	Azadine is indicated for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation with: • Intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS), • Chronic myelomonocytic leukaemia (CMML) with 10-29 % marrow blasts without myeloproliferative disorder, • Acute myeloid leukaemia (AML) with 20-30 % blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification. Azadine is indicated for the treatment of adult patients aged 65 years or older who are not eligible for HSCT with AML with >30% marrow blasts according to the WHO classification.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21012998P	Growell Scalp Lotion 5% w/v	Growell is used to treat male pattern hair loss in man and woman by rejuvenating hair follicles and stimulating hair growth. The preparation is intended for use in patients suffering from hair loss of hereditary type only. Consult your doctor or pharmacist to ensure that this treatment is appropriate for your type of hair loss.
BRU21012999NP	Eucalyptus Oil Kangaroo Brand	Common Colds For Wind and Flatulence For Muscle Stiffness, Minor Bruises and Minor Sprains
BRU21013000NP	Lion Ball Corn Remover Solution 20% w/v	For the treatment of corns, warts and callouses
BRU21033001P	Euthyrox 75mcg Tablet	• Treatment of benign euthyroid goitre. • Prophylaxis of relapse after surgery for euthyroid goitre. • Substitution therapy in hypothyroidism. • Concomitant therapy during anti-thyroid medicinal treatment of hyperthyroidism. • Suppression therapy in thyroid cancer. Applies only to tablets of 100 micrograms: • Diagnostic use for thyroid suppression testing.
BRU21033002P	ONTREX 500mg Powder For Concentrate For Solution For Infusion	<u>Malignant Pleural Mesothelioma:</u> ONTREX in combination with cisplatin is indicated for the treatment of chemotherapy naive patients with unresectable malignant pleural mesothelioma. <u>Non-small Cell Lung Cancer:</u> ONTREX in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. ONTREX is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. ONTREX is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic non- small cell lung cancer other than predominantly squamous cell histology.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21033003P	Rinvoq 15mg Extended Release Tablets	Rheumatoid arthritis RINVOQ® is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). RINVOQ® may be used as monotherapy or in combination with methotrexate. Psoriatic arthritis RINVOQ® is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. RINVOQ® may be used as monotherapy or in combination with methotrexate. Atopic dermatitis RINVOQ is indicated for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. Ankylosing Spondylitis (AS, radiographic axial spondyloarthritis) RINVOQ is indicated for the treatment of active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy.
BRU21033004P	Metrolex (Solution For Injection) 500mg/100ml	• Prevention of postoperative infections due to sensitive anaerobic bacteria particularly species of bacteroides and anaerobic streptococcus. • For the treatment of severe infection which sensitive anaerobic bacteria particularly bacteriodes and anaerobic are suspected to be the cause.
BRU21033005P	Atracurium Kalceks 10mg/ml Solution For Injection/Infusion	Atracurium is a highly selective, competitive or non-depolarising neuromuscular blocking agent which is used as an adjunct to general anaesthesia to enable tracheal intubation to be performed and to relax skeletal muscles during surgery or controlled ventilation, and to facilitate mechanical ventilation in Intensive Care Unit (ICU) patients.
BRU21033006P	Pemcord 500 Powder For Solution For Infusion 500mg/Vial	Malignant pleural mesothelioma Pemcord in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. Non-small cell lung cancer Pemcord in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-squamous non-small cell lung cancer. Pemcord is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-squamous non-small cell lung cancer in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemcord is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-squamous non-small cell lung cancer.

BRU21033007P	Zoledronic Acid Kabi 4mg/5ml Concentrate For Solution For Infusion	• Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in patients with advanced malignancies involving bone. • Treatment of hypercalcaemia of malignancy (HCM).
BRU21033008P	Seroflo-125 Inhaler	Reversible Obstructive Airways Disease (ROAD) Seroflo Inhaler (CFC Free) is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination bronchodilator and inhaled corticosteroid is appropriate. This may include: • Patients on effective maintenance doses of long -acting beta-agonists and inhaled corticosteroids. • Patients who are symptomatic on current inhaled corticosteroid therapy. • Patients on regular bronchodilator therapy who require inhaled corticosteroids. Chronic Obstructive Pulmonary Disease (COPD) Seroflo Inhaler (CFC Free) is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU21033009P	Seroflo-250 Inhaler	Reversible Obstructive Airways Disease (ROAD) Seroflo Inhaler (CFC Free) is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination bronchodilator and inhaled corticosteroid is appropriate. This may include: • Patients on effective maintenance doses of long -acting beta-agonists and inhaled corticosteroids. • Patients who are symptomatic on current inhaled corticosteroid therapy. • Patients on regular bronchodilator therapy who require inhaled corticosteroids. Chronic Obstructive Pulmonary Disease (COPD) Seroflo Inhaler (CFC Free) is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21033010P	Plazilin Injection BP 5mg/mL, 2mL Ampoule	Adult population PLAZILIN is indicated for use in adults for: • Prevention of post-operative nausea and vomiting. • Symptomatic treatment of nausea and vomiting, including nausea and vomiting induced by migraine attacks. • Prevention of radiotherapy induced nausea and vomiting. Pediatric population PLAZILIN is indicated in children aged 1 to 18 years for: • Prevention of delayed Chemotherapy induced nausea and vomiting as a second-line option. • Prevention of postoperative nausea and vomiting as a second-line option.
BRU21033011P	Rocuronium Kabi 10mg/ml Solution For Injection/Infusion	Rocuronium Kabi is indicated as an adjunct to general anaesthesia to facilitate endotracheal intubation, to provide skeletal muscle relaxation and to facilitate mechanical ventilation in adults, children and infants from one month of age. Rocuronium Kabi is also indicated as an adjunct in the intensive care unit (ICU) to facilitate mechanical ventilation as part of Rapid Sequence Induction, however, this has not been studied in infants and children.
BRU21033012P	Chloramphenicol Ear Drops 5% w/v	Infections of the ear caused by organisms susceptible to Chloramphenicol.

BRU21033013P	Ciflox Film-Coated Tablet 500mg	<u>Uncomplicated and complicated infections caused by ciprofloxacin sensitive pathogens:</u> • Infections of the respiratory tract In the treatment of outpatients with pneumonia due to Pneumococcus, ciprofloxacin should not be used as a first choice of drug. Ciprofloxacin can be regarded as an advisable treatment for pneumonias* caused by Klebsiella, Enterobacter, Proteus, E. coli, Pseudomonas, Haemophilus, Branhamella, Legionella, and Staphylococcus. • Infections of the middle ear (otitis media*), of the paranasal sinuses (sinusitis*), especially if these are caused by gram negative organisms including Pseudomonas or by Staphylococcus. • Infections of the eyes • Infections of the kidneys and/or the efferent urinary tract* • Infections of the genital organs, including adnexitis, gonnorhoea, prostatitis • Infections of the abdominal cavity (e.g. infections of the gastrointestinal tract or of the biliary tract, peritonitis) • Infections of the skin and soft tissue • Infections of the bones and joints • Sepsis* • Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or have neutropenia) *'Ciflox' Film-Coated Tablet should only be used: • When Pseudomonas is considered AND the patient is allergic to antipseudomonal penicillin/cephalosporins; • For resistant organisms with no other alternative antibiotics available <u>Inhalational anthrax (post-exposure) in adults and in children:</u> To reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis.
BRU21033014P	Bicalox 50mg Film Coated Tablet	Treatment of advanced prostate cancer in combination with luteinising hormone-releasing hormone (LHRH) analogue therapy or surgical castration.

BRU21033015PS1; BRU21033015PS2	Zepilen 1G Powder For Solution For Injection/Infusion	'Zepilen' is indicated for the treatment of the following infections caused by susceptible bacteria: • Biliary tract infections • Bone and joint infections • Endocarditis • Genito-urinary tract infections • Respiratory tract infections • Skin and soft tissue infections • Septicaemia It may also be used as a prophylactic, for perioperative administration to patients undergoing contaminated or potentially contaminated surgical procedures (hysterectomy, cholecystectomy, open heart surgery, bone and joint surgery), or in whom postoperative infection would be serious. In such cases it may reduce the incidence of postoperative infection. Cefazolin, in vitro, is active against: Gram positive organisms: Staphylococcus aureus (both penicillin sensitive and resistant), Staphylococcus epidermidis, group A β-haemolytic streptococci, and other strains of streptococci (many enterococci strains are resistant), Streptococci pneumoniae. Gram negative organisms: Enterobacter aerogenes, Escherichia coli, Haemophilus influenzae, Klebsiella sp., Proteus mirabilis.
BRU21033016P	Bonky Soft Capsule	• Osteoporosis • Rickets, osteomalacia (vitamin D dependent rickets, hypophosphatemic vitamin D resistant rickets) • Hypoparathyroidism (postoperative, idiopathic hypoparathyroidism, pseudohypoparathyroidism) • Patients with chronic renal failure. particularly renal osteodystrophy in patients undergoing hemodialysis.
BRU21033017P	Zithrolide Tablet 250mg	Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infection including bronchitis and pneumonia – skin and soft tissue infections – acute otitis media – upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present). In sexually transmitted disease in men and women, azithromycin is indicated in the treatment of uncomplicated genital infections due to Chlamydia trachomatis. It is also indicated in the treatment of Chancroid due to H.ducreyi and uncomplicated genital infection due to non-multiresistant Neisseria gonorrhoea, concurrent infection with Treponema pallidum should be excluded. Azithromycin is indicated, either alone or in combination with rifabutin, for prophylaxis against Mycobacterium avium-intracellulare complex (MAC) infection, an opportunistic infection prevalent in patients with advanced human immunodeficiency virus (HIV). Azithromycin is indicated in combination with ethambutol for the treatment of disseminated MAC (DMAC) infection in patients with advanced HIV infection.

BRU21033018P	Lynparza Film-Coated Tablets 100mg	<u>Ovarian cancer</u> Lynparza is indicated as monotherapy for the: • maintenance treatment of adult patients with advanced (FIGO stages III and IV) *BRCA1/2* -mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. • maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Lynparza is indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: • a deleterious or suspected deleterious BRCA mutation, and/or • genomic instability <u>Breast cancer</u> Lynparza is indicated as monotherapy for the treatment of adult patients with germline *BRCA1/2* -mutations, who have HER2 negative metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the neoadjuvant, adjuvant or metastatic setting unless patients were not suitable for these treatments (see section 5.1). Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy. <u>Pancreatic cancer</u> Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreaticc adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. <u>Prostate cancer</u> Lynparza is indicated as monotherapy for the treatment of adult patients with deleterious or suspected deleterious germline and/or somatic BRCA or ATM mutated metastatic castration resistant prostate cancer (mCRPC) who have progressed following prior treatment with a new hormonal agent (e.g. abiraterone or enzalutamide).

BRU21033019P	Lynparza Film-Coated Tablets 150mg	<u>Ovarian cancer</u> Lynparza is indicated as monotherapy for the: • maintenance treatment of adult patients with advanced (FIGO stages III and IV) *BRCA1/2* -mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. • maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Lynparza is indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: • a deleterious or suspected deleterious BRCA mutation, and/or • genomic instability <u>Breast cancer</u> Lynparza is indicated as monotherapy for the treatment of adult patients with germline *BRCA1/2* -mutations, who have HER2 negative metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the neoadjuvant, adjuvant or metastatic setting unless patients were not suitable for these treatments (see section 5.1). Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy. <u>Pancreatic cancer</u> Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreaticc adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. <u>Prostate cancer</u> Lynparza is indicated as monotherapy for the treatment of adult patients with deleterious or suspected deleterious germline and/or somatic BRCA or ATM mutated metastatic castration resistant prostate cancer (mCRPC) who have progressed following prior treatment with a new hormonal agent (e.g. abiraterone or enzalutamide).
BRU21033020P	Meropenem Kabi 500mg Powder For Solution For Injection Or Infusion	Meropenem IV is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem • Pneumonias and Nosocomial pneumonias • Urinary Tract Infections • Intra-abdominal Infections • Gynaecological Infections, such as endometritis and pelvic inflammatory disease • Bacterial Meningitis Septicaemia • Empiric treatment, for presumed infections in patients with febrile neutropenia, used as monotherapy or in combination with anti-viral or anti-fungal agents. Meropenem IV has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.

BRU21033021P	Yulareb 50mg Film-Coated Tablets	**1.1 Early Breast Cancer** YULAREB ™ (abemaciclib) is indicated: • YULAREB in combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence [see *Dosage and Administration (2.1) and Clinical Studies (14.1)*]. • In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. **1.2 Advanced or Metastatic Breast Cancer** YULAREB ™ (abemaciclib) is indicated: • in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. • in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advance or metastatic breast cancer with disease progression following endocrine therapy.
BRU21033022P	Yulareb 100mg Film-Coated Tablets	**1.1 Early Breast Cancer** YULAREB ™ (abemaciclib) is indicated: • YULAREB in combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence [see *Dosage and Administration (2.1) and Clinical Studies (14.1)*]. • In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. **1.2 Advanced or Metastatic Breast Cancer** YULAREB ™ (abemaciclib) is indicated: • in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. • in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advance or metastatic breast cancer with disease progression following endocrine therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21033023P	Yulareb 150mg Film-Coated Tablets	**1.1 Early Breast Cancer** YULAREB ™ (abemaciclib) is indicated: • YULAREB in combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence [see *Dosage and Administration (2.1) and Clinical Studies (14.1)*]. • In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. **1.2 Advanced or Metastatic Breast Cancer** YULAREB ™ (abemaciclib) is indicated: • in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. • in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advance or metastatic breast cancer with disease progression following endocrine therapy.
BRU21033024NP	Betadine Antiseptic Ointment 10% w/w	• Cuts and bruises • Burns • Bacterial and Mycotic (fungal) skin infections eg. at groins, feet • Cold sores • Herpes simplex, Herpes genitalis • Disinfection of skin for catheterization.
BRU21043025P	Nebilet Tablet	<u>Hypertension</u> Treatment of essential hypertension. <u>Chronic heart failure (CHF)</u> Treatment of stable mild and moderate chronic heart failure in addition to standard therapies in elderly patients ≥ 70 years
BRU21043026P	Trozet Tablet 2.5mg	Trozet (letrozole tablets) is indicated for: • The Adjuvant treatment of post menopausal women with hormone receptor positive early breast cancer. • The extended adjuvant treatment of early breast cancer in postmenopausal women cancer (positive or unknown oestrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy. • Treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy. • Pre-operative therapy in postmenopausal women with localized hormone receptor positive breast cancer to allow subsequent breast-conserving surgery in women not originally considered candidate for this type of surgery. Subsequent treatment after surgery should be in accordance with slandered of care. • First-line treatment for postmenopausal women with hormone-dependent advanced breast cancer.

BRU21043027P	Docetaxel Injection Concentrate 20mg/ml (Daxotel)	<u>Breast cancer</u> Docetaxel in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with: • operable node negative breast cancer. For patients with operable node-negative breast cancer, adjuvant treatment should be restricted to patients eligible to receive chemotherapy according to internationally established criteria for primary therapy of early breast cancer. Docetaxel in combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition. Docetaxel monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic therapy. Previous chemotherapy should have included an anthracycline or an alkylating agent. Docetaxel in combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. <u>Non-small cell lung cancer</u> Docetaxel is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior chemotherapy. Docetaxel in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer, in patients who have not previously received chemotherapy for this condition. <u>Prostate cancer</u> Docetaxel in combination with prednisone or prednisolone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer. <u>Gastric adenocarcinoma</u> Docetaxel in combination with cisplatin and 5 fluorouracil is indicated for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease. <u>Ovarian Cancer</u> Docetaxel is indicated for the treatment of metastatic carcinoma of the ovary after failure of first-line or subsequent chemotherapy. <u>Squamous Cell Carcinoma of the Head and Neck</u> Docetaxel is indicated as monotherapy in the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck after failure of a previous chemotherapy regimen. Docetaxel in combination with cisplatin and 5 fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

BRU21043028NP	B.Braun 0.9% Sodium Chloride Intravenous Infusion B.P.	• Fluid and electrolyte substitution in hypochloraemic alkalosis, • Sodium deficiency, • Chloride losses, • Short-term intravascular volume substitution, • Hypotonic dehydration or isotonic dehydration, • Vehicle solution for compatible electrolyte concentrates and medicinal products, • Externally for wound irrigation and for moistening of wound tamponades and dressings.
BRU21043029P	Pharmaniaga Phenytoin Sodium 250mg/5ml Injection	Phenytoin Sodium Injection is indicated for the control of status epilepticus of the tonic-clonic (grand mal) type and prevention and treatment of seizures occurring during or following neurosurgery.
BRU21043030P	Talzenna Capsule 0.25mg	TALZENNA is indicated for the treatment of adult patients with germline breast cancer susceptibility gene (BRCA) mutated human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer who have previously been treated with chemotherapy. These patients could have received chemotherapy in the neoadjuvant, adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments.
BRU21043031P	Talzenna Capsule 1mg	TALZENNA is indicated for the treatment of adult patients with germline breast cancer susceptibility gene (BRCA) mutated human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer who have previously been treated with chemotherapy. These patients could have received chemotherapy in the neoadjuvant, adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments.
BRU21043032P	Virox Tablet 400mg	Herpes simplex virus infections Treatment of herpes simplex virus infections of the skin and mucous membranes, including initial and recurrent genital herpes. Suppression (prevention of recurrence) of recurrent herpes simplex infections in immunocompetent patients. Prophylaxis of herpes simplex infections in immune-compromised patients. Varicella (Chickenpox) and herpes zoster infections Treatment of varicella (chickenpox) and herpes zoster (shingles) infections in immunocompromised and normally immune individuals. Studies have shown that early treatment of shingles with Acyclovir has a beneficial effect on pain and can reduce the incidence of post-herpetic neuralgia (zoster-associated pain).
BRU21043033P	Difflam Anti-Inflammatory Anti-Bacteria Lozenges (Honey Lemon)	For the temporary relief of painful conditions of the oral cavity including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, post-orosurgical and periodontal procedures, pharyngitis, swelling, redness and inflammatory conditions.
BRU21053034P	Notrixum Injection 10mg/ml	Atracurium Besylate is a highly selective, competitive or non-depolarizing neuromuscular-blocking agent which is used as an adjunct to general anaesthesia to enable tracheal intubations to be performed and to relax skeletal muscles during surgery or controlled ventilation; to facilitate mechanical ventilation in Intensive Care Unit (ICU) patients.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21053035P	Farsorbid Injection 1mg/ml	Isosorbide dinitrate is indicated in the treatment of unresponsive left ventricular failure of various etiologies, including left ventricular failure secondary to acute myocardial infarction. It is also indicated in the management of severe or unstable angina pectoris
BRU21053036NP	Zentel Tablet 200mg	Treatment of roundworm infection (ascariasis), whipworm infection (trichuriasis), hookworm disease (ancylostomiasis and necatoriasis), pinworm infection (enterobiasis), threadworm infection (strongyloidiasis), and tapeworm infection (hymenolepsiasis and taeniasis).
BRU21053038NP	Gelofusine® Solution for Infusion	As a colloidal volume substitute for, • prophylaxis and treatment of absolute and relative hypovolaemia (e.g. following shock due to haemorrhage or trauma, peri-operative blood losses, burns, sepsis) • prophylaxis of hypotension (e.g. in connection with induction of epidural or spinal anaesthesia) • haemodilution • extra-corporeal circulation (heart-lung machine, haemodialysis).
BRU21053039P	Trulicity 0.75mg Solution For Injection In Pre-Filled Pen	Type 2 Diabetes Mellitus Trulicity is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications • in addition to other medicinal products for the treatment of diabetes.
BRU21053040P	Trulicity 1.5mg Solution For Injection In Pre-Filled Pen	Type 2 Diabetes Mellitus Trulicity is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications • in addition to other medicinal products for the treatment of diabetes.
BRU21053041P	Gemcitabine For Injection USP 1G (Gemita)	Gemcitabine is indicated for the treatment of locally advanced or metastatic non-small cell-lung cancer. Gemcitabine is indicated for the treatment of adult patients with locally advanced or metastatic adrenocarcinoma of the pancreas. Gemcitabine is indicated for patients with 5-FU refractory pancreatic cancer. Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/ neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.
BRU21053042NP	Difflam HEXTRA™ Sore Throat Lozenges 2.4mg	As an antiseptic and local anaesthetic for the relief of sore throat and its associated pain.
BRU21053043NP	Cogesic Max Cream	COGESIC MAX Cream is indicated for the fast relief of Muscular & Joint Pains, Backache, Strains & Sprains and Leg Cramps.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21073044P	Apo-Theo LA Tablet 200mg	APO-THEO LA (theophylline) tablets are indicated for the symptomatic treatment of reversible bronchospasm associated with asthma, chronic bronchitis, emphysema and related bronchospastic disorders.
BRU21073045NP	Rexom Mist. Magnesium Trisilicate	It is indicated for symptomatic relief of stomach upset associated with hyperacidity (heartburn, acid indigestion, and sour stomach); hyperacidity associated with gastric and duodenal ulcers and in the management of reflux esophagitis.
BRU21073046P	Iotim Eye Drops 0.5%	Iotim ED is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open angle glaucoma.
BRU21073047NP	Balsem Gosok – Balsem Merah Cap Betet	Relief of simple backache, stiff neck, rheumatism, stiff, strained, painful muscles, and itchiness caused by insect bites.
BRU21073048NP	Balsem Gosok – Balsem Hijau Cap Betet	Relief of simple backache, stiff neck, rheumatism, stiff, strained, painful muscles, and itchiness caused by insect bites.
BRU21073049NP	Salonpas	For relief of aches and pains associated with: • Muscle fatigue • Muscle pain • Stiff shoulder • Simple backache • Bruises • Sprains • Strains • Arthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21073050P	Koact Tablet 625mg	Co-amoxiclav is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other beta-lactam antibiotic. Co-amoxiclav oral preparations are indicated for short-term treatment of bacterial infections at the following sites when amoxicillin resistant beta-lactamase producing strains are suspected as the cause. In other situations, amoxicillin alone should be considered. Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media. Lower respiratory tract infections e.g. acute exacerbation of chronic bronchitis, lobar and bronchopneumonia. Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis. Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections. Mixed infections caused by amoxicillin-susceptible organisms in conjunction with Co-amoxiclav-susceptible beta-lactamase-producing organisms may be treated with Co-amoxiclav. These infections should not require the addition of another antibiotic resistance to beta-lactamases.
BRU21073051NP	Guardian Fever & Pain Relief Tablet 500mg	Guardian fever & pain relief tablet is an analgesic and antipyretic agent which relieves fever, headache and muscular pain caused by cold and flu.
BRU21073052NP	B. Braun 5% Glucose Intravenous Infusion B.P.	Energy supply Hypertonic dehydration Vehicle solution for supplementary medication.
BRU21073053NP	Infusol® M20	• Prophylaxis of acute renal failure. • Post operative oliguria. • In forced diuresis for elimination toxic substances via the kidneys. • For decreasing intracranial pressure in case of cerebral oedema.

BRU21073054P	Simvacor Film-Coated Tablet 40mg	REDUCTIONS IN RISK OF CORONARY HEART DISEASE (CHD) MORTALITY AND CARDIOVCASCULAR EVENTS: In patients at high risk of coronary events because of existing CHD, history of stroke or other cerebrovascular disease, simvastatin is indicated to: reduce the risk of total mortality by reducing CHD deaths, reduce the risk of non-fatal myocardial infarction and stroke, reduce the need for coronary and non-coronary revascularization procedures. HYPERLIPIDEMIA: As an adjunct to diet to reduce elevated total-C, LDL-C, Apo B, and TG, and to increase HDL-C in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia, homozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate, Simvastatin, therefore, lowers the LDL-C/HDL-C and the total LDL-C/HDL-C ratios. PEDIATRIC PATIENTS WITH HETEROZYGOUS FAMILAL HYPERCHOLESTEROLEMIA: As an adjunct to diet to reduce total-C, LDL-C, TG, and Apo B levels in adolescent boys and girls who are at least one year post-menarche, 10-17 years of age, with heterozygous familial hypercholesterolemia (HeFH). GENERAL RECOMMENDATIONS: Prior to initiating therapy with simvastatin, secondary causes of hypercholesterolemia (e.g. poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemias, obstructive liver disease, other drug therapy, alcoholism) should be identified and treated.
BRU21073055P	UNIREN Gel	Treatment of: • Localized forms of soft-tissue rheumatism, e.g. tendovaginitis, shoulder-hand syndrome, bursitis, and peri-arthropathy. • Localized rheumatic disease, e.g. osteoarthritis of the spine and peripheral joints; • Post-traumatic inflammation of the tendons, ligaments, muscles, and joints, e.g. due to sprains, strains or bruises.
BRU21073056NP	BETADINE® Feminine Wash With Douching Apparatus	BETADINE® feminine wash is effective in: • Management of trichomonas vaginalis, vaginitis, monilial vaginitis and non-specific vaginitis; • Symptomatic relief of minor vaginal soreness, irritation, itching; • Cleansing and deodorizing after menstruation (Douching is not recommended during pregnancy); • Washing out vaginal medication, if so instructed by the physician; • Deodorizing and washing out the accumulations of normal secretions; • Removing contraceptive creams and jellies; • Cleansing the vaginal vault after sexual relations (Remember: It is cleanser, not a contraceptive); • Providing a refreshing feeling of being confidently clean.
BRU21073057P	Difflam Mouth Gel	Temporarily relieves painful inflamed conditions of the mouth, including mouth and denture ulcers and sore gum.
BRU21073058P	Pharmaniaga Labetalol Hydrochloride 25mg/5ml Injection	• Severe hypertension, including severe hypertension of pregnancy, when rapid control of blood pressure is essential. • Anaesthesia when a hypotensive technique is indicated • Hypertensive episode following acute myocardial infarction.

BRU21073059P	Z Mox Oral Suspension 250mg/5ml	Z MOX is useful in the treatment of infections caused by amoxicillin susceptible organisms: Respiratory tract infections • Upper airways and ENT infections • Lower airways infections, e.g. acute and chronic bronchitis, pneumonia, lung abscess, pertussis (incubation period and early stages) Urogenital infections • Acute and chronic pyelonephritis, pyelitis, prostatitis, epididymitis • Cystitis, urethritis, asymptomatic bacteriuria during pregnancy • Gonorrhoea Gynaecologic infections (septic abortion, adnexitis, endometritis, etc.) Gastro-intestinal infections • Typhoid fever, paratyphoid, particularly if complicated by septicemia (in combination with an aminoglycoside antibiotic); control of salmonella carriers • Shigellosis • Infections of the biliary system (cholangitis, cholecystitis) Skin and soft tissue infections Leptospirosis Acute and latent listeriosis Unless parenteral treatment (e.g. with ampicillin) is required, Z MOX is also active in the conditions below: • Short-term (24 to 48 hrs) prophylactic treatment of patients undergoing surgery (e.g. in the oral cavity) • Endocarditis, e.g. enterococcal endocarditis (alone or in combination with an aminoglycoside antibiotic) • Bacterial meningitis (pending the outcome of susceptibility test; particularly in children) • Septicemias caused by amoxicillin-susceptible pathogens. Infections caused by pathogens with established penicillin G susceptibility should preferentially be treated with penicillin G
BRU21073060NP	Nature’s Way Glucosamine HCL 1500mg	Nature's Way Glucosamine HCL 1500mg can help relieve symptoms of mild osteoarthritis such as mild joint pain, soreness, and stiffness by helping reduce mild inflammation in joints. Nature's Way Glucosamine HCL 1500mg helps support • Healthy joint function • Healthy joint cartilage growth • Healthy ligaments and tendons • Connective tissue health • Joint mobility and flexibility.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21073061P	Hovid Hoftrex Injection 1g	For treatment of the following infections caused by susceptible organisms: •Bone and joint infections •Uncomplicated gonorrhoea •Intra-abdominal infections •Lyme disease •Meningitis •Otitis media
BRU21073062NP	Wina Aqueous Cream	For topical application to the skin: As an emollient for the symptomatic relief of dry skin conditions. As a soap-substitute for skin washing
BRU21073063NP	Dermoplex Bite And Sting Cream	Dermoplex Bite and Sting Cream can be used to provide soothing relief of itching and pain due to:- •Minor burns •Minor skin irritations •Insect and mosquito bites •Scrapes and abrasions •Rashes •Shaving •Pimples
BRU21073064NP	SALONPAS Patch	For relief of aches and pains associated with: •Muscle fatigue •Muscle pain •Stiff shoulder •Simple backache •Bruises •Sprains •Strains •Arthritis
BRU21073065NP	Paracil Suspension 120mg/5ml	1. Relief of fever and discomfort associated with the common cold and flu. 2. Relief of teething pain, toothache and earache

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21073066NP	Uphamol 650 Tablet	It can be used to relieve the symptoms of various types of headaches including migraine and tension-type headache. Uphamol 650 can also be used to relieve pain due to colds and flu and to reduce fever.
BRU21073067P	Ramtace Tablet 5mg	1. Hypertension. 2. Congestive heart failure. 3. Treatment of patients who within the first few days after an acute myocardial infarction have demonstrated clinical signs of congestive heart failure. 4. For reducing the risk of myocardial infarction, stroke, cardiovascular death or the need for revascularization procedures in patients ≥ 55 years who have clinical evidence of coronary artery disease, stroke or peripheral vascular disease. 5. For reducing the risk of myocardial infarction, stroke, cardiovascular death or revascularization procedures in diabetic patients ≥ 55 years with ≥ 1 of the following risk factors: Systolic blood pressure > 160 mm Hg or diastolic blood pressure > 90 mm Hg (or on antihypertensive treatment); total cholesterol > 5.2 mmol/L; HDL cholesterol < 0.9 mmol/L; current smoker; known microalbuminuria; any evidence of previous vascular disease. 6. Prevention of progressive renal failure in patients with persistent proteinuria.
BRU21073068P	Lecetam 500 Film-Coated Tablet	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in adults and adolescents from 16 years of age with newly diagnosed epilepsy. Levetiracetam is indicated as adjunctive therapy in the treatment of: 1. partial onset seizures with or without secondary generalization in adults, adolescents and children from 1 month of age with epilepsy. 2. myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. 3. primary generalized tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalized Epilepsy.
BRU21073069P	Fentanyl Kalceks 0.05mg/ml Solution For Injection	Fentanyl is a short acting opioid used: • as an intravenous analgesic agent in surgical procedures; • as an adjunct in the maintenance of general anaesthesia; • in combination with a neuroleptic agent in the technique of neuroleptanalgesia; • as a respiratory depressant/analgesic in patients requiring prolonged assisted ventilation; • for induction of anaesthesia.
BRU21073070P	Leucovorin Calcium Injection USP 50mg/5ml	Leucovorin Calcium Injection is indicated: a) to diminish the toxicity and counteract the effects of inadvertently administered over dosage of folic acid antagonists, b) as a rescue after high dose methotrexate therapy. c) in the treatment of megaloblastic anaemia due to sprue, nutritional deficiency, pregnancy and infancy when oral therapy is not possible and, d) for use in combination with fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer;
BRU21073071NP	DifflamAB™ Sore Throat Lozenges (Honey Lemon)	For the symptomatic relief of mouth and throat infections.

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BRU21073072P	Difflam Anti-Inflammatory 3mg Lozenges	For the temporary relief of painful conditions of the oral cavity including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, post-orosurgical and periodontal procedures, pharyngitis, swelling, redness and in¬flammatory conditions.
BRU21073073NP	Dequadin Lozenges 0.25mg	For symptomatic relief of sore throat.
BRU21073074P	Axcel Amlodipine-10mg Tablet	Amlodipine is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with the thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme inhibitor. Amlodipine is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/ vasoconstriction (Prinzmetal's or variant angina) or coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but where vasospasm/ vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta blockers.
BRU21093075NP	Infusol® HM	Replacement of extracellular fluid loss (isotonic dehydration), sodium depletion, light metabolic acidosis and electrolyte substitution in burns.
BRU21093076NP	Daflon 1000mg Film-Coated Tablet	Treatment of symptoms related to venolymphatic insufficiency (heavy legs, pain, early morning restless legs). Treatment of functional symptoms related to acute hemorrhoidal
BRU21093077P	Avonox Tablet 10mg	Indications are limited to treatment of severe sleep disorders in the following cases: -Occasional insomnia -Transient insomnia
BRU21093078P	Ipraneb 500 (Ipratropium Bromide 500mcg/2ml Nebuliser Solution BP)	Maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. Used concomitantly with inhaled beta-agonists in the treatment of acute bronchospasm associated with chronic obstructive pulmonary disease including chronic bronchitis and asthma. IPRANEB is indicated, when used concomitantly with inhaled beta-agonists in the treatment of reversible airways obstruction as in acute and chronic asthma.

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BRU21093079P	Enerzair® Breezhaler® 150mcg/50mcg/160mcg Inhalation Powder, Hard Capsule	Enerzair Breezhaler is indicated as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.
BRU21093080P	Atectura® Breezhaler® 150mcg/80mcg Inhalation Powder, Hard Capsules	Atectura Breezhaler is indicated as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2-agonists.
BRU21093081P	Atectura® Breezhaler® 150mcg/160mcg Inhalation Powder, Hard Capsules	Atectura Breezhaler is indicated as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2-agonists.
BRU21093082P	Atectura® Breezhaler® 150mcg/320mcg Inhalation Powder, Hard Capsules	Atectura Breezhaler is indicated as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2-agonists.
BRU21093083P	Vastarel XR 80mg Prolonged-Release Hard Capsules	Trimetazidine is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line antianginal therapies.
BRU21093084NP	Lactus Syrup 66% w/v	1. Treatment of constipation: it encourages bowel movement by drawing water into the bowel from surrounding body tissues. This provides soft stool mass and increased bowel action. It may take up to 48 hours to take effect. 2. Helps in the treatment of hepatic encephalopathy: it reduces the amount of ammonia in the blood.
BRU21093085NP	Natural Wellness Aqueous Cream	As an emollient for the symptomatic relief of dry skin conditions As a soap substitute for skin washing.

BRU21093086P	Revcox 200mg Capsule	Management of acute pain in adults and for the treatment of primary dysmenorrhoea. Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis. Relief of signs and symptoms of ankylosing spondylitis. For the management of low back pain
BRU21093087P	Rovas-10 Film-Coated Tablet 10mg	Rosuvastatin is indicated for patients with primary hypercholesterolemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb; and heterozygous familial hypercholesterolemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin is indicated to treat patients with primary dysbetalipoproteinemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. Rosuvastatin also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. Rosuvastatin is also indicated in patients with homozygous familial hypercholesterolemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: Rosuvastatin is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, Rosuvastatin is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures. Rosuvastatin is indicated in children and adolescents 10 to 17 years of age as an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. Paediatric studies were conducted mainly in the non-Asian population and data on Asian children/adolescents is limited.

BRU21093088P	Rovas-20 Film-Coated Tablet 20mg	Rosuvastatin is indicated for patients with primary hypercholesterolemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb; and heterozygous familial hypercholesterolemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin is indicated to treat patients with primary dysbetalipoproteinemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. Rosuvastatin also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. Rosuvastatin is also indicated in patients with homozygous familial hypercholesterolemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: Rosuvastatin is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, Rosuvastatin is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures. Rosuvastatin is indicated in children and adolescents 10 to 17 years of age as an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. Paediatric studies were conducted mainly in the non-Asian population and data on Asian children/adolescents is limited.
BRU21093089NP	Shine J-Care Cream	Relief of joint and muscle pain, sprains, strains, pain associated with rheumatism and arthritis. Temporary relief of pain associated with musculoskeletal soreness and discomfort
BRU21093090P	Flutinide Nasal Spray 50mcg/Dose	For prophylaxis and treatment of allergic rhinitis.
BRU21093091P	Hovid-Celecoxib Capsule 200mg	For the management of acute pain in adults and for the treatment of primary dysmenorrhoea. Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis. Relief of signs and symptoms of ankylosing spondylitis. For the management of low back pain

BRU21103092NP	Ammeltz Yoko Yoko	Stiffness, Muscular ache, Joint pain, Limb languor, Bruise, Sprain, Loin pain and Chilblain.
BRU21103093P	Truxima 100mg/10ml Concentrate For Solution For Infusion	Truxima® is indicated for the treatment of patients with relapsed or chemoresistant indolent B-cell non-Hodgkin's lymphomas. Truxima® is indicated for the treatment of patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma (DLCL) in combination with CHOP (cyclophosphamide, doxorubicin vincristine and prednisone) chemotherapy. Truxima® is indicated for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. Truxima® maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy. Chronic Lymphocytic Leukaemia Truxima® is indicated in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL. Rheumatoid Arthritis Truxima® in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumour necrosis factor (TNF) inhibitor therapies
BRU21103094P	Truxima 500mg/50ml Concentrate For Solution For Infusion	Truxima® is indicated for the treatment of patients with relapsed or chemoresistant indolent B-cell non-Hodgkin's lymphomas. Truxima® is indicated for the treatment of patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma (DLCL) in combination with CHOP (cyclophosphamide, doxorubicin vincristine and prednisone) chemotherapy. Truxima® is indicated for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. Truxima® maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy. Chronic Lymphocytic Leukaemia Truxima® is indicated in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL. Rheumatoid Arthritis Truxima® in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumour necrosis factor (TNF) inhibitor therapies

BRU21103095P	Ogivri 440mg Powder For Concentrate For Solution For Infusion	Adjuvant Breast Cancer Ogivri™ is indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature [see Clinical Studies) breast cancer • as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel • as part of a treatment regimen with docetaxel and carboplatin • as a single agent following multi-modality anthracycline based therapy. Metastatic Breast Cancer Ogivri™ is indicated: • In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer. • As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease Metastatic Gastric Cancer Ogivri™ is indicated, in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease.
BRU21103096P	Omeprazole-Otto	Omeprazole is the treatment of choice for conditions when oral administration is not possible: reflux esophagitis, duodenal ulcer, gastric ulcer, and Zollinger-Ellison syndrome.
BRU21103098P	ONRON 4 Solution For Injection 2mg/mL	Adults: Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, Prevention and treatment of post-operative nausea and vomiting (PONV). Paediatric Population: Management of chemotherapy-induced nausea and vomiting. Prevention and treatment of post-operative nausea and vomiting.

BRU21103099P	Textas 80 Concentrate For Solution For Infusion 20mg/ml	Breast cancer Docetaxel Injection in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with: •Operable node-positive breast cancer •Operable node-negative breast cancer For patients with operable node-negative breast cancer, adjuvant treatment should be restricted to patients eligible to receive chemotherapy according to internationally established criteria for primary therapy of early breast cancer. Non-small cell lung cancer Docetaxel Injection is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer. Prostate cancer Docetaxel Injection in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer. Gastric adenocarcinoma Docetaxel Injection in combination with Cisplatin and 5-fluorouracil is indicated for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease. Head and neck cancer Docetaxel Injection in combination with Cisplatin and 5-fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.
BRU21103100P	ONRON 8 Solution For Injection 2mg/mL	Adults: Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, Prevention and treatment of post-operative nausea and vomiting (PONV). Paediatric Population: Management of chemotherapy-induced nausea and vomiting. Prevention and treatment of post-operative nausea and vomiting.

BRU21103101P	Nisolon Tablet 5mg	Collagen diseases: (eg. rheumatoid arthritis, acute rheumatic fever, SLE). Allergic diseases: (such as severe bronchial asthma, intractable allergic rhinitis, exfoliative dermatitis, serum sickness, and other acute drug reactions). Generalised dermatosis having an allergic component (eg. contact dermatitis, neurodermatitis, allergic eczema). Acute ocular inflammatory disease involving structures in the posterior segment (such as uveitis, chorioretinitis in vital areas, sympathetic ophthalmia). Certain lymphatic neoplastic diseases (to induce temporary remission). Various chronic or recurrent diseases of unknown aetiology such as ulcerative colitis and nephrosis. Since Nisolon lacks significant mineralocorticoid activity in usual therapeutic doses, it is not adequate for acute adrenocortical insufficiency. Adrenocortical steroids, hydrocortisone and cortisone should be used. Whenever corticosteroid therapy is indicated.
BRU21103102P	Prelica Capsule 75mg	Neuropathic pain Prelica is indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Prelica is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization. Generalized Anxiety Disorder Prelica is indicated for the treatment of Generalized Anxiety Disorder (GAD) in adults. Fibromyalgia Prelica is indicated for the management of fibromyalgia.
BRU21103103P	Prelica Capsule 150mg	Neuropathic pain Prelica is indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Prelica is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization. Generalized Anxiety Disorder Prelica is indicated for the treatment of Generalized Anxiety Disorder (GAD) in adults. Fibromyalgia Prelica is indicated for the management of fibromyalgia.

BRU21103104P	Zexate-50 Injection	Antineoplastic chemotherapy Methotrexate has a broad spectrum of antineoplastic activity. It is indicated for the treatment of breast cancer, gestational choriocarcinoma, and in patients with chorioadenoma destruens and hydatidiform mole. Methotrexate may be used in combination with other chemotherapeutic agents for the palliative treatment of acute leukaemias, particularly acute lymphoblastic leukaemia. It may also be used in the treatment of Burkitt lymphoma, advanced stages (III and IV, Petersa Staging System) of lymphosarcoma, especially in children, and in advanced cases of mycosis fungoides. High dose therapy In high-dose schedules, methotrexate may be effective alone or in combination therapy, in the treatment of epidermoid cancers of the head and neck, osteogenic sarcoma and bronchogenic carcinoma. Calcium folinate (leucovorin calcium) must be used in conjunction with high dose methotrexate therapy. Psoriasis chemotherapy Methotrexate may be of value in the symptomatic control of severe, recalcitrant, disabling psoriasis which is not adequately responsive to other forms of treatment. However, due to the high risk associated with its use, methotrexate should be used after the diagnosis has been definitely established, as by biopsy and/or after dermatologic consultation. Rheumatoid arthritis chemotherapy Management of severe, recalcitrant, active rheumatoid arthritis in adults not responding to, or intolerant of, an adequate trial of NSAIDs and one or more disease modifying drugs. Aspirin, NSAIDs and/or low dose steroids may be continued, although the possibility of increased toxicity with concomitant use of NSAIDs including salicylate has not been fully explored. Steroids may be reduced gradually in patients who respond to methotrexate. Combined use of methotrexate with gold, penicillamine, hydroxychloroquine, sulfasalazine or cytotoxic agents has not been studied and may increase the incidence of adverse effects. Rest and physiotherapy as indicated should be continued.
BRU21103105NP	Minyak Angin Menthol Oil (MAMO)	Helps to relieve headaches, blocked nose, insect bites, stomach ache and motion sickness.
BRU21103106NP	Shine Hepavite Forte Capsule	As an adjunct in the treatment of the following diseases such as chronic liver diseases, liver cirrhosis, fatty liver and intoxication by hepatotoxic substance.
BRU21103107NP	Gascovid Advance Liquid	Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn, indigestion occurring to the reflux of stomach contents, for instance, after gastric surgery, as a result of hiatus hernia, during pregnancy or accompanying reflux oesophagitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21103108P	Pharmaniaga Bupivacaine Hydrochloride 0.5% w/v Injection	Bupivacaine Hydrochloride 0.5% w/v Injection are indicated for the production of local or regional anaesthesia and analgesia in individuals as follows: - Surgical anaesthesia •Epidural block for surgery •Field block (minor and major nerve blocks and infiltration) Analgesia •Continuous epidural infusion or intermittent bolus epidural administration for analgesia in postoperative pain or labour pain •Field block (minor nerve block and infiltration).
BRU21103109P	Iqnyde Tablet 100mg	Iqnyde is indicated for the treatment of erectile dysfunction in adult males, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.
BRU21103110P	Simvacor Film Coated Tablet 20mg	In patients at high risk of coronary events because of existing CHD, history of stroke or other cerebrovascular disease, simvastatin is indicated to: reduce the risk of total mortality by reducing CHD deaths, reduce the risk of non-fatal myocardial infarction and stroke, reduce the need for coronary and non-coronary revascularization procedures. HYPERLIPIDEMIA: As an adjunct to diet to reduce elevated total-C, LDL-C, Apo B, and TG, and to increase HDL-C in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia, homozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate, Simvastatin, therefore, lowers the LDL-C/HDL-C and the total-C/HDL-C ratios. PEDIATRIC PATIENTS WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA: As an adjunct to diet to reduce total-C, LDL-C, TG, and Apo B levels in adolescent boys and girls who are at least one year post-menarche, 10-17 years of age, with heterozygous familial hypercholesterolemia (HeFH). GENERAL RECOMMENDATIONS: Prior to initiating therapy with simvastatin, secondary causes of hypercholesterolemia (e.g. poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemias, obstructive liver disease, other drug therapy, alcoholism) should be identified and treated.

BRU21103111P	Atswift 10 Tablet	Hypercholesterolaemia Atorvastatin Tablets is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin Tablets is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. Prevention of cardiovascular disease Atorvastatin Tablets is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥55 years, male sex, smoking, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminia or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥6, or premature family history of coronary heart disease. In adults with type 2 diabetes and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, Atorvastatin Tablet is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In adults with clinically evident coronary heart disease, atorvastatin is indicated to: - Reduce the risk of non-fatal myocardial infarction - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for CHF - Reduce the risk of angina.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21103112P	Atswift 20 Tablet	Hypercholesterolaemia Atorvastatin Tablets is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin Tablets is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. Prevention of cardiovascular disease Atorvastatin Tablets is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥55 years, male sex, smoking, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminia or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥6, or premature family history of coronary heart disease. In adults with type 2 diabetes and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, Atorvastatin Tablet is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In adults with clinically evident coronary heart disease, atorvastatin is indicated to: - Reduce the risk of non-fatal myocardial infarction - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for CHF - Reduce the risk of angina.
BRU21103113NP	Octenisept® Antiseptic Solution	Wound treatment •Antiseptic treatment of traumatic, acute, chronic, surgical and burn wounds Mucous membrane antiseptic •Prior to diagnostic and surgical interventions in the anogenital (e.g. before obliteration of haemorrids), the urogenital area (e.g. before placing an intra-uterine device (IUD), the vaginal area, before prenatal, intranatal and postnatal manipulations) and in the oral cavity (e.g. before tooth extractions) •Before placing urinary tract catheters •For preop. skin antisepsis in the area close to mucous membranes.
BRU21103114P	Allergo-Comod Eye Drops	Indicated in acute and chronic allergic conjunctivitis including hay-fever conjunctivitis, vernal keratoconjunctivitis.

BRU21103115P	Privigen Solution For Infusion 10%	Replacement therapy in • *Primary immunodeficiency syndromes (PID)* such as: – congenital agammaglobulinaemia and hypogammaglobulinaemia – common variable immunodeficiency – severe combined immunodeficiency – Wiskott-Aldrich syndrome • *Myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infection* s • *Children with congenital AIDS and recurrent infections* Immunomodulation • *Immune thrombocytopenic purpura (ITP) in children or adults at high risk of bleeding or prior to surgical interventions to correct the platelet count* • *Guillain-Barré syndrome* • *Kawasaki disease* • *Chronic inflammatory demyelinating polyneuropathy (CIDP)* Allogeneic bone marrow transplantation

BRU21103116PS1; BRU21103116PS2	Celmantin 10mg Film-Coated Tablet	CELMANTIN is indicated for patients with primary hypercholesterolaemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb; and heterozygous familial hypercholesterolaemia) as an adjunct to diet when response to diet and exercise is inadequate. CELMANTIN is indicated to treat patients with primary dysbetalipoproteinaemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. Rosuvastatin also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. CELMANTIN is also indicated in patients with homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: CELMANTIN is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, CELMANTIN is indicated to: • Reduce the risk of stroke • Reduce the risk of myocardial infarction • Reduce the risk of arterial revascularization procedures CELMANTIN is indicated in children and adolescents 10 to 17 years of age as an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year postmenarche, 10-17 years of age with heterozygous familial hypercholesterolaemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. Paediatric studies were conducted mainly in the non-Asian population and data on Asian children/adolescents is limited.

BRU21103117PS1; BRU21103117PS2	Celmantin 20mg Film-Coated Tablet	CELMANTIN is indicated for patients with primary hypercholesterolaemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb; and heterozygous familial hypercholesterolaemia) as an adjunct to diet when response to diet and exercise is inadequate. CELMANTIN is indicated to treat patients with primary dysbetalipoproteinaemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. Rosuvastatin also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. CELMANTIN is also indicated in patients with homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: CELMANTIN is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, CELMANTIN is indicated to: • Reduce the risk of stroke • Reduce the risk of myocardial infarction • Reduce the risk of arterial revascularization procedures CELMANTIN is indicated in children and adolescents 10 to 17 years of age as an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year postmenarche, 10-17 years of age with heterozygous familial hypercholesterolaemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. Paediatric studies were conducted mainly in the non-Asian population and data on Asian children/adolescents is limited.
BRU21103118NP	Siang Pure Relief Cream	For relief of muscle pain.
BRU21103119NP	Hot Minyak Gosok Cap Betet (Parrot Brand Hot Medicated Oil)	Relieve flatulence, muscle pain, sprain, joint stiffness, itchiness caused by insects bites and warm the body
BRU21103120P	Moxied-CLV Injection 600mg	i) Urinary Tract Infections ii) Respiratory Tract Infections iii) ENT Infections iv) Skin and Soft Tissue Infections

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21103121P	Moxied-CLV Injection 1.2g	i) Urinary Tract Infections ii) Respiratory Tract Infections iii) ENT Infections iv) Skin and Soft Tissue Infections
BRU21103122P	Pharmaniaga Ephedrine Hydrochloride 30mg/ml Injection	Treatment of bronchial spasm in asthma, adjunct to correct haemodynamic imbalances and treat hypotension in epidural and spinal anaesthesia.
BRU21103123NP	Ainiron (Iron Sucrose Injection 20mg/ml)	AINIRON is indicated for the treatment of iron deficiency anaemia in the following indications:- •Where there is a clinical need for a rapid iron supply, •In patients who cannot tolerate oral iron therapy or who are non-compliant, •In active inflammatory bowel disease where oral iron preparations are ineffective. AINIRON should only be administered where the indication is confirmed by appropriate investigations (e.g. Hb, serum ferritin, serum iron).
BRU21103124NP	Eagle Medicated Oil	Helps to relieve symptoms of common cold, giddiness, motion sickness, nausea, muscle fatigue and itching due to mosquito & insect bites.
BRU21103125NP	Minyak Gandapura	Helps to relieve pains associated with muscles and joints, aching joints and sprains. Thi product is also good for warming up purposes for sports persons.

BRU21103126P	Rosuccord 10 Film-Coated Tablet 10mg	ROSUCCORD is indicated for patients with primary hypercholesterolaemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb) as an adjunct to diet when response to diet and exercise is inadequate. ROSUCCORD is indicated to treat patients with primary dysbetalipoproteinaemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. ROSUCCORD reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. ROSUCCORD also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. ROSUCCORD is also indicated in patients with homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: ROSUCCORD is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, ROSUCCORD is indicated to: •Reduce the risk of stroke •Reduce the risk of myocardial infarction •Reduce the risk of arterial revascularization procedures.

BRU21103127P	Rosuccord 20 Film-Coated Tablet 20mg	ROSUCCORD is indicated for patients with primary hypercholesterolaemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb) as an adjunct to diet when response to diet and exercise is inadequate. ROSUCCORD is indicated to treat patients with primary dysbetalipoproteinaemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. ROSUCCORD reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. ROSUCCORD also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. ROSUCCORD is also indicated in patients with homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: ROSUCCORD is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, ROSUCCORD is indicated to: •Reduce the risk of stroke •Reduce the risk of myocardial infarction •Reduce the risk of arterial revascularization procedures.
BRU21103128NP	NW Povidone Iodine 10% w/v Solution	Use to prevent and treat infections that may occur in minor scrapes and cuts.
BRU21103129NP	NW Calamine Lotion With 0.25% w/w Menthol	NW Calamine Lotion with 0.25% w/w Menthol is used to soothe and relieve nappy rashes, prickly heat, minor skin irritations, insect bites and sunburn, pruritic skin conditions.
BRU21103130P	Rekaxime Injection 500mg	Infections of the respiratory tract, including throat and nose; of the ear; of the kidneys and urinary tract; of the skin and soft tissues; of the bones and joints; of the genital organs, including gonorrhoea; of the abdominal region. Septicaemia, bacterial endocarditis, meningitis; for perioperative prophylaxis in patients who are at increased risk from infection, and for the prophylaxis of infections in patients with reduced resistance.

BRU21103131P	Surotin 10mg Tablet	•As an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol (HDL-cholesterol ratio and triglycerides) and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: Prevention of cardiovascular events in adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers such as an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease. Rosuvastatin is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, MI, unstable angina or arterial revascularization). •As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia). •Primary hypercholesterolaemia (Type IIa including heterozygous familial hypercholesterolaemia and severe non-familial hypercholesterolaemia). •Combined (mixed) dyslipidemia (Type IIb). •Homozygous familial hypercholesterolaemia where rosuvastatin is used either alone or as an adjunct to diet and other lipid lowering treatment such as apheresis. • As an adjunct therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels. •Paediatric Patients (10-17 years) with Heterozygous Familial Hypercholesterolemia (HeFH): As an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C >190 mg/dL or >160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or ≥2 other CVD risk factors.

BRU21103132P	Surotin 20mg Tablet	•As an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol (HDL-cholesterol ratio and triglycerides) and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: Prevention of cardiovascular events in adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers such as an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease. Rosuvastatin is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, MI, unstable angina or arterial revascularization). •As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia). •Primary hypercholesterolaemia (Type IIa including heterozygous familial hypercholesterolaemia and severe non-familial hypercholesterolaemia). •Combined (mixed) dyslipidemia (Type IIb). •Homozygous familial hypercholesterolaemia where rosuvastatin is used either alone or as an adjunct to diet and other lipid lowering treatment such as apheresis. • As an adjunct therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels. •Paediatric Patients (10-17 years) with Heterozygous Familial Hypercholesterolemia (HeFH): As an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C >190 mg/dL or >160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or ≥2 other CVD risk factors.
BRU21103133P	Irstran® Film-Coated Tablet 150mg	1. For the treatment of essential hypertension. 2. For treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (> 300 mg/day) in patients with type 2 diabetes and hypertension. In this population, Irbesartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).

BRU21103134P	Xolair 75mg/0.5ml Solution For Injection In Pre-Filled Syringe	Allergic Asthma Adults and adolescents (12 years of age and above) Xolair (omalizumab) is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids (ICS). Children (6 to < 12 years of age) Xolair is indicated as add-on therapy to improve asthma control with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions. Chronic rhinosinusitis with nasal polyps (CRSwNP) Xolair is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with CRSwNP for whom therapy with INC does not provide adequate disease control. Chronic Spontaneous Urticaria (CSU) Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.

BRU21103135P	Xolair 150mg/ml Solution For Injection In Pre-filled Syringe	Allergic Asthma Adults and adolescents (12 years of age and above) Xolair (omalizumab) is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids (ICS). Children (6 to < 12 years of age) Xolair is indicated as add-on therapy to improve asthma control with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions. Chronic rhinosinusitis with nasal polyps (CRSwNP) Xolair is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with CRSwNP for whom therapy with INC does not provide adequate disease control. Chronic Spontaneous Urticaria (CSU) Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.
BRU21103136P	Besanta 300mg Tablet	BESANTA® is indicated in adults for the treatment of essential hypertension. It is also indicated for the treatment of diabetic nephropathy in adult patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.
BRU21103137P	Besanta 150mg Tablet	BESANTA® is indicated in adults for the treatment of essential hypertension. It is also indicated for the treatment of diabetic nephropathy in adult patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.
BRU21103138P	Fucon Syrup 1mg/ml	Gastro-intestinal tract spasm, spasm and dyskinesia of the biliary system, genito-urinary tract spasm.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21103139P	Orata 1 Film-Coated Tablet	Entecavir is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with: •Compensated liver disease and evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis. •Decompensated liver disease. For both compensated and decompensated liver disease, this indication is based on clinical trial data in nucleoside naïve patients with HBeAg positive and HBeAg negative HBV infection. With respect to patients with Lamivudine-refractory hepatitis B, see Dosage and Administration, Precaution and Mechanism of Action sections. Entecavir is also indicated for the treatment of chronic HBV infection in nucleoside naïve pediatric patients from 2 to <18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis. With respect to the decision to initiate treatment in pediatric patients, see Dosage and Administration, Precaution and Mechanism of Action sections
BRU21103140P	Ericox 90mg Tablets	Etoricoxib is indicated for: • Acute and chronic treatment of the signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA) • Treatment of ankylosing spondylitis (AS) • Treatment of acute gouty arthritis • Treatment of acute pain, including that related to primary dysmenorrhoea and minor dental procedures. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks

BRU21103141P	Pharmaniaga Simvastatin Tablet 40mg	Reductions in risk of coronary heart disease (CHD) mortality and cardiovascular events In patients at high risk of coronary events because of existing coronary heart disease, diabetes, peripheral vessel disease, history of stroke or other cerebrovascular disease, simvastatin is indicated to: •Reduce the risk of total mortality by reducing CHD deaths. •Reduce the risk of non-fatal myocardial infarction and stroke. •Reduce the need for coronary and non-coronary revascularization procedures. Hyperlipidemia Simvastatin is indicated as an adjunct to diet to reduce elevated total plasma cholesterol (total-C), low-density lipoprotein (LDL-C), apolipoprotein B (Apo B), and triglycerides (TG) and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate. Simvastatin therefore, lowers the LDL-C/HDL-C and the total-C/HDL-C ratios. Pediatric patients with heterozygous familial hypercholesterolemia Simvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, TG, and Apo B levels in adolescent boys and girls who are at least one year post-menarche, 10-17 years of age, with heterozygous familial hypercholesterolemia (HeFH).
BRU21103142P	Irstran® Film-Coated Tablet 300mg	1.For the treatment of essential hypertension. 2.For treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (> 300 mg/day) in patients with type 2 diabetes and hypertension. In this population, Irbesartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).
BRU21123143P	Amoxigran Granules	For treatment of: • Ear, nose and throat infections caused by streptococci, pneumococci, nonpenicillinase – producing staphylococci and *H. influenzae* . • Genitourinary tract infections caused by *E. coli, P. mirabilis, S. faecalis* . • Skin and soft tissues infections caused by streptococci, nonpenicillinase - producing staphylococci and *E. coli* . • Anogenital and urethral gonorrhoea caused by *N. gonorrhoeae* .
BRU21123144P	Nalopril 5mg Tablet	• Treatment of hypertension • Treatment of symptomatic heart failure • Prevention of symptomatic heart failure in patients with asymptomatic left ventricular dysfunction (ejection fraction ≤ 35%)

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21123145P	Flonoxin 400mg Tablet	Moxifloxacin tablets are indicated for treatment of adults (≥ 18 years of age) with the following bacterial infections caused by susceptible strains: • Acute bacterial sinusitis • Acute exacerbations of chronic bronchitis • Community acquired pneumonia • Mild to moderately severe inflammatory pelvic diseases (i.e. infections of the upper female genital tract, including salpingitis and endometritis) without an associated tubo-ovarian or pelvic abscess. Moxifloxacin is not recommended for monotherapy of mild to moderately severe inflammatory pelvic diseases. Preferably, they should be administered in combination with another suited antibiotic (e.g.: cephalosporin), due to the increasing resistance of Neisseria gonorrhoeae to moxifloxacin; that is, unless moxifloxacin-resistant Neisseria gonorrhoeae can be ruled out. • Complicated skin and skin structure infections • Complicated intraabdominal infections including polymicrobial such as abscesses Consideration should be given to official guidance on the appropriate use of antibacterial agents.
BRU21123146NP	Ranofer Injection 100mg/5ml	Ranofer is indicated for the treatment of iron deficiency anaemia in the following indications: • Where there is a clinical need for a rapid iron supply, • In patients who cannot tolerate oral iron therapy or who are non-compliant, • In active inflammatory bowel disease where oral iron preparations are ineffective. Ranofer should only be administered where the indication is confirmed by appropriate investigations (e.g. Hb, serum ferritin, serum iron)

BRU21123147P	Linezolid Sandoz Film-Coated Tablet 600mg	Linezolid formulations are indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms. Linezolid is active against Gram-positive bacteria only. Linezolid has no clinical activity against Gram-negative pathogens. Specific Gram-negative therapy is required if a concomitant Gram-negative pathogen is documented or suspected. Vancomycin-Resistant *Enterococcus faecium* infections, including cases with concurrent bacteremia. Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and –resistant strains), or *Streptococcus pneumonia* (penicillin-susceptible strains). Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms. Complicated skin and skin structure infections including diabetic foot infections, without concomitant osteomyelitis caused by *Staphylococcus aureus* (methicillin-susceptible and –resistant strains), *Streptococcus pyogenes* , or, *Streptococcus agalactiae* . Linezolid has not been studied in the treatment of decubitus ulcers. Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms. Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible only) or *Streptococcus pyogenes* . Community-acquired pneumonia caused by *Streptococcus pneumoniae* (penicillin-susceptible strains only), including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible strains only). Due to concerns about inappropriate use of antibiotics leading to an increase in resistant organisms, prescribers should carefully consider alternatives before initiating treatment with linezolid in the outpatient setting. Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to linezolid. Therapy may be instituted empirically while awaiting the results of these tests. Once these results become available, antimicrobial therapy should be adjusted accordingly.
BRU21123148P	Dexmedetomidine Kabi 0.1mg/ml Concentrate For Infusion	***Intensive Care Unit Sedation*** : Dexmedetomidine hydrochloride is indicated for sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting. Dexmedetomidine hydrochloride should be administered by continuous infusion not to exceed 24 hours. Dexmedetomidine hydrochloride has been continuously infused in mechanically ventilated patients prior to extubation, during extubation, and post-extubation. It is not necessary to discontinue Dexmedetomidine hydrochloride prior to extubation. **Procedural Sedation**: Dexmedetomidine hydrochloride is indicated for sedation of non-intubated patients prior to and/or during surgical and other procedures.

BRU21123149P	Rosuvastatin Sandoz 10mg Film-Coated Tablet	As an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol: HDL-cholesterol ratio and triglycerides and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: Prevention of Cardiovascular Events: In adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers e.g., an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease. Rosuvastatin Sandoz is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, myocardial infarction (MI), unstable angina, or arterial revascularization). As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (type III hyperlipoproteinemia). Primary hypercholesterolaemia. Combined (mixed) dyslipidemia (type IIb). Homozygous familial hypercholesterolaemia where Rosuvastatin Sandoz is used either alone or as an adjunct to diet, and other lipid-lowering treatment e.g., apheresis. As adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total-C and LDL-C to target levels.
BRU21123150P	Rosuvastatin Sandoz 20mg Film-Coated Tablet	As an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol: HDL-cholesterol ratio and triglycerides and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: Prevention of Cardiovascular Events: In adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers e.g., an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease. Rosuvastatin Sandoz is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, myocardial infarction (MI), unstable angina, or arterial revascularization). As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (type III hyperlipoproteinemia). Primary hypercholesterolaemia. Combined (mixed) dyslipidemia (type IIb). Homozygous familial hypercholesterolaemia where Rosuvastatin Sandoz is used either alone or as an adjunct to diet, and other lipid-lowering treatment e.g., apheresis. As adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total-C and LDL-C to target levels.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21123151P	GABTIN 300	GABTIN is an antiepileptic used as monotherapy or adjunctive therapy in the treatment of partial seizures with or without secondary generalisation. Gabapentin is also used in the treatment of neuropathic pain.
BRU21123152NP	Promag Tablet	Symptomatic relief of excess stomach acid associated with ulcers or dyspepsia such as heartburn, nausea, bloating and stomach pain.
BRU21123153P	Lydocan Injection 2%	To be used for most major nerve blocks, e.g. sciatic and retrobulbar.
BRU21123154P	Tabrecta™ 150mg Film-Coated Tablets	TABRECTA is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping.
BRU21123155P	Tabrecta™ 200mg Film-Coated Tablets	TABRECTA is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping.

BRU21123156P	Remsima Powder For Concentrate For Solution For Infusion 100mg/Vial	**Rheumatoid Arthritis** REMSIMA®, in combination with methotrexate (MTX), is indicated for: The reduction of signs and symptoms as well as the improvement in physical function in - patients with active disease when the response to disease modifying drugs, including methotrexate, has been inadequate. - patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. In these patient populations, a reduction in the rate of the progression of joint damage, as measured by x ray, has been demonstrated. **Crohn's Disease** REMSIMA® is indicated for: - Treatment of moderately to severely active Crohn s disease, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and an immunosuppressant: or who are intolerant to or have medical contraindications for such therapies. - Treatment of fistulising Crohn s disease, in patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). **Paediatric Crohn's Disease** REMSIMA® is indicated for: Treatment of severe, active Crohn s disease, in paediatric patients aged 6 to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. REMSIMA® has been studied only in combination with conventional immunosuppressive therapy. **Ulcerative Colitis** REMSIMA® is indicated for: Treatment of moderately to severely active ulcerative colitis in patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Paediatric Ulcerative Colitis** REMSIMA® is indicated for: Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy. **Ankylosing Spondylitis** REMSIMA® is indicated for: Treatment of ankylosing spondylitis, in patients who have severe axial symptoms, elevated serological markers of inflammatory activity and who have responded inadequately to conventional therapy. **Psoriatic Arthritis** REMSIMA®, in combination with methotrexate, is indicated for: Treatment of active and progressive psoriatic arthritis in patients who have responded inadequately to disease-modifying anti-rheumatoid drugs. **Psoriasis** REMSIMA® is indicated for: Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen ultraviolet A (PUVA).

BRU21123157P	Herzuma 440mg Powder For Concentrate For Solution For Infusion	*Metastatic Breast Cancer (MBC)* Herzuma® is indicated for the treatment of patients with metastatic breast cancer who have tumors that overexpress HER2: a) as monotherapy for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease b) in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease c) in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive metastatic breast cancer, not previously treated with trastuzumab. This indication is based on data from one Phase III trial which studied the use of Herzuma® in combination with anastrozole (see 3.1.2 Clinical/ Efficacy Studies). Experience with other aromatase inhibitors is limited. *Early Breast Cancer (EBC)* Herzuma® is indicated for the treatment of patients with HER2 positive early breast cancer. - following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable). - following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel. - in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin. - in combination with neoadjuvant chemotherapy followed by adjuvant Herzuma® therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter. Herzuma® should only be used in patients whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay. *Metastatic Gastric Cancer (MGC)* Herzuma® in combination with capecitabine or 5-fluorouracil and cisplatin is indicated for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro- esophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Herzuma® should only be used in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.

BRU21123158P	Herzuma 150mg Powder For Concentrate For Solution For Infusion	*Metastatic Breast Cancer (MBC)* Herzuma® is indicated for the treatment of patients with metastatic breast cancer who have tumors that overexpress HER2: a) as monotherapy for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease b) in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease c) in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive metastatic breast cancer, not previously treated with trastuzumab. This indication is based on data from one Phase III trial which studied the use of Herzuma® in combination with anastrozole (see 3.1.2 Clinical/ Efficacy Studies). Experience with other aromatase inhibitors is limited. *Early Breast Cancer (EBC)* Herzuma® is indicated for the treatment of patients with HER2 positive early breast cancer. - following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable). - following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel. - in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin. - in combination with neoadjuvant chemotherapy followed by adjuvant Herzuma® therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter. Herzuma® should only be used in patients whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay. *Metastatic Gastric Cancer (MGC)* Herzuma® in combination with capecitabine or 5-fluorouracil and cisplatin is indicated for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro- esophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Herzuma® should only be used in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.
BRU21123159P	Pregeb Capsules 150mg	<u>Neuropathic pain</u> Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. <u>Epilepsy</u> Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. <u>Generalised Anxiety Disorder</u> Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21123160NP	Salonpas 30 Patch	For relief of aches and pains associated with: •Muscle fatigue • Muscle pain • Stiff shoulder • Simple backache •Bruises •Sprains •Strains • Arthritis
BRU21123161P	Adrim Injection 50mg/25ml	ADRIM® has been used successfully to produce regression in neoplastic conditions such as: acute leukaemia, Wilms' tumour, neuroblastoma, soft tissue and bone sarcomas, breast carcinoma, lymphomas of both Hodgkin's and non-Hodgkin's type, bronchogenic (lung) carcinoma, thyroid carcinoma, hepatomas, ovarian carcinoma, etc. The main antitumour activities are listed below. ADRIM® is also indicated by intravesical administration in the primary management of non-metastatic carcinoma of the bladder. (Tis, T1, T2) (refer to PI).
BRU21123162P	Cymbalox 60mg Delayed Release Capsules	Treatment of major depressive disorder. Management of Neuropathic pain associated with diabetic peripheral neuropathy in adults. Treatment of generalised anxiety disorder.
BRU21123163P	Cymbalox 30mg Delayed Release Capsules	Treatment of major depressive disorder. Management of Neuropathic pain associated with diabetic peripheral neuropathy in adults. Treatment of generalised anxiety disorder.
BRU21123164NP	Three Legs Wintergreen Liniment	For symptomatic relief of strains, sprains and muscular pains.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21123165P	Voritrop 50 Film-Coated Tablet 50mg	Voriconazole is a broad spectrum, triazole antifungal agent and is indicated as follows: - Treatment of invasive aspergillosis; - Treatment of candidemia in non-neutropenic patients; - Treatment of fluconazole-resistant serious invasive Candida infections (including C. krusei); - Treatment of serious fungal infections caused by Scedosporium spp. and Fusarium spp.; - Prophylaxis in patients ≥12 years old who are at high risk of developing invasive fungal infections. The indication is based on a study which includes patients ≥12 years old undergoing allogeneic haematopoietic stem cell transplantation.
BRU21123166P	Voritrop 200 Film-Coated Tablet 200mg	Voriconazole is a broad spectrum, triazole antifungal agent and is indicated as follows: - Treatment of invasive aspergillosis; - Treatment of candidemia in non-neutropenic patients; - Treatment of fluconazole-resistant serious invasive Candida infections (including C. krusei); - Treatment of serious fungal infections caused by Scedosporium spp. and Fusarium spp.; - Prophylaxis in patients ≥12 years old who are at high risk of developing invasive fungal infections. The indication is based on a study which includes patients ≥12 years old undergoing allogeneic haematopoietic stem cell transplantation.
BRU21123167P	Entecavir Sandoz Film-Coated Tablet 0.5mg	Entecavir Sandoz is indicated for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. The following points should be considered when initiating therapy with Entecavir Sandoz: • This indication is based on histologic, virologic, biochemical, and serologic responses in nucleoside-treatment- naïve and lamivudine-resistant adult patients with HBeAg-positive or HBeAg-negative chronic HBV infection with compensated liver disease. • Virologic, biochemical, serologic, and safety data are available from a controlled study in adult subjects with chronic HBV infection and decompensated liver disease. • Virologic, biochemical, serologic, and safety data are available for a limited number of adult subjects with HIV/HBV co-infection who have received prior lamivudine therapy.
BRU21123168P	Otagil 10 Film-Coated Tablet	<u>Treatment of hypercholesterolemia</u> Adults, adolescents and children aged 6 years or older with primary hypercholesterolemia (type IIa including heterozygous familial hypercholesterolemia) or mixed dyslipidemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate. Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolemia as an adjunct to diet and other lipid lowering treatment (e.g. LDL apheresis) or if such treatment are not appropriate. <u>Prevention of Cardiovascular Events</u> Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

BRU21123169P	Otagil 20 Film-Coated Tablet	Treatment of hypercholesterolemia Adults, adolescents and children aged 6 years or older with primary hypercholesterolemia (type IIa including heterozygous familial hypercholesterolemia) or mixed dyslipidemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate. Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolemia as an adjunct to diet and other lipid lowering treatment (e.g. LDL apheresis) or if such treatment are not appropriate. Prevention of Cardiovascular Events Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
BRU21123170P	RO-CAL 0.25mcg	Established postmenopausal osteoporosis. Renal osteodystrophy in patients with chronic renal failure, particularly those undergoing hemodialysis. Management of hypocalcemia and its clinical manifestations in patients with postsurgical hypoparathyroidism, idiopathic hypoparathyroidism, and pseudohypoparathyroidism. Vitamin D dependent rickets. Hypophosphatemic vitamin – D resistant rickets. Predialysis Patients : Management of secondary hyperparathyroidism and resultant metabolic bone disease in patients with moderate to severe chronic renal failure (Ccr 15 to 55 mL/min) not yet on dialysis. Dialysis Patients : Management of hypocalcemia and the resultant metabolic bone disease in patients undergoing chronic renal dialysis.
BRU21123171P	Acetan Tablet 50mg	**Hypertension** ACETAN is indicated for the treatment of hypertension. **Hypertensive Patients with Left Ventricular Hypertrophy** ACETAN is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients. **Nephropathy in Type 2 Diabetic Patients** Indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio ≥300mg/g) in patients with type 2 diabetes and a history of hypertension. In this population, ACETAN reduces the rate of progression of nephropathy as measured by the occurrence of doubling the serum creatinine or end stage renal disease (need for dialysis or renal transplantation) or death.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21123172P	Acetan Tablet 100mg	**Hypertension** ACETAN is indicated for the treatment of hypertension. **Hypertensive Patients with Left Ventricular Hypertrophy** ACETAN is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients. **Nephropathy in Type 2 Diabetic Patients** Indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio ≥300mg/g) in patients with type 2 diabetes and a history of hypertension. In this population, ACETAN reduces the rate of progression of nephropathy as measured by the occurrence of doubling the serum creatinine or end stage renal disease (need for dialysis or renal transplantation) or death.
BRU21123173NP	B.Braun 0.9% Sodium Chloride & 5% Glucose Intravenous Infusion B.P	-Dehydration -Sodium and chloride depletion -Caloric supply -Vehicle solution for supplementary medication
BRU21123174P	Fucon Solution For Injection 20mg/ml	Fucon Solution for Injection 20mg/ml is indicated in acute spasm, as in renal or biliary colic, in radiology for differential diagnosis of obstruction. It is also indicated to reduce spasm and pain in pyelography, and in other diagnostic procedures where spasm may be a problem.
BRU21123175P	Flomist Aqueous Nasal Spray 50mcg	Flomist Aqueous Nasal Spray is indicated for the prophylaxis and treatment of seasonal allergic rhinitis including hayfever, and perennial rhinitis. Fluticasone propionate has potent anti-inflammatory activity but when used topically on the nasal mucosa has no detectable systemic activity.
BRU21123176P	Hepuri 0.5mg Film-Coated Tablets	Entecavir are indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum alanine aminotransferases (ALT or AST) or histological active disease. This indication is based on the reported histologic, virologic, biochemical, and serological response in: a) nucleoside treatment naive and lamivudine resistant adult patient with HBeAg positive and HBeAg negative HBV infection with compensated liver disease b) adult patent with chronic HBV infection and decompensated liver disease c) adult patient with HIV/HBV co infection who have received prior lamivudine therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU21123177P	Lebreta 2.5mg Tablets	• Adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. • Adjuvant treatment of postmenopausal women with early breast cancer (positive or unknown estrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy (extended adjuvant therapy). • First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer. • Treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antiestrogens. • Pre-operative therapy in postmenopausal women with localized hormone receptor positive breast cancer, to allow subsequent breast-conserving surgery in women not originally considered candidates for this type of surgery. Subsequent treatment after surgery should be in accordance with standard of care.
BRU22023178P	Bepen Injection 1.0MU	Benzylpenicillin is indicated for most wound infections, pyogenic infections of the skin, soft tissue infections and infections of the respiratory tract. It is also indicated for the following infections caused by penicillin-sensitive microorganisms: Generalised infections and septicaemia from susceptible bacteria. Acute and chronic osteomyelitis, sub-acute bacterial endocarditis and meningitis caused by susceptible organisms. Tetanus, actinomycosis, anthrax, rat-bite fever, listeriosis and severe Lyme disease. Complications secondary to gonorrhoea and syphilis (e.g. gonococcal arthritis or endocarditis, congenital syphilis and neurosyphilis). Diphtheria, brain abscesses and pasteurellosis. Consideration should be given to official local guidance (e.g. national recommendations) on the appropriate use of antibacterial agents. Susceptibility of the causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available.
BRU22023179NP	Referis Iron Sucrose Injection USP 100mg/5ml	Referis is indicated for the treatment of iron deficiency in the following indications: • Where there is a clinical need for a rapid iron supply • In patients who cannot tolerate oral iron therapy or who are noncompliant • In active inflammatory bowel disease where oral iron preparations are ineffective • In chronic kidney disease when oral iron preparations are less effective The diagnosis of iron deficiency must be based on appropriate laboratory tests (e.g. Hb, serum ferritin, TSAT, serum iron, etc.) (Hb haemoglobin, TSAT transferrin saturation)
BRU22023180NP	Salonpas Hot Patch	For relief of aches, pains and inflammation associated with stiff shoulder, simple backache, muscle pain, bruises, sprains and joint pains.

		ADULTS **Rheumatoid Arthritis** AMGEVITA is indicated for reducing signs and symptoms and inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs. AMGEVITA can be used alone or in combination with methotrexate or other DMARDs. AMGEVITA, in combination with MTX, can also be used in the treatment of patients with recently diagnosed moderate to severely active rheumatoid arthritis who have not received methotrexate. **Psoriatic Arthritis** AMGEVITA is indicated for reducing signs and symptoms of active arthritis in adult patients with moderate to severe psoriatic arthritis when the response to previous DMARD therapy has been inadequate. AMGEVITA has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. AMGEVITA can be used alone or in combination with DMARDs. **Ankylosing Spondylitis** AMGEVITA is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis who have had an inadequate response to conventional therapy. **Crohn's Disease** AMGEVITA is indicated for the treatment of moderate to severe active Crohn's disease in adults to reduce the signs and symptoms of the disease and to induce and maintain clinical remission in patients who have had an inadequate response to conventional therapies, or who have lost response to or are intolerant of infliximab. For induction treatment, AMGEVITA should be given in combination with corticosteroids. AMGEVITA can be given as monotherapy in case of intolerance to corticosteroids or when continued treatment with corticosteroids is inadequate.

BRU22023181P	Amgevita Solution For Injection In Prefilled Syringe 40mg/0.8ml	**Ulcerative Colitis** AMGEVITA is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Plaque Psoriasis** AMGEVITA is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Hidradenitis Suppurativa** AMGEVITA is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** AMGEVITA is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. **PEDIATRICS** **Juvenile Idiopathic Arthritis** *Polyarticular Juvenile Idiopathic Arthritis* AMGEVITA in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA), in patients 2 years of age and older, who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs 23 (DMARDS). AMGEVITA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate (for the efficacy in monotherapy see CLINICAL STUDIES). AMGEVITA has not been studied in patients aged less than 2 years.

		Enthesitis-Related Arthritis AMGEVITA is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. **Pediatric Crohn's Disease** AMGEVITA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients, 6 years of age and older, with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. **Pediatric Plaque Psoriasis** AMGEVITA is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. **Adolescent Hidradenitis Suppurativa** AMGEVITA is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Uveitis** AMGEVITA is indicated for the treatment of chronic non-infectious anterior uveitis in pediatric patients 2 years of age and older who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

		ADULTS **Rheumatoid Arthritis** AMGEVITA is indicated for reducing signs and symptoms and inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs. AMGEVITA can be used alone or in combination with methotrexate or other DMARDs. AMGEVITA, in combination with MTX, can also be used in the treatment of patients with recently diagnosed moderate to severely active rheumatoid arthritis who have not received methotrexate. **Psoriatic Arthritis** AMGEVITA is indicated for reducing signs and symptoms of active arthritis in adult patients with moderate to severe psoriatic arthritis when the response to previous DMARD therapy has been inadequate. AMGEVITA has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. AMGEVITA can be used alone or in combination with DMARDs. **Ankylosing Spondylitis** AMGEVITA is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis who have had an inadequate response to conventional therapy. **Crohn's Disease** AMGEVITA is indicated for the treatment of moderate to severe active Crohn's disease in adults to reduce the signs and symptoms of the disease and to induce and maintain clinical remission in patients who have had an inadequate response to conventional therapies, or who have lost response to or are intolerant of infliximab. For induction treatment, AMGEVITA should be given in combination with corticosteroids. AMGEVITA can be given as monotherapy in case of intolerance to corticosteroids or when continued treatment with corticosteroids is inadequate.

BRU22023182P	Amgevita Solution For Injection In Prefilled Autoinjector 40mg/0.8ml	**Ulcerative Colitis** AMGEVITA is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Plaque Psoriasis** AMGEVITA is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Hidradenitis Suppurativa** AMGEVITA is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** AMGEVITA is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. **PEDIATRICS** **Juvenile Idiopathic Arthritis** *Polyarticular Juvenile Idiopathic Arthritis* AMGEVITA in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA), in patients 2 years of age and older, who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs 23 (DMARDS). AMGEVITA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate (for the efficacy in monotherapy see CLINICAL STUDIES). AMGEVITA has not been studied in patients aged less than 2 years.

		Enthesitis-Related Arthritis AMGEVITA is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. **Pediatric Crohn's Disease** AMGEVITA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients, 6 years of age and older, with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. **Pediatric Plaque Psoriasis** AMGEVITA is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. **Adolescent Hidradenitis Suppurativa** AMGEVITA is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Uveitis** AMGEVITA is indicated for the treatment of chronic non-infectious anterior uveitis in pediatric patients 2 years of age and older who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.
BRU22023183P	Forvic 300 Film-Coated Tablet	*HIV-1 infection* Tenofovir disoproxil is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults. Tenofovir disoproxil is also indicated for the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents, aged 12 to < 18 years. The choice of Tenofovir disoproxil to treat antiretroviral-experienced patients with HIV-1 infection should be based on individual viral resistance testing and/or treatment history of patients. *Hepatitis B infection* Tenofovir disoproxil is indicated for the treatment of chronic hepatitis B in adults with: • compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis. • evidence of Lamivudine-resistant hepatitis B virus. • decompensated liver disease. Tenofovir disoproxil is indicated for the treatment of chronic hepatitis B in adolescents 12 to < 18 years of age with: • compensated liver disease and evidence of immune active disease, i.e. active viral replication and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis.
BRU22023184P	Haemostop Injection 100mg/ml	For local fibrinolysis as epistaxis, prostatectomy, cervical conization, and dental extraction in patients with coagulopathies. Hereditary angioneurotic edema. General fibrinolysis after major surgery.

BRU22023185P	Letimble 10mg Tablets	*Primary hypercholesterolaemia* Ezetimibe, administered alone, or with an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia. Ezetimibe, administered in combination with fenofibrate, is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B and non-HDL-C in patients with mixed hyperlipidemia. *Prevention of Cardiovascular Events* Ezetimibe, administered with a statin, is indicated to reduce the risk of cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, hospitalization for unstable angina, or need for revascularization), in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS). *Homozygous Familial Hypercholesterolaemia (HoFH)* Ezetimibe, administered with a statin, is indicated for patients with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis). *Homozygous Sitosterolaemia (Phytosterolaemia)* Ezetimibe is indicated for the reduction of elevated sitosterol and campesterol levels in patients with homozygous familial sitosterolaemia.
BRU22023186P	Imaccord 400 Film Coated Tablet	**Imaccord** is indicated for the • treatment of adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML) (for paediatric use see section DOSAGE AND ADMINISTRATION). • treatment of adult and paediatric patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy (for paediatric use see section DOSAGE AND ADMINISTRATION). • treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy. • treatment of adult patients with relapsed or refractory Ph+ ALL as monotherapy. • treatment of adult patients with Kit+ (CD117) unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST). • adjuvant treatment of adult patients following complete gross resection of Kit+ GIST. The effectiveness of Imaccord is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in relapsed or refractory adult Ph+ ALL, on objective response rates in unresectable and/or metastatic GIST and on recurrence free survival in adjuvant GIST. Except in newly diagnosed chronic phase CML there are no controlled trials demonstrating increased survival.

BRU22023187P	Imaccord 100 Film Coated Tablet	**Imaccord** is indicated for the • treatment of adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML) (for paediatric use see section DOSAGE AND ADMINISTRATION). • treatment of adult and paediatric patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy (for paediatric use see section DOSAGE AND ADMINISTRATION). • treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy. • treatment of adult patients with relapsed or refractory Ph+ ALL as monotherapy. • treatment of adult patients with Kit+ (CD117) unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST). • adjuvant treatment of adult patients following complete gross resection of Kit+ GIST. The effectiveness of Imaccord is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in relapsed or refractory adult Ph+ ALL, on objective response rates in unresectable and/or metastatic GIST and on recurrence free survival in adjuvant GIST. Except in newly diagnosed chronic phase CML there are no controlled trials demonstrating increased survival.
BRU22023188P	Pharmaniaga Dermasole Ointment 0.1% w/w	Betamethasone is a potent topical corticosteroid indicated for adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These include the following: -Atopic dermatitis (including infantile atopic dermatitis) -Nummular dermatitis (discoid eczema) -Prurigo nodularis -Psoriasis (excluding widespread plaque psoriasis) -Lichen simplex chronicus (neurodermatitis) and lichen planus -Seborrhoeic dermatitis -Irritant or allergic contact dermatitis -Discoid lupus erythematosus -Adjunct to systemic steroid therapy in generalized erythroderma, -Insect bite reactions -Miliara (prickly heat)
BRU22023189P	Amdepin 5 Tablet	•Hypertension •Chronic stable anginal pectoris •Vasospastic (Prinzmetal's) angina

BRU22023190P	Amdepin 10 Tablet	•Hypertension •Chronic stable anginal pectoris •Vasospastic (Prinzmetal's) angina
BRU22023191P	Copan Injection 1ml Amp	Spasm of the gastrointestinal tract, biliary spasm, renal spasm, diagnostic aid in radiology.
BRU22023192P	Lygaba Capsule 75mg	*Neuropathic Pain* : Treatment of neuropathic pain in adults. *Epilepsy* : As adjunctive therapy in adults with partial seizures with or without secondary generalisation. *Generalised Anxiety Disorder* : Treatment of Generalised Anxiety Disorder (GAD) in adults. *Fibromyalgia* : Management of fibromyalgia.
BRU22023193P	Ternolol 50 Film-Coated Tablet	For treatment of hypertension, angina pectoris, acute myocardial infarction and cardiac arrhythmias.
BRU22023194P	Hosolvon Elixir 4mg/5ml (Sugar Free)	Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport.
BRU22023195P	Mavenclad Tablet 10mg	MAVENCLAD is indicated for the treatment of relapsing-remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical disability.
BRU22023196P	Imbruvica 140mg Film-Coated Tablets	IMBRUVICA as a single agent is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). IMBRUVICA as a single agent or in combination with rituximab or obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). IMBRUVICA as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with lymphocytic leukaemia (CLL) who have received at least one prior therapy. IMBRUVICA in combination with rituximab is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM). IMBRUVICA is indicated for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

BRU22023197P	Imbruvica 280mg Film-Coated Tablets	IMBRUVICA as a single agent is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). IMBRUVICA as a single agent or in combination with rituximab or obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). IMBRUVICA as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with lymphocytic leukaemia (CLL) who have received at least one prior therapy. IMBRUVICA in combination with rituximab is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM). IMBRUVICA is indicated for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.
BRU22023198P	Imbruvica 420mg Film-Coated Tablets	IMBRUVICA as a single agent is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). IMBRUVICA as a single agent or in combination with rituximab or obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). IMBRUVICA as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with lymphocytic leukaemia (CLL) who have received at least one prior therapy. IMBRUVICA in combination with rituximab is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM). IMBRUVICA is indicated for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.
BRU22033199P	Amsubac 1.5g Injection	For infections caused by susceptible microorganisms. Typical indications are upper and lower respiratory tract infections including sinusitis, otitis media and epiglottitis; bacterial pneumonias; urinary tract infections and pyelonephritis; intra-abdominal infections including peritonitis, cholecystitis, endometritis and pelvic cellulitis; bacterial septicaemia; skin, soft tissue, bone and joint infections and gonococcal infections. Ampicillin sodium & Sulbactam sodium may also be administered preoperatively to reduce the incidence of postoperative wound infections in patients undergoing abdominal or pelvic surgery, in which peritoneal contamination may be present. In termination of pregnancy or caesarean section, Ampicillin sodium & Sulbactam sodium may be used prophylactically to reduce postoperative sepsis.
BRU22033200P	Xylocon 0.025% Nasal Drops	Rhinitis acuta, sinusitis, eustachitis and otitis media.
BRU22033201P	Xylocon 0.05% Nasal Drops	Rhinitis acuta, sinusitis, eustachitis and otitis media.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU22033202NP	Salonpas 30 Hot Patch	For relief of aches and pains associated with: •Muscle fatigue •Muscle pain •Stiff shoulder •Simple backache •Bruises •Sprains •Strains •Arthritis
BRU22033203P	GPO-A-Flu (Oseltamivir Capsules 75mg)	GPO-A-FLU™ (oseltamivir capsules) is used for the symptomatic treatment and the prophylaxis of influenza A or B virus infection in adults and adolescents 13 years of age or older. The World Health Organization (WHO) recommends that oseltamivir be available for the treatment of suspected avian influenza A (H5N1) respiratory infections in individuals involved in mass poultry culling operations.
BRU22033204P	Iobrim Eye Drops	Brimonidine Eye Drops are effective for lowering intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension. Brimonidine Eye Drops may also be used as adjunctive therapy when intraocular pressure (IOP) is not adequately controlled by a topical beta-blocking agent. There is no known cure for glaucoma. Treatment with Brimonidine Eye Drops (as with any other therapy) aims to preserve visual field through decrease of IOP.
BRU22033205P	Pharmaniaga Erythromycin Suspension 200mg	Erythromycin is used in the treatment of infections due to susceptible organisms; it is often used as an alternative to penicillin in infections due to Gram-positive cocci, especially Streptococci, and *Listeria monocytogenes* . In penicillin sensitive patients it is given in place of penicillin in the prophylaxis of endocarditis and in the treatment of syphilis. For the treatment of otitis media caused by *Haemophilus influenzae* it may be given in combination with sulphonamide. Erythromycin may be given as an adjunct to antitoxin in the treatment of diphtheria or used alone to eradicate the carrier state. In the prevention of pertussis, it may be used in non- or partially immune patients. It is used in infections due to *Mycoplasma pneumoniae* and *Chlamydia trachomatis* in Legionnaires' disease, in enteritis due to *Campylobacter* spp., chancroid and similarly to tetracycline, in the treatment of severe acne vulgaris.
BRU22033206P	Mycofit 500 Tablets 500mg	Mycophenolate Mofetil is indicated for: • prophylaxis of acute organ rejection and treatment of refractory organ rejection in patients receiving allogeneic renal transplants. • prophylaxis of acute organ rejection and increased graft and patient survival in patients receiving allogeneic cardiac transplants. • prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplants. Mycophenolate Mofetil should be used concomitantly with cyclosporin and corticosteroids.

BRU22033207P	Zynomax Tablet 250mg	Zynomax is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes pharyngitis, including the prophylaxis of rheumatic fever. Zynomax is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of Zynomax and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, Zynomax is indicated in the treatment of uncomplicated genital infections due to Chlamydia trachomatis. It is also indicated in the treatment of chancroid due to Haemophilus ducreyi and uncomplicated genital infection due to non- multiresistant Neisseria gonorrhoea; concurrent infection with Treponema pallidum should be excluded.
BRU22033208P	Urief 4mg Film-Coated Tablets	Bladder outlet obstruction associated with benign prostatic hyperplasia in patients ≥ 50 years.
BRU22033209P	Mycofit 250 Capsules 250mg	Mycofit is indicated for: • Prophylaxis of acute organ rejection and treatment of refractory organ rejection in patients receiving allogeneic renal transplants. • Prophylaxis of acute organ rejection and increased graft and patient survival in patients receiving allogeneic cardiac transplants. • Prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplants. Mycofit should be used concomitantly with cyclosporin and corticosteroids.
BRU22033210P	Pharmaniaga Dopamine Hydrochloride 40mg/ml Injection	Dopamine hydrochloride is indicated for the correction of haemodynamic imbalances present in the shock syndrome due to myocardial infarctions, trauma, endotoxic septicaemia, open heart surgery, renal failure and chronic cardiac decompensation as in congestive failure. *Poor Perfusion of Vital Organs* : Urine flow appears to be one of the better diagnostic signs by which adequacy of vital organ perfusion can be monitored. Nevertheless, the physician should also observe the patient for signs of reversal of confusion or comatose condition. In a number of oliguric or anuric patients, administration of dopamine hydrochloride has resulted in an increase in urine flow which in some cases reached normal levels. Dopamine hydrochloride may also increase urine flow in patients whose output is within normal limits and thus may be of value in reducing the degree of pre-existing fluid accumulation. It should be noted that at doses above those optimal for the individual patient, urine flow may decrease, necessitating reduction of dosage. Concurrent administration of dopamine hydrochloride and diuretic agents may produce an additive or potentiating effect. *Low Cardiac Output* : Increased cardiac output is related to the direct inotropic effect of dopamine hydrochloride on the myocardium. Increased cardiac output at low or moderate doses appears to be related to a favourable prognosis. In many instances, the renal fraction of the total cardiac output has been found to increase. Increase in cardiac output produced by dopamine hydrochloride is not associated with substantial decreases in systemic vascular resistance (SVR) as may occur with isoproterenol. *Hypotension* : Hypotension due to inadequate cardiac output can be managed by administration of low to moderate doses of dopamine hydrochloride which have little effect on SVR. At high therapeutic doses, the alpha adrenergic activity of dopamine hydrochloride becomes more prominent and thus may correct hypotension due to diminished SVR. It is suggested that the physician administer dopamine hydrochloride as soon as a definite trend toward decreased systolic and diastolic pressure becomes evident.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU22043211NP	Daneuron Tablet	DANEURON promotes effectively the treatment of pain due to disturbance of the peripheral nerves such as lumbago, neuritis, polyneuritis, post-herpetic neuralgia. It is also effective in the treatment of hyperemesis gravidarum and during the convalescent period of disease.
BRU22043212NP	Three Legs Septyc-Kare Antiseptic Spray 1% w/v	As an antiseptic for treatment of skin lesions, cuts, abrasions, infected wounds and burns.
BRU22043213P	Carbopa 10mg/ml Injection	Carboplatin is indicated in the treatment of advanced stage ovarian cancer of epithelial origin.
BRU22043214P	Amtas 5 (Amlodipine Tablets 5mg)	<u>Hypertension</u> Amlodipine is indicated for the first-line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme (ACE) inhibitor. <u>Coronary Artery Disease</u> *Chronic Stable Angina* Amlodipine is indicated for the symptomatic treatment of chronic stable angina. Amlodipine may be used alone or in combination with other antianginal drugs. *Vasospastic Angina (Prinzmetal's or variant angina)* Amlodipine is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy, or in combination with other antianginal drugs. *Angiographically Documented Coronary Artery Disease* In patients with recently documented coronary artery disease (CAD) by angiography and without heart failure or an ejection fraction <40%, amlodipine is indicated to reduce the risk of hospitalization due to angina and to reduce the risk of a coronary revascularization procedure.
BRU22043215P	Celexib 200mg Capsules	Celecoxib is indicated in adults for the symptomatic relief in the treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The decision to prescribe a selective cyclooxygenase-2 (COX-2) inhibitor should be based on an assessment of the individual patient's overall risks.

BRU22043216P	Gemibine-200 Gemcitabine For Injection USP 200mg	Gemcitabine is indicated for the treatment of advanced bladder cancer (muscle invasive Stage IV tumours with or without metastases) in combination with cisplatin. Gemcitabine is indicated for treatment of adult patients with locally advanced or metastatic adenocarcinoma of the pancreas. Gemcitabine, in combination with cisplatin is indicated as first line treatment of patients with locally advanced (inoperable Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer (NSCLC). Gemcitabine is indicated for the palliative treatment of adult patients with locally advanced or metastatic NSCLC. Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.
BRU22043217P	Pharmaniaga Co-Amoxiclav Suspension 228mg	It is indicated for the treatment of the following infections: a) Upper & lower respiratory tract infections – sinusitis, otitis media, bronchitis. b) Skin and soft tissue infections – boils, abscesses, cellulitis, wound infections. c) Genitounrinary tract infections – cystitis, urethritis, pyelonephritis. d) Bone & joint infections – osteomyelitis.
BRU22043218P	Lorviqua 25mg Film-Coated Tablet	LORVIQUA as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor. LORVIQUA as monotherapy is indicated for the treatment of adult patients with ALK positive advanced NSCLC whose disease has progressed after: • alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or • crizotinib and at least one other ALK TK1.
BRU22043219P	Lorviqua 100mg Film-Coated Tablet	LORVIQUA as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor. LORVIQUA as monotherapy is indicated for the treatment of adult patients with ALK positive advanced NSCLC whose disease has progressed after: • alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or • crizotinib and at least one other ALK TK1.
BRU22043220P	Uniquin (Hydroxychloroquine Sulfate 200mg Film Coated Tablet)	Treatment of rheumatoid arthritis, juvenile chronic arthritis, discoid and systemic lupus erythematosus, and dermatological conditions caused or aggravated by sunlight.

BRU22043221P	Atorvon 10mg Film-Coated Tablets	***Hypercholesterolaemia*** : Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides in patients with primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia, or combined (mixed) hyperlipidaemia (Fredrickson Types IIa and IIb) when response to diet and other non-pharmacological measures is inadequate. Atorvastatin is also indicated as an adjunct to diet and other non-dietary measures in reducing elevated total cholesterol, LDL-cholesterol and apolipoprotein B in patients with homozygous familial hypercholesterolaemia when response to these measures is inadequate. ***Prevention of cardiovascular disease*** : Atorvastatin is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥ 55 years, male sex, smoking, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminia or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥ 6, or premature family history of coronary heart disease. In patients with type 2 diabetes and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, Atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • Reduce the risk of non-fatal myocardial infarction • Reduce the risk of fatal and non-fatal stroke • Reduce the risk of revascularization procedures • Reduce the risk of hospitalization of CHF • Reduce the risk of angina
BRU22043222P	Caditor 10 Film-Coated Tablets	**<u>Hypercholesterolaemia</u>** Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. **<u>Prevention of cardiovascular disease</u>** Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

BRU22043223P	Caditor 20 Film-Coated Tablets	**Hypercholesterolaemia** Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. **Prevention of cardiovascular disease** Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
BRU22043224NP	Rexom Winamol 500mg Tablet	For relief of fever. For relief from mild-to-moderate pain including: Headache, Migraine Muscle ache, Dysmenorrhea, Sore throat, Musculoskeletal pain, Fever and pain after vaccination, Pain after dental procedures / tooth extraction, Toothache, Pain of osteoarthritis.
BRU22043225NP	B. Braun Water for Injection B.P.	Preparation and dilution of parenteral preparations.

BRU22043226P	Rosmi 10 Tablet	**Hyperlipidemia and Mixed Dyslipidemia** ROSUVASTATIN is indicated as adjunctive therapy to diet to reduce elevated Total-C, LDL-C, ApoB, nonHDL-C, and triglycerides and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and nonpharmacological interventions alone has been inadequate. **Pediatric Patients 10 to 17 years of age with Heterozygous Familial Hypercholesterolemia (HeFH)** Adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. **Hypertriglyceridemia** ROSUVASTATIN is indicated as adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia. **Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia)** ROSUVASTATIN is indicated as an adjunct to diet for the treatment of patients with Dysbetalipoproteinemia (Type III Hyperlipoproteinemia). **Homozygous Familial Hypercholesterolemia** ROSUVASTATIN is indicated as adjunctive therapy to other lipid-lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable to reduce LDL-C, Total-C, and ApoB in adult patients with homozygous familial hypercholesterolemia. **Slowing of the Progression of Atherosclerosis** ROSUVASTATIN is indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels. **Primary Prevention of Cardiovascular Disease** In individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age > 50 years old in men and > 60 years old in women, hsCRP > 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, ROSUVASTATIN is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures **Limitations of Use** ROSUVASTATIN has not been studied in Fredrickson Type I and V dyslipidemias.

BRU22043227P	Rosmi 20 Tablet	**Hyperlipidemia and Mixed Dyslipidemia** ROSUVASTATIN is indicated as adjunctive therapy to diet to reduce elevated Total-C, LDL-C, ApoB, nonHDL-C, and triglycerides and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and nonpharmacological interventions alone has been inadequate. **Pediatric Patients 10 to 17 years of age with Heterozygous Familial Hypercholesterolemia (HeFH)** Adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. **Hypertriglyceridemia** ROSUVASTATIN is indicated as adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia. **Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia)** ROSUVASTATIN is indicated as an adjunct to diet for the treatment of patients with Dysbetalipoproteinemia (Type III Hyperlipoproteinemia). **Homozygous Familial Hypercholesterolemia** ROSUVASTATIN is indicated as adjunctive therapy to other lipid-lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable to reduce LDL-C, Total-C, and ApoB in adult patients with homozygous familial hypercholesterolemia. **Slowing of the Progression of Atherosclerosis** ROSUVASTATIN is indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels.
		Primary Prevention of Cardiovascular Disease In individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age > 50 years old in men and > 60 years old in women, hsCRP > 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, ROSUVASTATIN is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures **Limitations of Use** ROSUVASTATIN has not been studied in Fredrickson Type I and V dyslipidemias.

BRU22063228P	Atorvon 20mg Film-Coated Tablets	***Hypercholesterolaemia*** : Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides in patients with primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia, or combined (mixed) hyperlipidaemia (Fredrickson Types IIa and IIb) when response to diet and other non-pharmacological measures is inadequate. Atorvastatin is also indicated as an adjunct to diet and other non-dietary measures in reducing elevated total cholesterol, LDL-cholesterol and apolipoprotein B in patients with homozygous familial hypercholesterolaemia when response to these measures is inadequate. ***Prevention of cardiovascular disease*** : Atorvastatin is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥ 55 years, male sex, smoking, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminia or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥ 6, or premature family history of coronary heart disease. In patients with type 2 diabetes and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, Atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • Reduce the risk of non-fatal myocardial infarction • Reduce the risk of fatal and non-fatal stroke • Reduce the risk of revascularization procedures • Reduce the risk of hospitalization of CHF • Reduce the risk of angina
BRU22063229P	Siranalen 75mg Capsules	<u>Neuropathic pain</u> Siranalen is indicated for the treatment of neuropathic pain, which includes diabetic peripheral neuropathy and post-herpetic neuralgia in adults. <u>Epilepsy</u> Siranalen is indicated as adjunctive therapy of partial seizures, with or without secondary generalization, in adults. <u>Generalised Anxiety Disorder</u> Siranalen is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.
BRU22063230P	YSP Knowful Injection 200mg/ml	1. Treatment of the elderly with some degree of cerebral functional impairment such as loss of memory, a lack of concentration or alertness and vertigo. 2. Indicated for patients suffering from myoclonus of cortical origin, irrespective of aetiology and should be used in combination with other anti-myoclonic therapies. 3. Used in the treatment of sickle-cell vaso-occlusive crises.

BRU22063231P	Entacapone HEC 200mg Film-Coated Tablets	Entacapone is indicated as an adjunct to standard preparations of levodopa/benserazide or levodopa/carbidopa for use in adult patients with Parkinson's disease and end-of-dose motor fluctuations, who cannot be stabilised on the levodopa combinations.
BRU22063232P	Vytan Tablet 80mg	**Hypertension** Treatment of hypertension. **Heart failure** Treatment of heart failure (NYHA class II-IV) in patients receiving usual therapy (such as diuretics, digitalis) who are intolerant to ACE inhibitors. Valsartan improves morbidity in these patients, primarily via reduction in hospitalization for heart failure. Valsartan also slows the progression of heart failure, improves NYHA functional class, ejection fraction and signs and symptoms of heart failure and improves quality of life. **Post-myocardial infarction** Valsartan is indicated to improve survival following myocardial infarction in clinically stable patients with signs, symptoms or radiological evidence of left ventricular failure and/or with left ventricular systolic dysfunction.
BRU22063233P	Vytan Tablet 160mg	**Hypertension** Treatment of hypertension. **Heart failure** Treatment of heart failure (NYHA class II-IV) in patients receiving usual therapy (such as diuretics, digitalis) who are intolerant to ACE inhibitors. Valsartan improves morbidity in these patients, primarily via reduction in hospitalization for heart failure. Valsartan also slows the progression of heart failure, improves NYHA functional class, ejection fraction and signs and symptoms of heart failure and improves quality of life. **Post-myocardial infarction** Valsartan is indicated to improve survival following myocardial infarction in clinically stable patients with signs, symptoms or radiological evidence of left ventricular failure and/or with left ventricular systolic dysfunction.

BRU22063234P	Stelara Solution for Injection In Single-Use Vial 45mg/0.5ml	**Plaque Psoriasis** ***(via subcutaneous administration only)*** STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A) (see *Pharmacodynamic Properties*). **Pediatric Plaque Psoriasis** ***(via subcutaneous administration only with single-use vial)*** STELARA is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies (see *Pharmacodynamic Properties*). **Psoriatic Arthritis (PsA)** ***(via subcutaneous administration only)*** STELARA alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate (see *Pharmacodynamic Properties*). **Crohn's Disease** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies (see *Pharmacodynamic Properties*). **Ulcerative Colitis** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies (see *Pharmacodynamic Properties*).
BRU22063235P	Piri Syrup	For symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, and allergic conjunctivitis due to inhalant allergens and foods. Symptomatic treatment of mild, uncomplicated allergic skin manifestation of urticaria and angioedema.
BRU22063236NP	Cardin Orodispersible Tablet	Conditions where modification of platelet behaviour is considered beneficial, including transient ischaemic attacks, secondary prevention of myocardial infarction, and for prophylaxis against stroke, vascular occlusion and deep vein thrombosis.
BRU22083237P	Allercrom Eye Drops 2% w/v	Prevention and relief of the ocular symptoms that appear with allergic conjunctivitis and seasonal conjunctivitis.
BRU22083238NP	Eagle Inhaler	**Eagle Inhaler** helps clear a blocked nose that come with colds and influenza.

BRU22083239P	Spizef Tablet 250mg	Upper respiratory tract infections for example, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis. Lower respiratory tract infections for example, pneumonia, acute bronchitis, and acute exacerbations of chronic bronchitis. Genito-urinary tract infections for example, pyelonephritis, cystitis and urethritis. Skin and soft-tissue infections for example, furunculosis, pyoderma, and impetigo. Gonorrhoea, acute uncomplicated gonococcal urethritis and cervicitis.
BRU22083240P	Tecentriq® Concentrate for Solution for Infusion 840mg/14ml	**Non-small cell lung cancer** Tecentriq, in combination with Avastin, paclitaxel and carboplatin, is indicated for the treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) who had not received prior chemotherapy. Tecentriq as monotherapy is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving Tecentriq. Tecentriq, in combination with nab-paclitaxel and carboplatin, is indicated for first-line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumor aberrations. Tecentriq as monotherapy is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have a PD-L1 expression ≥ 50% tumor cells (TC) or ≥ 10% tumor-infiltrating immune cells (IC) and who do not have EGFR or ALK genomic tumor aberrations. **Small cell lung cancer** Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). **Triple-negative breast cancer** Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors have PD-L1 expression of ≥1% on IC, and who have not received prior chemotherapy for metastatic disease. **Hepatocellular carcinoma** Tecentriq, in combination with Avastin, is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.
BRU22083241P	Herpesan Gel 2% w/w	Treatment of Lip Sores, Mouth Ulcers and Orofacial Lesions caused by virus infections.
BRU22083242NP	Rowatanal Cream	For the treatment of haemorrhoids and proctitis (anal irritation).
BRU22083243NP	Rowarolan Powder	For the treatment of minor cuts, abrasions, bed sores, leg ulcers and similar conditions.

BRU22083244P	Diabetmin XR 500mg Tablet	Metformin is used in the treatment of non-insulin-dependent diabetes mellitus (type 2) in adults, not responding to exercise and dietary modification. Diabetmin may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.
BRU22083245P	Zynomax Powder for Oral Suspension 200mg/5ml	Zynomax is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes pharyngitis, including the prophylaxis of rheumatic fever. Zynomax is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of Zynomax and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, Zynomax is indicated in the treatment of uncomplicated genital infections due to Chlamydia trachomatis. It is also indicated in the treatment of chancroid due to Haemophilus ducreyi and uncomplicated genital infection due to non- multiresistant Neisseria gonorrhoea; concurrent infection with Treponema pallidum should be excluded.
BRU22083246P	Febuton Film-Coated Tablet 80mg	Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis). Febuton is indicated in adults.
BRU22093247NP	Hexidine Solution 0.2% w/v	Hexidine Mouthwash is an antimicrobial solution which inhibits the formation of dental plaque. It is indicated as an aid in the treatment and prevention of gingivitis and in the maintenance of oral hygiene, particularly in situations where tooth brushing cannot be adequately employed (e.g. following oral surgery, in mentally or physically handicapped patients).
BRU22093248P	Pregatas-150 Capsules 150mg	<u>Epilepsy</u> Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. <u>Generalised Anxiety Disorder</u> Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Neuropathic pain</u> Pregabalin is indicated for the treatment of neuropathic pain which includes diabetic peripheral neuropathy and post-herpetic neuralgia in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU22093249P	Pregatas-75 Capsules 75mg	Epilepsy Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised Anxiety Disorder Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. Neuropathic pain Pregabalin is indicated for the treatment of neuropathic pain which includes diabetic peripheral neuropathy and post-herpetic neuralgia in adults. Fibromyalgia Pregabalin is indicated for the management of fibromyalgia.
BRU22093250NP	Promag Oral Suspension	Symptomatic relief of excess stomach acid associated with ulcers or dyspepsia such as heartburn, nausea, bloating and stomach pain.
BRU22093251P	Candefar 16	- Treatment of essential hypertension in adults - Treatment of adult patients with heart failure and impaired left ventricular systolic function (left ventricular ejection fraction < 40%) as add-on therapy to Angiotensin Converting Enzyme (ACE) inhibitors or when ACE inhibitors are not tolerated.
BRU22093252P	Letero (Letrozole Tablets 2.5mg)	• Adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. • Adjuvant treatment of postmenopausal women with early breast cancer (positive or unknown oestrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy (extended adjuvant therapy). • First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer. • Treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antioestrogens. • Pre-operative therapy in postmenopausal women with localized hormone receptor positive breast cancer, to allow subsequent breast-conserving surgery in women not originally considered candidates for this type of surgery. Subsequent treatment after surgery should be in accordance with standard of care.

BRU22093253P	Pharmaniaga Cefuroxime Injection 750mg	Cefuroxime is a bactericidal cephalosporin antibiotic which is resistant to most beta-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for the treatment of infections before the infecting organism has been identified or when caused by sensitive bacteria. Respiratory tract infections for example acute and chronic bronchitis, infected bronchiectasis, bacterial pneumonia, lung abscess and post-operative chest infections. Ear, nose and throat infections for example sinusitis, tonsillitis, pharyngitis and otitis media. Urinary tract infections for example acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria. Soft-tissue infections for example cellulitis, erysipelas and wound infections. Bone and joint infections for example osteomyelitis and septic arthritis. Obstetric and gynaecological infections, pelvic inflammatory diseases. Gonorrhoea particularly when penicillin is unsuitable. Other infections including septicaemia, meningitis and peritonitis. Prophylaxis against infection in abdominal, pelvic, orthopaedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk from infection. Usually cefuroxime will be effective alone, but when appropriate it may be used in combination with an aminoglycoside antibiotic, or in conjunction with metronidazole, especially for prophylaxis in colonic or gynaecological surgery. Where appropriate Cefuroxime is effective when used prior to oral therapy with cefuroxime axetil in the treatment of pneumonia and acute exacerbations of chronic bronchitis.
BRU22093254P	Calquence® Capsules 100mg	Calquence as monotherapy or in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). Calquence as monotherapy is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.
BRU22093255P	Ibrance Film-Coated Tablets 75mg	IBRANCE is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU22093256P	Ibrance Film-Coated Tablets 100mg	IBRANCE is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.
BRU22093257P	Ibrance Film-Coated Tablets 125mg	IBRANCE is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.
BRU22093258P	TS-ONE OD Tablet 25	TS-ONE® is indicated in adults • For the treatment of advanced gastric cancer when given in combination with cisplatin. • For post operative adjuvant chemotherapy for locally advanced (stage II (excluding T1), IIIA or IIIB) gastric cancer. • For the treatment of locally advanced or metastatic pancreatic cancer when given as monotherapy. • For the treatment of locally advanced or metastatic non-small cell lung cancer when given in combination with carboplatin. • For the treatment of metastatic colorectal cancer when given in combination with oxaliplatin as first-line treatment or in combination with irinotecan as second-line treatment.
BRU22093259P	TS-ONE OD Tablet 20	TS-ONE® is indicated in adults • For the treatment of advanced gastric cancer when given in combination with cisplatin. • For post operative adjuvant chemotherapy for locally advanced (stage II (excluding T1), IIIA or IIIB) gastric cancer. • For the treatment of locally advanced or metastatic pancreatic cancer when given as monotherapy. • For the treatment of locally advanced or metastatic non-small cell lung cancer when given in combination with carboplatin. • For the treatment of metastatic colorectal cancer when given in combination with oxaliplatin as first-line treatment or in combination with irinotecan as second-line treatment.
BRU22113260NP	Panadol Caplet 500mg Optizorb Formulation	Paracetamol is an analgesic and an antipyretic. Relief of fever. Relief of headache, migraine, sore throat, fever and toothache.

BRU22113261P	Eperon 1mg Film-Coated Tablets	Eperon is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. Eperon alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. Eperon is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Risperidone is indicated for the short-term treatment of persistent aggression in patients with moderate to severe dementia of the Alzheimer's type unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. Eperon is indicated for the treatment of behavioural disorders associated with autism (eg irritability, social withdrawal, stereotypic behaviour, hyperactivity and inappropriate speech) in children and adolescents. Eperon is also indicated for bipolar mania. Adjunctive therapy: Eperon is indicated as adjunctive therapy to mood stabilizers in the treatment of manic episodes associated with bipolar disorders. These episodes are characterized by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviors. Monotherapy: Eperon is indicated in the treatment of acute manic episodes associated with bipolar 1 disorder. The effectiveness of Eperon for more than 12 weeks of treatment of an acute episode, and for the prevention of new manic episodes has not been established. Eperon is indicated in the treatment of conduct and other disruptive behavior disorders in children (over 5 years), adolescents and adults with subaverage intellectual functioning or mental retardation in whom destructive behaviors (e.g. aggression, impulsivity and self-injurious behaviors) are prominent.
BRU22113262NP	Healthy Care High Strength Vitamin B12 1000mcg	**Healthy Care Vitamin B12 1000mcg** has been specially formulated to promote energy production and helps to relieve tiredness and fatigue. **Other benefits**: • Supports blood vessel health. • Supports heart health and healthy cardiovascular system function. • Helps relieve symptoms of stress.
BRU22113263P	Tremfya® One-Press® 100mg/ml Solution For Injection In Pre-Filled Pen	**Plaque Psoriasis** TREMFYA is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis** TREMFYA, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. **Palmoplantar pustulosis** TREMFYA is indicated for the treatment of moderate to severe palmoplantar pustulosis (PPP) in adult patients who do not adequately respond to conventional therapy.

BRU22113264P	Neufar 150 Capsule	Neuropathic Pain Pregabalin is indicated for the treatment of peripheral neuropathic pain in adults. Epilepsy Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization.
BRU22113265P	Midazolam Kalceks 5mg/ml Solution For Injection/Infusion	Midazolam Kalceks is a short-acting sleep-inducing drug that is indicated as follows: **In adults** • CONSCIOUS SEDATION before or during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of anaesthesia - Induction of anaesthesia - As a sedative component in combined anaesthesia • SEDATION IN INTENSIVE CARE UNITS **In paediatric** • CONSCIOUS SEDATION before or during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of anaesthesia • SEDATION IN INTENSIVE CARE UNITS For dosage recommendation in specific age range see section 4.2 below, Table 1.
BRU22113266P	Femcord Solution For Injection 250mg/5ml	Femcord is indicated for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy, or with disease relapse on or after adjuvant antiestrogen therapy, or disease progression on antiestrogen therapy. Combination therapy with palbociclib Femcord is indicated in combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women with disease progression following endocrine therapy. Combination therapy with abemaciclib Femcord is indicated in combination with abemaciclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women with disease progression after endocrine therapy. Combination therapy with ribociclib Femcord is indicated in combination with ribociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in postmenopausal women as initial endocrine based therapy or following disease progression on endocrine therapy.

BRU22113267P	YSP Tidact 150mg/ml Solution For Injection	Clindamycin has been shown to be effective in the treatment of the following infections when caused by susceptible anaerobic bacteria: susceptible strains of gram positive aerobic bacteria such as streptococci, staphylococci and pneumococci; and susceptible strains of *Chlamydia trachomatis* . a) Upper respiratory infections including tonsillitis, pharyngitis, sinusitis, otitis media and scarlet fever. b) Lower respiratory infection including bronchitis, pneumonia, empyema and lung abscess. c) Skin and soft tissue infections including acne, furuncles, cellulitis, impetigo, abscesses, and wound infections, specific skin and soft tissue infections caused by susceptible organisms like erysipelas and paranychia (panaritium) d) Bone and joint infections including osteomyelitis and septic arthritis. e) Gynecological infections including endometritis, cellulitis, vaginal cuff infection and tubo-ovarian abscess, salpingitis, and pelvic inflammatory disease when given in conjunction with an antibiotic of appropriate gram negative spectrum. In cases of cervicitis due to *Chlamydia trachomatis* , single drug therapy with clindamycin has been shown to be effective in eradicating the organism. f) Intra-abdominal infections including peritonitis and abdominal abscess when given in conjunction with an antibiotic of appropriate gram negative aerobic spectrum. g) Septicemia and endocarditis – the effectiveness of clindamycin in the treatment of selected cases of endocarditis has been documented when clindamycin is determined to be bactericidal to the infecting organism by in vitro testing of appropriate achievable serum concentrations. h) Dental infections such as periodontal abscess and periodontitis. i) Toxoplasmic encephalitis in patients with AIDS. In patients who are intolerant to conventional treatment, clindamycin in combination with pyrimethamine has been shown to be efficacious. j) *Pneumocystis jiroveci* (previously classified as *Pneumocystis carinii*) pneumonia in patients with AIDS. In patients who are intolerant to, or do not respond adequately to conventional treatment, clindamycin may be used in combination with primaquine. Clindamycin phosphate, when used concurrently with an aminoglycoside antibiotic such as gentamicin or tobramycin, has been shown to be effective in preventing peritonitis or intra-abdominal abscess after bowel perforation and bacterial contamination secondary to trauma. In-vitro susceptibility to clindamycin has been shown for the following organisms: *B.melaninogenicus, B.disiens, B.bivius, Peptostreptococcus spp., G. vaginalis, M.mulieris, M.curtisii and Mycoplasma hominis* .
BRU22113268P	Azith® (Oral Suspension 200mg/5ml)	Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, azithromycin is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated in the treatment of chancroid due to *Haemophilus ducreyi* ; and uncomplicated genital infection due to non-multiresistant *Neisseria gonorrhoea* ; concurrent infection with *Treponema pallidum* should be excluded. Azithromycin is indicated, either alone or in combination with rifabutin, for prophylaxis against *Mycobacterium avium-intracellulare complex* (MAC) infection, an opportunistic infection prevalent in patients with advanced human immunodeficiency virus (HIV). Azithromycin is indicated in combination with ethambutol for the treatment of disseminated MAC (DMAC) infection in patients with advanced HIV infection.

BRU22113269P	Vizimpro 15mg Film-Coated Tablet	VIZIMPRO is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution *mutations [see Dosage and Administration (2.1)]* .
BRU22113270P	Vizimpro 30mg Film-Coated Tablet	VIZIMPRO is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution *mutations [see Dosage and Administration (2.1)]* .
BRU22113271P	Vizimpro 45mg Film-Coated Tablet	VIZIMPRO is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution *mutations [see Dosage and Administration (2.1)]* .
BRU22113272P	Skyrizi Solution For Injection In Pre-Filled Syringe 150mg/ml	**Plaque Psoriasis** Skyrizi is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **Psoriatic Arthritis** Skyrizi, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).
BRU22113273P	Skyrizi Solution For Injection In Pre-Filled Pen 150mg/ml	**Plaque Psoriasis** Skyrizi is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **Psoriatic Arthritis** Skyrizi, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).
BRU23013274P	Olumiant 2mg Film-Coated Tablets	Rheumatoid Arthritis Olumiant is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Olumiant may be used as monotherapy or in combination with methotrexate. Atopic Dermatitis Olumiant is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy.

BRU23013275P	Olumiant 4mg Film-Coated Tablets	Rheumatoid Arthritis Olumiant is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Olumiant may be used as monotherapy or in combination with methotrexate. Atopic Dermatitis Olumiant is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy.
BRU23013276P	Bisodac-HF 5mg Tablets	For 5mg & 10 mg • Treatment of high blood pressure (hypertension) • Treatment of coronary heart disease (angina pectoris) • Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.
BRU23013277P	Bisodac-HF 2.5mg Tablets	For 2.5 mg • Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.
BRU23013278P	Gemibine-1000 Gemcitabine For Injection USP 1000mg	Gemcitabine is indicated for the treatment of advanced bladder cancer (muscle invasive Stage IV tumours with or without metastases) in combination with cisplatin. Gemcitabine is indicated for treatment of adult patients with locally advanced or metastatic adenocarcinoma of the pancreas. Gemcitabine, in combination with cisplatin is indicated as first line treatment of patients with locally advanced (inoperable Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer (NSCLC). Gemcitabine is indicated for the palliative treatment of adult patients with locally advanced or metastatic NSCLC. Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.
BRU23013279P	Qilu Palonosetron Hydrochloride Injection 0.25mg/5ml	Palonosetron Hydrochloride Injection is indicated for **Chemotherapy-Induced Nausea and Vomiting** ***Adults and Paediatric Patients 1 month of Age and Older*** • the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy. • the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

BRU23013280P	PeBarin® (75mg Capsule)	*Neuropathic pain* Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. *Epilepsy* Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. *Generalised anxiety disorder* Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.
BRU23013281P	PeBarin® (150mg Capsule)	*Neuropathic pain* Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. *Epilepsy* Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. *Generalised anxiety disorder* Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.
BRU23013282P	Liobac Tablet 10mg	**Liobac** is indicated for the alleviation of spasticity of the skeletal muscles in multiple sclerosis and other spastic conditions occurring from spinal cord diseases of infectious, degenerative, traumatic, neoplastic or unknown origin (e.g. spastic spinal paralysis, amyotrophic lateral sclerosis, syringomyelia, transverse myelitis, traumatic paraplegia or paraparesis, and compression of the spinal cord), muscle spasticity of cerebral origin, especially where due to infantile cerebral palsy. Because of the likelihood of intolerance, **Liobac** is less suitable for spasticity due to cerebrovascular accident or degenerative or neoplastic brain disease, but it may be tried if administered cautiously.
BRU23013283P	Pitomate 25mg Tablet	*Epilepsy* PITOMATE is indicated as monotherapy in patients with newly diagnosed epilepsy or for conversion to monotherapy in patients with epilepsy. PITOMATE is indicated as adjunctive therapy for adults and children aged 2 years and above with partial onset seizures or generalized tonic-clonic seizures. PITOMATE is also indicated in adults and children as adjunctive therapy for the treatment of seizures associated with Lennox-Gastaut syndrome. *Migraine* PITOMATE is indicated in adults for the prophylaxis of migraine headache. The usefulness of PITOMATE in the acute treatment of migraine headache has not been studied.

BRU23013284P	Pitomate 50mg Tablet	*Epilepsy* PITOMATE is indicated as monotherapy in patients with newly diagnosed epilepsy or for conversion to monotherapy in patients with epilepsy. PITOMATE is indicated as adjunctive therapy for adults and children aged 2 years and above with partial onset seizures or generalized tonic-clonic seizures. PITOMATE is also indicated in adults and children as adjunctive therapy for the treatment of seizures associated with Lennox-Gastaut syndrome. *Migraine* PITOMATE is indicated in adults for the prophylaxis of migraine headache. The usefulness of PITOMATE in the acute treatment of migraine headache has not been studied.
BRU23013285P	Pitomate 100mg Tablet	*Epilepsy* PITOMATE is indicated as monotherapy in patients with newly diagnosed epilepsy or for conversion to monotherapy in patients with epilepsy. PITOMATE is indicated as adjunctive therapy for adults and children aged 2 years and above with partial onset seizures or generalized tonic-clonic seizures. PITOMATE is also indicated in adults and children as adjunctive therapy for the treatment of seizures associated with Lennox-Gastaut syndrome. *Migraine* PITOMATE is indicated in adults for the prophylaxis of migraine headache. The usefulness of PITOMATE in the acute treatment of migraine headache has not been studied.
BRU23013286NP	Trovite IV Injection	For the rapid treatment of severe vitamin deficiencies which can occur in association with: alcoholism; Wernicke's encephalopathy and Korsa-Koff's psychosis; subacute confusional delirium or amnesic states; specific deficiency syndrome-pellagra, beri-beri, anorexia nervosa; parenteral nutrition, severe malnutrition.
BRU23013287P	Monem 1g Powder For Injection	Meropenem is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem: Pneumonias including hospital acquired pneumonias, Urinary Tract Infection, Intra abdominal Infections, Gynaecological Infections, such as endometritis and pelvic inflammatory diseases, Bacterial Meningitis, Septicaemia, and Empiric treatment for presumed infections in patients with febrile neutropenia used as monotherapy or in combination with anti-viral or anti-fungal agents. Meropenem has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.
BRU23013288P	Kertet 20 Tablet	Leflunomide is indicated for the treatment of adult patients with: - active rheumatoid arthritis as a "disease-modifying antirheumatic drug" (DMARD) - active psoriatic arthritis Recent or concurrent treatment with hepatotoxic or hematotoxic DMARDs (e.g. Methotrexate) may result in an increased risk of serious adverse reactions; therefore, the initiation of Leflunomide treatment has to be carefully considered regarding these benefit/risk aspects. Moreover, switching from Leflunomide to another DMARD without following the washout procedure may also increase the risk of serious adverse reactions even for a long time after the switching.
BRU23013289P	Pontevia 120mg Solution For Injection In Pre-Filled Syringe	PONTEVIA is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month.

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BRU23013290P	Pontevia 120mg Solution For Injection In Pre-Filled Pen	PONTEVIA is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month.
BRU23013291NP	Norphenadol® Tablet	Tension headache, occipital headaches associated with spasm of skeletal muscles in the region of the head and neck. Acute and traumatic conditions of the limbs and trunk: sprains, strains, whiplash injuries, acute torticollis, prolapsed intervertebral disc.
BRU23013292P	Sisalon 50 Tablet	Sertraline is indicated for the treatment of: - Major depressive episodes. Prevention of recurrence of major depressive episodes - Panic disorder, with or without agoraphobia - Obsessive compulsive disorder (OCD) in adults and pediatric patients aged 6-17 years - Social anxiety disorder - Post traumatic stress disorder (PTSD)
BRU23013293P	Pharmaniaga Isoniazid Tablet 100mg	Isoniazid is used primarily in conjunction with other anti-tuberculosis drugs in the treatment of all forms of tuberculosis. Isoniazid is also used in the treatment of tuberculosis meningitis and non-tuberculosis mycobacterium infections.
BRU23023294NP	Siang Pure Oil Formula 1	Bottle: Inhale or rub over for relief of dizziness, faint, muscle pains, insect bites and itches. Ball Tip: Rub over for relief of itches from insect bites.
BRU23023295NP	Ferrovit Capsule	For patients with anemia or pregnant women with anemic symptoms.
BRU23023296P	Gemtero 1g (Gemcitabine For Injection 1g)	• Gemcitabine is indicated for the treatment of locally advanced or metastatic non-small cell-lung cancer • Gemcitabine is indicated for the treatment of adult patients with locally advanced or metastatic adrenocarcinoma of the pancreas. Gemcitabine is indicated for patients with 5-FU refractory pancreatic cancer • Gemcitabine is indicated for the treatment of patients suffering from bladder cancer, at the invasive stage • Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated • Gemcitabine, in combination with carboplatin, is indicated for the treatment of patients with recurrent epithelial ovarian carcinoma, who have relapse > 6 months, following platinum-base therapy

BRU23023297P	Prega-75 (Pregabalin Hard Capsules 75mg)	**Neuropathic Pain:** Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. **Epilepsy:** As adjunctive therapy in adults with partial seizures with or without secondary generalisation. **Generalised Anxiety Disorder:** Treatment of Generalised Anxiety Disorder (GAD) in adults. **Fibromyalgia**: Management of fibromyalgia.
BRU23023298P	Prega-150 (Pregabalin Hard Capsules 150mg)	**Neuropathic Pain:** Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. **Epilepsy:** As adjunctive therapy in adults with partial seizures with or without secondary generalisation. **Generalised Anxiety Disorder:** Treatment of Generalised Anxiety Disorder (GAD) in adults. **Fibromyalgia**: Management of fibromyalgia.
BRU23023299P	Pharmaniaga Co-Amoxiclav Tablet 625mg	It is indicated for the treatment of the following infections: a) Upper & lower respiratory tract infections – sinusitis, otitis media, bronchitis. b) Skin and soft tissue infections – boils, abscesses, cellulitis, wound infections. c) Genitourinary tract infections – cystitis, urethritis, pyelonephritis. d) Bone & joint infections – osteomyelitis.
BRU23023300P	Flumazenil Kabi 0.1mg/ml Solution For Injection	Flumazenil 0.1mg/ml injection is indicated for the complete or partial reversal of the central sedative effects of benzodiazepines. It may therefore be used in anaesthesia and in intensive care in the following situations: In anaesthesia - Termination of hypnosedative effects in general anaesthesia induced and/or maintained with benzodiazepines in hospitalized patients. - Reversal of benzodiazepine sedation in short-term diagnostic and therapeutic procedures in ambulatory patients and hospitalized patients. In intensive care situations: - For diagnosis of intoxication with benzodiazepines or to rule out such intoxication. - As a diagnostic measure in unconsciousness unknown origin to differentiate between involvement of benzodiazepines, other drugs or brain damage. - For specific reversal of the central effects of benzodiazepines in drug overdose (return to spontaneous respiration and consciousness in order to render intubation unnecessary or allow extubation).

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BRU23023301P	Afstyla 250 IU Powder And Solvent For Solution For Injection	*AFSTYLA* is indicated in adults and pediatrics with hemophilia A (congenital factor VIII deficiency) for: • Control and prevention of bleeding episodes, • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes. • Perioperative prophylaxis (surgical prophylaxis)
BRU23023302P	Afstyla 500 IU Powder And Solvent For Solution For Injection	*AFSTYLA* is indicated in adults and pediatrics with hemophilia A (congenital factor VIII deficiency) for: • Control and prevention of bleeding episodes, • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes. • Perioperative prophylaxis (surgical prophylaxis)
BRU23023303P	Covee Cream 1% w/w	Covee is indicated for the treatment of fungal skin infections such as dermatophytoses (athlete's foot, ringworm), pityriasis versicolour, fungal infection of the tissue adjacent to nails and skin folds and erythrasma (skin redness/irritation).
BRU23023304P	YSP Pulin Injection 5mg/ml	Adult population This product is indicated in adults for: - Prevention of post-operative nausea and vomiting - Symptomatic treatment of nausea and vomiting, including nausea and vomiting induced by migraine attacks - Prevention of radiotherapy-induced nausea and vomiting Pediatric population This product is indicated in children aged 1 to 18 years for: - Prevention of delayed chemotherapy-induced nausea and vomiting as a second-line option - Prevention of post-operative nausea and vomiting as a second-line option
BRU23023305P	Idaman Pharma Diazepam Tablet 5mg	1) Treatment of anxiety. 2) Treatment of acute alcohol withdrawal symptoms. 3) Indicated for preoperative procedures to relieve anxiety and tension. 4) Indicated as an adjunct prior to endoscopic procedures. 5) Indicated as short-term (7-14 days) adjunctive therapy in convulsive disorder. 6) Indicated as an adjunct for the treatment of skeletal muscle spasm. 7) Treatment of familial, senile or essential action tremors.

BRU23023306P	Amlocord 5 Tablet 5mg	**Hypertension** Amlodipine is indicated for the first-line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme (ACE) inhibitor. **Coronary Artery Disease** *Chronic Stable Angina* Amlodipine is indicated for the symptomatic treatment of chronic stable angina. Amlodipine may be used alone or in combination with other antianginal drugs. *Vasospastic Angina (Prinzmetal's or variant angina)* Amlodipine is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy, or in combination with other antianginal drugs. *Angiographically Documented Coronary Artery Disease* In patients with recently documented coronary artery disease (CAD) by angiography and without heart failure or an ejection fraction <40%, amlodipine is indicated to reduce the risk of hospitalization due to angina and to reduce the risk of a coronary revascularization procedure.
BRU23053307P	Tiaryt Injection	Serious rhythm disorders when the oral route is not appropriate, namely: • Atrial rhythm disorders, with rapid ventricular rhythm. • Wolf-Parkinson-White syndrome tachycardia. • Documented symptomatic and disabling ventricular rhythm disorders.
BRU23053308P	Valoin Injection	Valoin is indicated for the treatment of epileptic patients who would normally be maintained on oral sodium valproate, and for whom oral therapy is temporarily not possible.
BRU23053309P	Bendamustine Hydrochloride 2.5mg/ml Powder For Concentrate For Solution For Infusion	First-line treatment of chronic lymphocytic leukaemia (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate. Indolent non-Hodgkin's lymphomas as monotherapy in patients who have progressed during or within 6 months following treatment with rituximab or a rituximab containing regimen. Front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment.
BRU23053310P	Mixagrip Extra Caplet	MIXAGRIP is a cold preparation to alleviate and relieve any influenza symptoms, such as sneezing, catarrh, nasal congestion, muscle pain, headache/dizziness and fever.

BRU23053311P	Cefmex 1g Powder For Injection	**Adult**: Cefmex is indicated in adults for the treatment of the following infections when caused by susceptible strains of bacteria: Lower respiratory tract infections (including pneumonia and bronchitis). Urinary tract infections (both complicated, including pyelonephritis and uncomplicated infections). Skin and skin structure infections. Intra-abdominal infections (including peritonitis and biliary tract infections). Gynecological infections. Septicemia. Empiric treatment in febrile neutropenic patients. **Pediatrics**: Cefmex is indicated in pediatric patients for treatment of infections when caused by susceptible bacteria: Pneumonia Urinary tract infections (both complicated and uncomplicated, including pyelonephritis) Skin and skin structure infections Septicemia Empiric treatment in febrile neutropenia. Culture and susceptibility studies should be performed when appropriate to determine susceptibility of the causative organism(s) to cefepime. Empiric therapy with Cefmex may be instituted before results of susceptibility studies are known; however, once these results become available, the antibiotic treatment should be adjusted accordingly. Because of its broad spectrum of bactericidal activity against gram-positive and gram-negative bacteria, Cefmex can be used as monotherapy prior to identification of the causative organism(s). In patients who are at risk of mixed aerobic-anaerobic infection, particularly if bacteria not susceptible to cefepime may be present, concurrent initial therapy with anti-anaerobic agent is recommended before the causative agents may or may not be necessary, depending on the susceptibility profile.

BRU23053312P	Penatone Injection 4mg/ml (2ml Ampoule)	**By intravenous or intramuscular injection when oral therapy is not feasible: Adrenocortical insufficiency:** Dexamethasone phosphate Injection has predominantly glucocorticoid activity with low mineralocorticoid activity. Therefore, it does not offer complete replacement therapy, and its use must be supplemented with salt and/or desoxycorticosterone. When so supplemented, Dexamethasone Phosphate Injection is indicated in the impairment of all adrenocortical activity, as in Addison's disease or following bilateral adrenalectomy that requires replacement of both glucocorticoid and mineralocorticoid activity. **Relative Adrenocortical Insufficiency:** In the relative adrenocortical insufficiency that may occur following cessation of long-term therapy with suppressive doses of adrenocortical hormones, mineralocorticoid secretion may be unimpaired. Replacement with a hormone that acts predominantly as a glucocorticoid may be sufficient to restore adrenocortical function. When immediate support is mandatory, Dexamethasone Phosphate Injection may be effective within minutes after administration and can be life-saving. **Pre-operative and Post-operative support:** Patients undergoing bilateral adrenalectomy, or hypophysectomy, or any other surgical procedure when adrenocortical reserve is doubtful, and in post-operative shock unresponsive to conventional therapy. **Non-supportive Thyroiditis:** Shock: Injection Dexamethasone Phosphate is recommended for the adjunctive therapy of shock where high (Pharmacological) doses of corticosteroids are needed; severe shock of haemorrhagic, traumatic or surgical origin. Treatment with Injection Dexamethasone Phosphate is an adjunct, to and not a substitute for, specific or supportive measures that the patient may require. **Rheumatic Disorders:** As adjunctive therapy for short-term administration to support the patient during an acute episode or exacerbation in: Post-traumatic osteoarthritis; synovitis of osteoarthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); acute subacute bursitis; epicondylitis; acute nonspecific tenosynovitis; acute gouty arthritis; psoriatic arthritis; ankylosing arthritis; ankylosing spondylitis. **Collagen disease**: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus; acute rheumatic carditis. **Dermatological Disease:** Pemphigus; severe erythema multiforme (Stevens Johnson Syndrome); exfoliative dermatitis; bullous dermatitis herpetiformis; severe seborrhoeic dermatitis; severe psoriasis; mycosis fungoides. **Allergic states:** Control of severe of incapacitating allergic conditions intractable to adequate trials of conventional treatment in: bronchial asthma; contact dermatitis; atopic dermatitis; serum sickness; seasonal or perennial allergic rhinitis; drug hypersensitivity reactions; urticarial transfusion reactions; acute noninfectious laryngeal oedema; anaphylaxis (epinephrine is the drug of first choice). **Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis; keratitis; allergic corneal marginal ulcers; herpes zoster ophthalmicus; iritis, iridocyclitis; chorioretinitis; diffuse posterior uveitis and choroiditis; optic neuritis; sympathetic ophthalmia; anterior segment inflammation. **Gastrointestinal diseases:** To support the patient during a critical period of disease in: ulcerative colitis (systemic therapy); regional enteritis (systemic therapy); regional enteritis (systemic therapy).

		Respiratory Disease: Symptomatic sarcoidosis: Loeffler's syndrome not manageable by other means; Berylliosis; fulminating or disseminated pulmonary tuberculosis when concurrently accompanied by appropriate antituberculous chemotherapy; aspiration pneumonitis. **Haematological Disorders:** Acquired (autoimmune) haemolytic anaemia; idiopathic thrombocytopenic purpura in adults (I.V. only, I.M. administration is contraindicated); secondary thrombocytopenia in adults; erythroblastopenia (R.B.C. anaemia); congenital (erythroid) hypoplastic anaemia. **Neoplastic Diseases:** For palliative management of: hypercalcaemia associated with cancer; leukamias and lymphomas in adults; acute leukamia of childhood. **Oedematous States:** To induce diuresis or remission of proteinuria in the nephrotic syndrome without uraemia of the idiopathic type, or that due to lupus erythematosus. **Cerebral oedema:** Dexamethasone Phosphate Injection may be used to treat patients with cerebral oedema from various causes: (a) associated with primary or metastatic brain tumours, (b) associated with neurosurgery, (c) associated with head injury or pseudo-tumour cerebri, (d) associated with cerebral vascular accident (acute stroke) involving the cerebral cortex. It may be used also in the preoperative preparation of patients with increased intracranial pressure secondary to brain tumours or for pallation of patients with inoperable or recurrent brain neoplasms. Use of Dexamethasone Phosphate Injection in cerebral oedema is not a substitute for careful neurological evaluation and definitive management such as neurosurgery or other specific therapy. **Diagnostic Testing of Adrenocortical Hyperfunction** **Neonatal respiratory distress syndrome; antenatal prophylaxis:** Use of Dexamethasone Phosphate Injection in mothers at high risk for premature delivery has been shown to reduce the incidence of neonatal respiratory distress syndrome. **By intra-articular or soft-tissue injection:** As adjunctive therapy for short-term administration (to support patient during an acute episode or exacerbation) in: synovitis of osteoarthritis; rheumatoid arthritis; acute and subacute bursitis; acute gouty arthritis; epicondylitis; acute non-specific tenosynovitis; post-traumatic osteoarthritis. **By intralesional injection: Keloids:** localised hypertrophic, infiltrated, inflammatory lesions of: lichen planus, psoriatic plaques, granuloma annulare, and lichen simplex chronicus (neurodermatitis); discoid lupus erythematosus; necrobiosis lipoidica diabeticorum; alopecia areata; may also be useful in cystic tumours of an aponeurosis or tendon (ganglia).
BRU23053313P	Azacitidine Seacross 25mg/ml Powder For Suspension For Injection	Azacitidine Seacross is indicated for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with: • intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS), • chronic myelomonocytic leukaemia (CMML) with 10-29% marrow blasts without myeloproliferative disorder, • acute myeloid leukaemia (AML) with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification, • AML with >30% marrow blasts according to the WHO classification.
BRU23053314P	YSP Tren Injection 100mg/ml	1. Bleeding tendencies in which systemic hyperfibrinolysis is considered to be involved. (Leukemia, aplastic anemia, purpura, etc., abnormal bleeding during or after operation.) 2. Abnormal bleeding in which local hyperfibrinolysis is considered to be involved. (Pulmonary hemorrhage, nasal hemorrhage, vaginal hemorrhage, renal hemorrhage, abnormal bleeding during or after prostate surgery.) 3. Symptoms, such as erythema, swelling or pruritus in the following diseases: Eczema or similar conditions, urticaria, drug eruptions or toxicoderma. 4. Symptoms, such as pharyngalgia, redness, hyperemia or swelling in the following diseases: Tonsillitis, pharyngolaryngitis. 5. Pain in the oral cavity or mucosal aphtha in cases of stomatitis.

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BRU23053315P	MenQuadfi – Meningococcal Vaccine, Solution For Injection In 0.5ml Vial	MenQuadfi is indicated for active immunisation of individuals from the age of 12 months and older against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y. The use of this vaccine should be in accordance with available official recommendations.
BRU23053316P	Naldebain® Extended Release Injection 75mg/ml	**NALDEBAIN** is indicated for the relief of moderate to severe acute postsurgical pain.
BRU23053317P	RINVOQ® 30mg Extended-Release Tablets	<u>Rheumatoid arthritis</u> RINVOQ® is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). RINVOQ® may be used as monotherapy or in combination with methotrexate. <u>Psoriatic arthritis</u> RINVOQ® is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. RINVOQ® may be used as monotherapy or in combination with methotrexate. <u>Atopic dermatitis</u> RINVOQ is indicated for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.
BRU23053318NP	Viquprin Tablet	VIQUPRIN is used as a platelet aggregation inhibitor in patients following aortocoronary by-pass surgery, to prevent graft occlusion. Conditions where modification of platelet behaviour is considered beneficial, including transient ischaemic attacks, secondary prevention of myocardial infarction, and for prophylaxis against stroke, vascular occlusion and deep vein thrombosis.
BRU23053319NP	Salonpas Jet Spray	For relief of aches, pains and inflammations associated with: ▪ Muscle fatigue ▪ Muscle pain ▪ Backache ▪ Stiff shoulder ▪ Joint pain ▪ Strains ▪ Sprains ▪ Bruises ▪ Arthritis

BRU23053320P	Amlocord 10 Tablet 10mg	**Hypertension** Amlodipine is indicated for the first-line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme (ACE) inhibitor. **Coronary Artery Disease** *Chronic Stable Angina* Amlodipine is indicated for the symptomatic treatment of chronic stable angina. Amlodipine may be used alone or in combination with other antianginal drugs. *Vasospastic Angina (Prinzmetal's or variant angina)* Amlodipine is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy, or in combination with other antianginal drugs. *Angiographically Documented Coronary Artery Disease* In patients with recently documented coronary artery disease (CAD) by angiography and without heart failure or an ejection fraction <40%, amlodipine is indicated to reduce the risk of hospitalization due to angina and to reduce the risk of a coronary revascularization procedure.
BRU23053321P	Rabirox Capsule 200mg	• For the management of acute pain in adults and for the treatment of primary dysmenorrhea. • Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis. • Relief of signs and symptoms of ankylosing spondylitis. • For the management of low back pain (200 mg only).
BRU23053322P	Rabirox Capsule 400mg	• For the management of acute pain in adults and for the treatment of primary dysmenorrhea. • Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis. • Relief of signs and symptoms of ankylosing spondylitis.
BRU23063323P	Motidom Tablet	Domperidone is indicated for the relief of the symptoms of nausea and vomiting. This includes: • Nausea and vomiting of functional, organic, infectious or dietary origin. • Nausea and vomiting induced by: - radiotherapy or drug therapy - dopamine agonists (such as L-dopa and bromocriptine) used in the treatment of Parkinson's disease.
BRU23063324NP	Healthy Care Super Hair Skin & Nail Capsules	Maintain collagen formation and enhance healthy hair, skin and strong nails.
BRU23063325P	Gluvox (Metformin HCl Film-Coated Tablet 500mg)	• Type 2 Diabetes Mellitus [monotherapy or in combination with other antidiabetic drugs (including insulin)] • Type 2 Diabetes Mellitus [reduction in risk or delay of onset]

BRU23063326P	Nevox XR	• **NEVOX XR** is indicated in patients 17 years of age and older. • **NEVOX X**R, as monotherapy, is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. • **NEVOX XR** may be used concomitantly with a Sulfonylurea or Insulin to improve glycemic control in adults (17 years of age and older).
BRU23063327P	Difflam Forte Anti-Inflammatory Throat Spray 0.3% w/v	Difflam® Forte Anti-Inflammatory Throat Spray 0.3% w/v is indicated for the temporary relief of painful conditions of the mouth and throat including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, pharyngitis, swelling, redness, inflammatory conditions, post orosurgical and periodontal procedures.
BRU23063328P	Pitasor 2 Tablet	Indicated for the reduction of elevated total cholesterol (TC) and LDL-C, in adults, adolescents and children aged 6 years or older with primary hypercholesterolemia, including heterozygous familial hypercholesterolemia, and combined (mixed) dyslipidaemia, when response to diet and other non-pharmacological measures is inadequate.
BRU23063329P	Pharmaniaga Dermapro Cream 0.05% w/w	Clobetasol is indicated for short-term treatment of inflammation and/or pruritus associated with acute and chronic corticosteroid-responsive skin disorders.
BRU23063330P	Pradox 50 Tablet	***Epilepsy*** Monotherapy in adults, adolescents and children over 6 years of age with partial seizures with or without secondary generalized seizures, and primary generalized tonic-clonic seizures. Adjunctive therapy in children aged 2 years and above, adolescents and adults with partial onset seizures with or without secondary generalization or primary generalized tonic-clonic seizures and for the treatment of seizures associated with Lennox-Gastaut syndrome. ***Migraine*** Topiramate is indicated in adults for the prophylaxis of migraine headache after careful evaluation of possible alternative treatment options. Topiramate is not intended for acute treatment.
BRU23063331P	Pharmaniaga Diphenhydramine Expectorant	Cough, nasal and bronchial congestion.
BRU23063332P	Bilkate 5 Tablet	<u>Hypertension</u> Treatment of essential hypertension. <u>Chronic heart failure (CHF)</u> Treatment of stable mild to moderate chronic heart failure (CHF) in addition to standard therapies in elderly patients ≥70 years.
BRU23063333P	Celxib 400 Capsule	- For the management of acute pain in adults and For the treatment of primary dysmenorrhea - Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis - Relief of signs and symptoms of ankylosing spondylitis

BRU23063334P	Gonal-F 150IU/0.25ml (11mcg/0.25ml) Solution For Injection In Pre-Filled Pen	In adult women • Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. • Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer.
BRU23063335P	DARZALEX Faspro™ 1,800mg Solution For Injection	**Multiple Myeloma** DARZALEX FASPRO is indicated for the treatment of adult patients with multiple myeloma: • in combination with lenalidomide and dexamethasone - in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. - in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. • in combination with bortezomib, melphalan, prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. • in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant • in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. • in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. • as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. **Light chain (AL) amyloidosis** DARZALEX FASPRO is indicated in combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of adult patients with newly diagnosed systemic AL amyloidosis.
BRU23063336P	Inhixa 2000 IU/0.2ml Solution For Injection In Pre-Filled Syringe	Inhixa is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure, respiratory insufficiency, severe infections or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Prevention of thrombus formation in extra corporeal circulation during haemodialysis. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI).

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BRU23063337P	Inhixa 4000 IU/0.4ml Solution For Injection In Pre-Filled Syringe	Inhixa is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure, respiratory insufficiency, severe infections or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Prevention of thrombus formation in extra corporeal circulation during haemodialysis. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI).
BRU23063338P	Inhixa 6000 IU/0.6ml Solution For Injection In Pre-Filled Syringe	Inhixa is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure, respiratory insufficiency, severe infections or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Prevention of thrombus formation in extra corporeal circulation during haemodialysis. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI).
BRU23063339P	Enerzair® Breezhaler® 150/50/80mcg Inhalation Powder, Hard Capsules	Enerzair Breezhaler is indicated as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.
BRU23063340P	Remabrex 200mg Capsules	**REMABREX** is indicated for: • Relief of the signs and symptoms of OA (osteoarthritis), RA (rheumatoid arthritis), and AS (ankylosing spondylitis). • Short treatment of acute pain in adults following surgery or musculoskeletal injury.

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BRU23063341P	Caeseva Film-Coated Tablet 800mg	CAESEVA is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. CAESEVA is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease (CKD) not on dialysis with serum phosphorus ≥ 1.78 mmol/l. CAESEVA should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy Vitamin D3 or one of its analogues to control the development of renal bone disease.
BRU23073342P	Rosucor Tablets 10mg	Mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and exercise is inadequate. Homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) when response to diet and exercise is inadequate.
BRU23073343P	Rosucor Tablets 20mg	Mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and exercise is inadequate. Homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) when response to diet and exercise is inadequate.
BRU23073344P	Fusix Injection 20mg/2ml	Frusemide is indicated in the treatment of edema associated with congestive heart failure, hepatic cirrhosis and renal disease (including nephrotic syndrome). It is also indicated as an adjunct in the treatment of acute pulmonary edema and hypertensive crisis.
BRU23073345NP	Oracue Gel	ORACUE helps to relieve pain, inflammation, and to treat minor infection due to common mouth ulcers, cold sores, denture and sore spots, as well as mouth ulcers and sore spots due to orthodontic devices. To help to fight minor mouth infection and healing of sore spots and ulcers due to dentures and orthodontic devices. Oracue helps to relieve and soothe teething.
BRU23073346P	Vastinor Tablet 10mg	<u>Treatment of hypercholesterolaemia</u> Adults, adolescents and children aged 6 years or older with primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate. Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate. <u>Prevention of Cardiovascular Events</u> Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

BRU23073347P	Atswift 40 Tablet	**Hypercholesterolaemia** Atorvastatin Tablets is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin Tablets is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. **Prevention of cardiovascular disease** Atorvastatin Tablets is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥ 55 years, male sex, smoking, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminia or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥ 6, or premature family history of coronary heart disease. In adults with type 2 diabetes and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, Atorvastatin Tablet is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In adults with clinically evident coronary heart disease, atorvastatin is indicated to: - Reduce the risk of non-fatal myocardial infarction - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for CHF - Reduce the risk of angina

		Treatment: Doxycycline is indicated for treatment of the following infections: • Rocky Mountain spotted fever, typhus fever and the typhus group; • Q fever, rickettsial pox and tick fevers caused by *Rickettsiae* ; • Respiratory infections caused by *Mycoplasma pneumoniae* ; • Psittacosis caused by *Chlamydia psittaci* ; • Lymphogranuloma venereum, caused by *Chlamydia trachomatis* ; • Uncomplicated urethral, endocervical or rectal infections in adults caused by *Chlamydia trachomatis* ; • Trachoma caused by *Chlamydia trachomatis* although the infectious agent is not always eliminated, as judged by immunofluorescence; • Inclusion conjunctivitis caused by *Chlamydia trachomatis* may be treated with oral doxycycline alone or with a combination of topical agents; • Granuloma inguinale (donovanosis) caused by *Calymmatobacterium granulomatis* ; • Early (Stage 1) Lyme disease caused by *Borrelia burgdorferi* ; • Louse-borne relapsing fever caused by *Borrelia recurrentis* ; • Tick-borne relapsing fever caused by *Borrelia duttonii* ; • Non-gonococcal urethritis (NGU) caused by *Ureaplasma urealyticum (T-Mycoplasma)* . Doxycycline is also indicated for the treatment of infections caused by the following gram-negative microorganisms: • *Acinetobacter* species; • *Bacteroides* species; • *Fusobacterium* species; • Brucellosis caused by *Brucella* species (in conjunction with streptomycin); • Plague caused by *Yersinia pestis* ; • Tularemia caused by *Francisella tularensis* ; • Bartonellosis caused by *Bartonella bacilliformis* ; • *Campylobacter fetus* . Because many strains of the following groups of microorganisms have been shown to be resistant to tetracyclines, culture and susceptibility testing are recommended.

BRU23073348P	Pharmaniaga Doxycycline Capsule 100mg	Doxycycline is indicated for treatment of infections caused by the following gram-negative microorganisms, when bacteriologic testing indicates appropriate susceptibility to the drug: • *Shigella* species; • Uncomplicated gonorrhea caused by *Neisseria gonorrhoeae* ; • Respiratory infections caused by *Haemophilus influenzae* ; • Respiratory and urinary infections caused by *Klebsiella species* ; • *Escherichia coli* ; • *Enterobacter aerogenes* ; • *Moraxella catarrhalis* . Doxycycline is indicated for treatment of infections caused by the following gram-positive microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug: • *Streptococcus* species: A certain percentage of strains of *Streptococcus pyogenes* and *Streptococcus faecalis* have been found to be resistant to tetracycline drugs. Tetracyclines should not be used for streptococcal infections unless the organism has been demonstrated to be sensitive. • For upper respiratory infections due to group A beta-hemolytic streptococci, penicillin is the usual drug of choice, including prophylaxis of rheumatic fever. This includes: - Upper respiratory tract infections caused by *Streptococcus pneumoniae* ; Respiratory, skin and soft-tissue infections caused by *Staphylococcus aureus* . Tetracyclines are not the drug of choice in the treatment of staphylococcal infections. When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of: • Actinomycosis caused by *Actinomyces* species; • Infections caused by *Clostridium* species; • Syphilis caused by *Treponema pallidum* and yaws caused by *Treponema pertenue* ; • Listeriosis caused by *Listeria monocytogenes* ; • Vincent's infection (acute necrotizing ulcerative gingivitis) caused by *Leptotrichia buccalis* (formerly, *Fusobacterium fusiform*).

		Adjunctive treatment In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides. In severe acne caused by *acne vulgaris* , doxycycline may be useful adjunctive therapy. Treatment and Prophylaxis Doxycycline is indicated for the prophylaxis and treatment of the following infections: • Malaria caused by *Plasmodium falciparum* (in areas with chloroquine-resistant *P. falciparum*). • Leptospirosis caused by genus *Leptospira* . • Cholera caused by *Vibrio cholerae* . Prophylaxis Doxycycline is indicated as prophylaxis in the following conditions: • Scrub typhus caused by Rickettsia *tsutsugamushi* ; • Traveler's diarrhea caused by enterotoxigenic *Escherichia coli* .
BRU23093349NP	Peppermint Field Inhaler	Peppermint Field Inhaler provides symptomatic relief of nasal congestion and dizziness.
BRU23093350P	Meropenem Kabi 1g, Powder For Solution For Injection Or Infusion	Meropenem IV is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem: -pneumonias and nosocomial pneumonias -urinary tract infections -intra-abdominal infections -gynaecological infections, such as endometritis and pelvic inflammatory disease -bacterial meningitis -septicaemia -empiric treatment, for presumed infections in patients with febrile neutropenia, used as monotherapy or in combination with anti-viral or anti-fungal agents Meropenem IV has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.
BRU23093351NP	Axcel Paracetamol-500 Tablet	Paracetamol is used to relieve fever and mild to moderate pain associated with conditions such as headache, migraine, backache, toothache, aches due to the colds and flu, muscular rheumatism and dysmenorrhea.

BRU23093352P	Vultin 300 Capsule	Epilepsy Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above. Gabapentin is indicated as monotherapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above. Treatment of peripheral neuropathic pain Gabapentin is indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults.
BRU23093353P	Ondavell Injection 4mg/2ml	***Adults*** Ondansetron injection is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. Ondansetron is also indicated for the prevention and treatment of post-operative nausea and vomiting. **Paediatric Population** **Injection and oral formulations:** Ondansetron is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy. No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting; IV injection is recommended for this purpose.
BRU23093354P	Ondavell Film-Coated Tablet 8mg	**Adults** Ondansetron is indicated to manage nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. Ondansetron is also indicated for the prevention of post-operative nausea and vomiting. **Paediatric Population** Ondansetron is indicated to manage nausea and vomiting induced by cytotoxic chemotherapy.
BRU23093355P	Novorin Injection 10mg/ml	Calcium Folinate is indicated a) To diminish the toxicity and counteract the action of folic acid antagonists such as methotrexate in cytotoxic therapy and overdose in adults and children. In cytotoxic therapy, this procedure is commonly known as 'Calcium Folinate Rescue'. b) In combination with 5-fluorouracil in cytotoxic therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU23093356P	Vastinor Tablet 20mg	Treatment of hypercholesterolaemia Adults, adolescents and children aged 6 years or older with primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate. Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate. Prevention of Cardiovascular Events Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
BRU23093357P	Kemocarb Solution For Injection 10mg/ml	Carboplatin is used as initial chemotherapy of advanced ovarian carcinoma in combination with other approved chemotherapeutic agents. Carboplatin is used as palliative treatment of patients with ovarian carcinoma recurrent after prior chemotherapy, including patients who have been previously treated with cisplatin.
BRU23093358P	Imiquad Cream (Imiquimod Cream USP 5% w/w)	Imiquimod cream is indicated for: 1. Treatment of external genital and perianal warts/condyloma accuminata in adults. 2. Treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adults. 3. Treatment of biopsy-confirmed, primary superficial basal cell carcinoma (sBCC) in immunocompetent adults, with a maximum tumor diameter of 2.0 cm, located on the trunk (excluding anogenital skin), neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured. The histological diagnosis of superficial basal cell carcinoma should be established prior to treatment, since safety and efficacy of imiquimod cream have not been established for other types of basal cell carcinomas, including nodular and morpheaform (fibrosing or sclerosing) types.
BRU23093359P	Bioxitide 25/250mcg/Dose HFA Inhalation Aerosol	**Asthma (Reversible Obstructive Airways Disease)** Bioxitide™ is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: • Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. • Patients who are symptomatic on current inhaled corticosteroid therapy. • Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** Bioxitide™ is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU23093360P	Novomin Syrup 15mg/5ml	**Novomin** has anti-emetic properties and is used for the prevention and treatment of nausea and vomiting, such as in travel or motion sickness.
BRU23103361P	Isoniazid 300mg Tablets	Isoniazid Tablets BP 300 mg is indicated for the treatment of tuberculosis, caused by *Mycobacterium tuberculosis* .

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU23103362P	Cosyrel 10mg/5mg Film-Coated Tablet	Cosyrel 10mg/5mg are indicated as substitution therapy for treatment of hypertension and/or stable coronary artery disease (in patients with a history of myocardial infarction and/or revascularisation) and/or stable chronic heart failure with reduced systolic left ventricular function in adult patients adequately controlled with bisoprolol and perindopril given concurrently at the same dose level.
BRU23103363P	Cosyrel 10mg/10mg Film-Coated Tablet	Cosyrel 10mg/10mg are indicated as substitution therapy for treatment of hypertension and/or stable coronary artery disease (in patients with a history of myocardial infarction and/or revascularisation) in adult patients adequately controlled with bisoprolol and perindopril given concurrently at the same dose level.
BRU23103364P	Cosyrel 5mg/10mg Film-Coated Tablet	Cosyrel 5mg/10mg are indicated as substitution therapy for treatment of hypertension and/or stable coronary artery disease (in patients with a history of myocardial infarction and/or revascularisation) in adult patients adequately controlled with bisoprolol and perindopril given concurrently at the same dose level.
BRU23103365P	Cosyrel 5mg/5mg Film-Coated Tablet	Cosyrel 5mg/5mg are indicated as substitution therapy for treatment of hypertension and/or stable coronary artery disease (in patients with a history of myocardial infarction and/or revascularisation) and/or stable chronic heart failure with reduced systolic left ventricular function in adult patients adequately controlled with bisoprolol and perindopril given concurrently at the same dose level.
BRU23103366P	Herbesser R200 Sustained Release Capsule	- Essential hypertension (mild to moderate) - Angina pectoris, variant angina pectoris
BRU23103367P	Abiranat Tablets 250mg	Abiraterone acetate tablets are indicated with prednisone or prednisolone for: • the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT) (see section 5.1). • the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated (see section 5.1). • the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.
BRU23103368P	Biosone 100mcg Per Dose HFA Inhalation Aerosol	Indicated for the prophylactic management of mild, moderate or severe asthma.
BRU23103369P	Claritrox 250 Tablet	Treatment of infections due to susceptible organisms of the upper respiratory tract infections (e.g. streptococcal pharyngitis/tonsillitis, acute maxillary sinusitis), lower respiratory tract infections (e.g. bronchitis, pneumonia), acute otitis media, skin and skin structure infections (e.g. impetigo, folliculitis, cellulitis, abscesses).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU23103370P	Maforan 1mg Tablet	**MAFORAN** is indicated for: • Prophylaxis and/or treatment of venous thrombosis and its extension, and pulmonary embolism. • Prophylaxis and/or treatment of the thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement. • Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction in patients with poor LV function.
BRU23103371P	Maforan 2mg Tablet	**MAFORAN** is indicated for: • Prophylaxis and/or treatment of venous thrombosis and its extension, and pulmonary embolism. • Prophylaxis and/or treatment of the thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement. • Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction in patients with poor LV function.
BRU23103372P	Zithronam Powder For Oral Suspension 200mg/5ml	Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, azithromycin is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated in the treatment of chancroid due to *Haemophilus ducreyi* ; and uncomplicated genital infection due to non-multiresistant *Neisseria gonorrhoea* ; concurrent infection with *Treponema pallidum* should be excluded.
BRU23103373P	Afzoline XL 10 Tablet	Treatment of the functional symptoms of benign prostatic hypertrophy (BPH). For information on use in acute urinary retention (AUR) related to BPH (see section *Dosage and Administration and Mechanism of Action- Pharmacology*).
BRU23103374P	Salvado 1 Capsule	Primary immunosuppression in liver and kidney allograft recipients and liver and kidney allograft rejection resistant to conventional immunosuppressive agents.
BRU23103375P	Elonza-100 Tablet	Indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

BRU23103376P	Nervica 75 Capsule	Neuropathic Pain Indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised Anxiety Disorder Indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.
BRU23103377P	Nervica 150 Capsule	Neuropathic Pain Indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised Anxiety Disorder Indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.
BRU23113378P	Herbesser Tablet 30mg	-Angina pectoris, variant angina pectoris -Essential hypertension (mild to moderate)
BRU23113379P	Fluclonazole Kabi 2mg/ml Solution For Infusion	Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. 1. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g. pulmonary, cutaneous). Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. Fluconazole Kabi can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS. 2. Systemic candidiasis, including candidemia, disseminated candidiasis and other forms of invasive candidal infection. These include infections of the peritoneum, endocardium, eye and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. 3. Mucosal candidiasis. These include oropharyngeal, esophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated. Prevention of relapse of oropharyngeal candidiasis in patients with AIDS. 4. Genital candidiasis. Vaginal candidiasis, acute or recurrent and prophylaxis to reduce the incidence of recurrent vaginal candidiasis (3 or more episodes a year). Candidal balanitis. 5. Prevention of fungal infections in patients with malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy or radiotherapy. 6. Dermatomycosis including tinea pedis, tinea corporis, tinea cruris, tinea versicolor, and dermal candida infections.

BRU23113380P	Candesartan HCT Sandoz 16mg/12.5mg Tablet	Hypertension when a monotherapy is not sufficiently effective.
BRU23113381P	Fraizeron 300mg/2ml Solution For Injection In Pre-Filled Pen	**Plaque psoriasis** Fraizeron is indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy. **Psoriatic arthritis** Fraizeron, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **Axial spondyloarthritis (axSpA)** **Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)** Fraizeron is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. **Non-radiographic axial spondyloarthritis (nr-axSpA)** Fraizeron is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs). **Juvenile idiopathic arthritis (JIA)** **Enthesitis-related arthritis (ERA)** Fraizeron, alone or in combination with methotrexate (MTX), is indicated for the treatment of active enthesitis-related arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy. **Juvenile psoriatic arthritis (JPsA)** Fraizeron, alone or in combination with methotrexate (MTX), is indicated for the treatment of active juvenile psoriatic arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.

BRU23113382P	Cosentyx 300mg/2ml Solution For Injection In Pre-Filled Syringe	**Plaque psoriasis** Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in in patients 6 years and older who are candidates for systemic therapy or phototherapy. **Psoriatic arthritis** Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **Axial spondyloarthritis (axSpA)** **Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)** Cosentyx is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. **Non-radiographic axial spondyloarthritis (nr-axSpA)** Cosentyx is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs). **Juvenile idiopathic arthritis (JIA)** **Enthesitis-related arthritis (ERA)** Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active enthesitis-related arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy. **Juvenile psoriatic arthritis (JPsA)** Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active juvenile psoriatic arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.
BRU23113383NP	Winmyco Antiseptic Cream 0.1%	For the treatment of minor wounds and burns.
BRU23113384P	Kanolone Oral Base	Kanolone® Oral Base is for local application. It is for adjunctive treatment and for the temporary relief of symptoms associated with oral inflammatory lesions and ulcerative lesions resulting from trauma.
BRU23113385P	Zirin Softgel Capsules 10mg	Adults: Symptomatic treatment of seasonal allergic rhinitis, perennial allergic rhinitis and urticaria of allergic origin.
BRU23113386P	Lonsurf Film-Coated Tablet 15mg/6.14mg	**Metastatic Colorectal Cancer** Lonsurf® is indicated for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. **Metastatic Gastric Cancer** Lonsurf® is indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED FEBRUARY 2024)

BRU23113387P	Lonsurf Film-Coated Tablet 20mg/8.19mg	**Metastatic Colorectal Cancer** Lonsurf® is indicated for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. **Metastatic Gastric Cancer** Lonsurf® is indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.
BRU23113388P	Mianserin-Remedica 30mg Film-Coated Tablets	Depressive illness, particularly with anxiety.
BRU23113389P	Atorvastatin 40mg Film-Coated Tablet	Atorvastatin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines. Atorvastatin is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, Atorvastatin can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.
BRU23113390P	Atorvastatin 20mg Film-Coated Tablet	Atorvastatin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines. Atorvastatin is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, Atorvastatin can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.
BRU23113391P	Atorvastatin 10mg Film-Coated Tablet	Atorvastatin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines. Atorvastatin is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, Atorvastatin can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

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BRU23113392P	Ceftriaxone-Zhijun 1g (Ceftriaxone Sodium Powder For Injection)	CEFTRIAXONE-ZHIJUN is indicated in the treatment of the following infections caused by pathogens sensitive to ceftriaxone, e.g.: -Sepsis; -Meningitis; -Infections of the bones, joints, soft tissue, skin and of wounds; -Infections in patients with impaired defense mechanisms; -Respiratory tract infections, particularly pneumonia; -Genital infections, including gonorrhea; -Peri-operative prophylaxis of infections associated with surgery.
BRU23113393P	Cerator 400 Extended-Release Tablet	Indicated in the treatment of peripheral vascular disease, including intermittent claudication and rest pain.
BRU23113394P	Phesgo Solution For Subcutaneous Injection 600mg/600mg/10ml	**Early Breast Cancer (EBC)** Phesgo is indicated for use in combination with chemotherapy for the: • neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer (*see 3.1.2 Clinical studies*). This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival. • adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence (*see 3.1.2 Clinical Studies*) **Metastatic Breast Cancer (MBC)** Phesgo is indicated for use in combination with docetaxel for the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.
BRU23113395P	Phesgo Solution For Subcutaneous Injection 1200mg/600mg/15ml	**Early Breast Cancer (EBC)** Phesgo is indicated for use in combination with chemotherapy for the: • neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer (*see 3.1.2 Clinical studies*). This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival. • adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence (*see 3.1.2 Clinical Studies*) **Metastatic Breast Cancer (MBC)** Phesgo is indicated for use in combination with docetaxel for the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.
BRU24013396P	Paxus (Paclitaxel) Injection USP 100mg/16.7ml	1. **PAXUS** is indicated as first-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy **PAXUS** is indicated in combination with cisplatin. 2. **PAXUS** is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

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BRU24013397P	Zynor Tablet 5mg	**Hypertension**: Zynor is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of Zynor, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin converting enzyme inhibitor. **Myocardial Ischemia**: Zynor is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Zynor may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but vasospastic/vasoconstrictive has not been confirmed. Zynor may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta blockers.
BRU24013398P	Zynor Tablet 10mg	**Hypertension**: Zynor is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of Zynor, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin converting enzyme inhibitor. **Myocardial Ischemia**: Zynor is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Zynor may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but vasospastic/vasoconstrictive has not been confirmed. Zynor may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta blockers.
BRU24013399P	Valgan 450 (Valganciclovir 450mg Film Coated Tablet)	Valganciclovir is indicated: • For the treatment of cytomegalovirus (CMV) retinitis is acquired immunodeficiency syndrome (AIDS) patients. • For the prevention of CMV disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor.
BRU24013400P	Zoledronic Acid 4mg/5ml Concentrate For Solution For Infusion	- Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone. - Treatment of adult patients with tumour-induced hypercalcaemia (TIH).

BRU24013401P	Zanaflox Eye Drop 0.5% w/v	Zanaflox is indicated for the treatment of patients 1 year of age and older with bacterial conjunctivitis caused by susceptible strains of the following organisms: **Gram-positive bacteria**: *Corynebacterium species* * *Microbacterium species* *Micrococcus luteus* * [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains] *Staphylococcus aureus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus epidermidis* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus haemolyticus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus hominis* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus warneri* * [including erythromycin resistant strains] *Streptococcus mitis* * [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains] *Streptococcus pneumoniae* [including penicillin, erythromycin, gentamicin, tetracycline and/or trimethoprim resistant strains] *Streptococcus viridans* [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains] Gram-negative bacteria: *Acinetobacter species* *Haemophilus "alconae"* [including ampicillin resistant strains] *Haemophilus influenzae* [including ampicillin resistant strains] *Klebsiella pneumoniae** *Moraxella catarrhalis** *Pseudomonas aeruginosa** Other microorganisms: *Chlamydia trachomatis* * Efficacy for this organism was studied in fewer than 10 infections. Preoperative and postoperative sterilization (when prophylactic antibiotic treatment is required).
BRU24013402P	Arite Beclometasone 100mcg/Actuation Metered Dose Inhaler	For prophylactic management of asthma.
BRU24013403NP	Ridped Lotion	For the treatment of head lice and scabies.
BRU24013404NP	Win-Aid Antiseptic Cream 0.5% w/w	Win-Aid Antiseptic Cream is for the treatment of cuts, abrasions, burns and wounds.

BRU24013405P	Voltaren 12 Hours Emulgel 2% Gel	For the relief of pain, inflammation and swelling in the following situations: – soft-tissue injuries: trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains, bruises and backache (sports injuries); – localised forms of soft tissue rheumatism such as tendinitis (tennis elbow), shoulder-hand syndrome, bursitis, periarthropathy; – and for the symptomatic treatment of osteoarthritis of small and medium-sized joints located close to the skin such as the finger joints or knee joints.
BRU24013406P	Bioxitide 25/125mcg/Dose HFA Inhalation Aerosol	**Asthma (Reversible Obstructive Airways Disease)** Bioxitide™ is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: • Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. • Patients who are symptomatic on current inhaled corticosteroid therapy. • Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** Bioxitide™ is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU24013407P	Glix Tablet 5mg	For control of hyperglycaemia and its associated symptomology in patients with non-insulin dependent diabetes mellitus after an adequate trial of dietary therapy has proved unsatisfactory.
BRU24013408P	Bralon 5 Tablet	<u>Symptomatic treatment of chronic stable angina pectoris</u> Ivabradine is indicated for the symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm and heart rate ≥ 70 bpm. Ivabradine is indicated: - in adults unable to tolerate or with a contra-indication to the use of beta-blockers - or in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose. <u>Treatment of chronic heart failure</u> Ivabradine is indicated in chronic heart failure NYHA II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥ 75 bpm, in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated.

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BRU24013409P	RINVOQ® 45mg Extended-Release Tablets	Rheumatoid arthritis RINVOQ® is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). RINVOQ® may be used as monotherapy or in combination with methotrexate. Psoriatic arthritis RINVOQ® is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. RINVOQ® may be used as monotherapy or in combination with methotrexate. Atopic dermatitis RINVOQ® is indicated for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. Ulcerative Colitis RINVOQ® is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.
BRU24013410P	Xofluza Film-Coated Tablets 40mg	*Treatment of Influenza* Xofluza is indicated for the treatment of acute uncomplicated influenza in patients aged 12 and above who have been symptomatic for no more than 48 hours and who are: • otherwise healthy, or • at high risk of developing influenza-related complications (see section 3.1.2 Clinical/ Efficacy Studies). *Prophylaxis of Influenza* Xofluza is indicated for the post-exposure prophylaxis of influenza in individuals aged 12 and above. **Limitations of Use** Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Xofluza (see section 3.1.2 Clinical/Efficacy Studies, Resistance Monitoring during Clinical Development).

BRU24013411P	Saxenda® 6mg/ml, Solution For Injection In Pre-Filled Pen	<u>Adults</u> Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of • ≥30 kg/m^2 (obesity), or • ≥27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. Treatment with Saxenda® should be discontinued after 12 weeks on the 3.0 mg/day dose if patients have not lost at least 5% of their initial body weight. <u>Adolescents (≥12 years)</u> Saxenda® can be used as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescent patients from the age of 12 years and above with: • obesity (BMI corresponding to ≥30 kg/m^2 for adults by international cut-off points)* and • body weight above 60 kg. Treatment with Saxenda® should be discontinued and re-evaluated if patients have not lost at least 4% of their BMI or BMI z score after 12 weeks on the 3.0 mg/day or maximum tolerated dose. *IOTF BMI cut-off points for obesity by sex between 12–18 years (refer to PI).