

LIST OF PRODUCTS APPROVED FOR NEW REGISTRATION BY THE BRUNEI DARUSSALAM MEDICINES CONTROL AGENCY (BDMCA) IN THE 34TH BDMCA MEETING ON 22 APRIL 2020

No	Product Licence Number	Product Name	Active Ingredient(s)	Manufacturer(s)	Product Licence Holder	Forensic Classification	Pack size
1	BRU20012754NP	Eye Glo Regular Eye Drops	1. Boric Acid 1%w/v 2. Borax 0.25%w/v	Duopharma (M) Sdn. Bhd., Malaysia	Bintang Ria Sdn. Bhd.	GSL	10ml
2	BRU20012755P	Axcel Ketotifen Syrup	Each 5ml contains Ketotifen Hydrogen Fumarate equivalent to Ketotifen 1mg	Kotra Pharma (M) Sdn. Bhd., Malaysia	Medicorp Sdn. Bhd.	POM	100ml
3	BRU20012756P	Fusix Tablet 40mg	Frusemide 40mg	SM Pharmaceuticals Sdn. Bhd., Malaysia	G & H Trading Company	POM	100 x 10's
4	BRU20012757P	Non-Preg Injection	Each vial of 3ml contains Medroxyprogesterone Acetate 150mg	L.B.S Laboratory Ltd., Part., Thailand	Medicorp Sdn. Bhd	POM	1 x 10's
5	BRU20012758P	Bisloc 5 Tablet	Bisoprolol Fumarate 5mg	Unison Laboratories Co., Ltd., Thailand	K-Seri Pharma Sdn. Bhd.,	POM	10 x 10's
6	BRU20012759P	Comazole N Tablet	Sulphamethoxazole 400mg Trimethoprim 80mg	SM Pharmaceutical Sdn. Bhd., Malaysia.	G & H Trading Company	POM	100 x 10's
7	BRU20012760P	QUANTIA 25 Film Coated Tablet	Quetiapine fumarate 28.7825mg equivalent to Quetiapine 25mg	Unison Laboratories Co., Ltd, Thailand	K-Seri Pharma Sdn Bhd.	POM	3 x 10's
8	BRU20012761P	QUANTIA 100 Film Coated Tablet	Quetiapine fumarate 115.130mg equivalent to Quetiapine 100mg	Unison Laboratories Co., Ltd, Thailand	K-Seri Pharma Sdn Bhd.	POM	3 x 10's
9	BRU20012762P	QUANTIA 200 Film Coated Tablet	Quetiapine fumarate 230.260mg equivalent to Quetiapine 200mg	Unison Laboratories Co., Ltd, Thailand	K-Seri Pharma Sdn Bhd.	POM	3 x 10's
10	BRU20012763NP	IFIMOL IV (Paracetamol Solution for Intravenous Infusion 10mg/ml)	Paracetamol 10mg/ml	Unique Pharmaceutical Laboratories, India	K-Seri Pharma Sdn Bhd	POM	1 vial of 100ml
11	BRU20012764P	Sofilex Capsule 250mg	Cephalexin monohydrate equivalent to Cephalexin 250mg	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	Syarikat BumiMedic	POM	100 x 10's
12	BRU20012765P	Cavumox 1.2g Injection	Amoxicillin (as Sodium) 1.0g & Clavulanic Acid (as Potassium Salt) 0.2g	Siam Bheasach Co., Ltd. Thailand	K-Seri Pharma Sdn. Bhd.	POM	1 vial per box
13	BRU20012766P	Combiwave SF 125 (Salmeterol 25mcg/actuation and Fluticasone Propionate 125mcg/actuation pressurised inhalation)	Each actuation delivers: Salmeterol Xinafoate BP equivalent to Salmeterol 25mcg; Fluticasone Propionate BP 125mcg	Glenmark Pharmaceuticals Limited, India	Kingsley Medical Supplies Sdn Bhd	POM	1 x 150 metered doses / inhaler
14	BRU20012767P	Combiwave SF 250 (Salmeterol 25mcg/actuation and Fluticasone Propionate 250mcg/actuation pressurised inhalation)	Each actuation delivers: Salmeterol Xinafoate BP equivalent to Salmeterol 25mcg; Fluticasone Propionate BP 250mcg	Glenmark Pharmaceuticals Limited, India	Kingsley Medical Supplies Sdn Bhd	POM	1 x 150 metered doses / inhaler

15	BRU20012768P	Salbutamol Sandoz 100mcg/dose pressurised inhalation	One metered dose contains 120 micrograms of salbutamol sulphate equivalent to 100 micrograms of salbutamol. The delivered dose through the mouthpiece contains 108 micrograms of salbutamol sulphate equivalent to 90 micrograms of salbutamol (as sulphate).	Aeropharm GmbH, Germany	Zuellig Pharma (B) Sdn Bhd	POM	1 x 200 metered actuations
16	BRU20012769P	COVASTIN TABLET 20MG	Simvastatin 20mg	Xepa-Soul Pattinson (Malaysia), Malaysia	Syarikat BumiMedic	POM	3 X 10's
17	BRU20012770NP	FlameX Suspension	Sodium Alginate 250mg/5ml, Dried Aluminium Hydroxide 100mg/5ml, Calcium Carbonate 75mg/5ml	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	Kingsley Medical Supplies Sdn Bhd	GSL	i) Bottle of 100ml ii) Bottle of 200ml
18	BRU20012771P	Letrozole Mevon Tablet 2.5mg	Letrozole 2.5mg	Atlas Pharma SA, Morocco.	Kingsley Medical Supplies Sdn Bhd.	POM	15's x 2 (30's)
19	BRU20012772P	Fluozole (Intravenous Infusion) 2mg/ml	Fluconazole 2mg/ml	Siam Bheasach Co. Ltd., Thailand	K-Seri Pharma Sdn Bhd	POM	i) 1 x 50ml ii) 1 x 100ml
20	BRU20022773NP	PATENT BLUE V SODIUM GUERBET 2.5%	Patent Blue V Sodium 2.5%	Delpharm Tours, France	Manning Jaya Trading (B) Sdn Bhd	POM	5 x 2ml
21	BRU20022774P	Micosten Cream 2%	Miconazole Nitrate Micronised (100%) 20mg/1g	Noripharma Sdn Bhd, Malaysia	K-Seri Pharma Sdn Bhd	GSL	1) 10g x 50 tubes per box; 2) 15g x 12 tubes per box
22	BRU20022775P	Mobitil Injection 20ml Vial	Dobutamine HCl BP equivalent to Dobutamine 12.5mg/ml	Duopharma (M) Sdn Bhd, Malaysia	K-Seri Pharma Sdn Bhd	POM	1 x 20ml and 10 x 20ml
23	BRU20022776P	Fytosid Injection 20mg/ml	Etoposide 20mg /ml	Fresenius Kabi Oncology Limited, India	Zuellig Pharma (B) Sdn Bhd	POM	1 x 5ml
24	BRU20022777P	Fleming Oral Suspension (457mg/5ml)	Each 5 ml after reconstitution contains: • Amoxicillin Trihydrate BP equivalent to Amoxicillin 400 mg • Potassium Clavulanate BP (as diluted Potassium Clavulanate BP) equivalent to Clavulanic acid 57 mg	Medreich Limited, India	Medicorp Sdn Bhd	POM	70ml
25	BRU20022778P	Repatha Solution for Injection in Prefilled Syringe 140mg/ml	Evolocumab 140mg/ml	Amgen Manufacturing Limited, USA	MediPharm Sdn Bhd	POM	1's
26	BRU20022779P	Repatha Solution for Injection in Prefilled Autoinjector 140mg/ml	Evolocumab 140mg/ml	Amgen Manufacturing Limited, USA	MediPharm Sdn Bhd	POM	1's
27	BRU20022780P	Pemetrexed Seacross 500mg Powder for Concentrate for Solution for Infusion	Each vial contains Pemetrexed 500mg (as Pemetrexed Disodium)	Sichuan Huiyu Pharmaceutical Co. Ltd, China	Kingsley Medical Supplies Sdn Bhd	POM	One 500mg vial per box
28	BRU20022781P	Pemetrexed Seacross 100mg Powder for Concentrate for Solution for Infusion	Each vial contains Pemetrexed 100mg (as Pemetrexed Disodium)	Sichuan Huiyu Pharmaceutical Co. Ltd, China	Kingsley Medical Supplies Sdn Bhd	POM	One 100mg vial per box
29	BRU20022782P	Pemenon 500mg Powder for Concentrate for Solution for Infusion	Pemetrexed (as pemetrexed sodium) 500mg	Gland Pharma Limited, India	Zuellig Pharma (B) Sdn Bhd	POM	1 vial
30	BRU20022783P	Momate Nasal Spray 50mcg	Mometasone Furoate Monohydrate equivalent to Mometasone Furoate 0.05% w/w	Glenmark Pharmaceuticals Ltd., India	Kingsley Medical Supplies	POM	1 x 60 metered doses spray or 1 x 120 metered doses spray

31	BRU20022784P	Somidem Tablet 10mg	Zolpidem Tartrate 10mg	Duopharma (M) Sdn Bhd, Malaysia	K-Seri Pharma Sdn Bhd	POM	100 tablets per box (10 x 10's)
32	BRU20022785P	Ibicar 100 (Beclometasone Pressurised Inhalation BP 100µg/actuation)	Beclometasone Dipropionate Anhydrous EP 100µg/actuation	Glenmark Pharmaceuticals Ltd., India	Kingsley Medical Supplies	POM	1 x 200 metered dose aerosol inhalation spray
33	BRU20022786NP	Tonbien Solution Jen Sheng 150mg/ml	Each ml contains Sodium Chloride 150mg	Jen Sheng Pharmaceutical Co. Ltd., Taiwan	Chop Khong Lin Dispensary	GSL	2 x 20ml tube applicator
34	BRU20022787P	Apo-Allopurinol Tablet 300mg	Allopurinol 300mg	Apotex Inc, Canada	Medicorp Sdn Bhd	POM	10's x 50 (500's)
35	BRU20022788P	Azimax 250mg Tablet	Azithromycin Dihydrate 262.05mg (equivalent to Azithromycin 250mg)	Hovid Bhd, Malaysia	G&H Trading Company	POM	1 x 6's (6 tablets per box), 10 x 6's (60 tablets per box)
36	BRU20032789P	Kisan Injection 10mg/ml	Vitamin K1 (Phytomenadione) 10mg/ml	Duopharma (M) Sdn Bhd, Malaysia	K-Seri Pharma Sdn Bhd	POM	10 x 1ml
37	BRU20032790P	Basalog one Insulin Glargine Injection (rDNA origin) 100 IU/mL Prefilled Pen	Each mL of prefilled pen contains: Insulin Glargine (rDNA origin) 100 IU/mL	Biocon Limited, India	K-Seri Pharma Sdn Bhd	POM	1) 1 x 3ml 2) 3 x 3ml 3) 5 x 3ml
38	BRU20032791P	Tasigna 50mg capsule	Nilotinib (as hydrochloride monohydrate) 50mg	Novartis Pharma Stein AG, Switzerland	Zuellig Pharma (B) Sdn Bhd	POM	3 x 5 x 8 s
39	BRU20032792P	Lochol 10mg Tablet	Simvastatin 10mg	Siam Bheasach Co., Ltd., Thailand	K-Seri Pharma Sdn Bhd	POM	3 x 10's & 10 x 10's
40	BRU20032793P	Xgeva Solution for Injection 120mg/vial	Each vial contains 120mg of denosumab in 1.7ml of solution (70mg/ml)	Amgen Manufacturing Limited (AML), United States	MediPharm Sdn Bhd	POM	1 vial x 1.7 ml
41	BRU20032794P	Rekaxime Injection 1000mg	Cefotaxime Sodium equivalent to Cefotaxime 1000mg	Duopharma (M) Sdn Bhd, Malaysia	K-Seri Pharma Sdn Bhd	POM	1 X 10ml & 25 X 10ml
42	BRU20032795P	Setisin Injection 2.5mg/ml (1ml Amp)	Neostigmine Methylsulphate BP 2.5mg/ml	Duopharma (M) Sdn Bhd, Malaysia	K-Seri Pharma Sdn Bhd	POM	10 x 1ml
43	BRU20032796P	Avarin Softgel Capsule	Alverine Citrate 60mg & Simeticone 300mg	Mega Lifesciences Public Company Limited, Thailand	Hongkiat Trading & Company	POM	3 x 10's, 5 x 10's
44	BRU20032797P	MENOPUR® Multidose 600iu Powder and Solvent for Solution for Injection	Each vial with powder contains highly purified menotrophin (human menopausal gonadotrophin, HMG) corresponding to follicle stimulating hormone activity FSH 600 IU and luteinizing hormone activity LH 600 IU	Ferring GmbH, Germany	Zuellig Pharma (B) Sdn Bhd	POM	1's
45	BRU20032798P	Fleming Oral Suspension (228.5mg/5ml)	Each 5 ml after reconstitution contains: • Amoxicillin Trihydrate BP equivalent to Amoxicillin 200 mg • Potassium Clavulanate BP equivalent to Clavulanic acid 28.5 mg	Medreich Limited, India	Medicorp Sdn Bhd	POM	1 x 70ml
46	BRU20032799P	Netil Injection	Netilmicin sulfata equivalent to Netilmicin base 50mg/ml	Siam Bheasach Co., Ltd., Thailand	K-Seri Pharma Sdn Bhd	POM	10 x 2ml
47	BRU20032800P	Vivocin (Vancomycin Hydrochloride for Injection USP 500mg/Vial)	Vancomycin Hydrochloride USP equivalent to Vancomycin 500mg	Gland Pharma Limited, India	Kingsley Medical Supplies Sdn Bhd	POM	10 x 10ml

48	BRU20032801P	Humira Solution for Injection in pre-filled syringe 80mg/0.8ml	Adalimumab 80mg/0.8ml	Vetter Pharma-Fertigung GmbH & Co. KG, Germany	Zuellig Pharma (B) Sdn Bhd	POM	1's
49	BRU20032802P	Humira Solution for Injection in pre-filled pen 80mg/0.8ml	Adalimumab 80mg/0.8ml	Vetter Pharma-Fertigung GmbH & Co. KG, Germany	Zuellig Pharma (B) Sdn Bhd	POM	1's
50	BRU20032803NP	Betadine Antiseptic Cream 5% w/w	Povidone-Iodine 5.0% w/w	Mundipharma Pharmaceuticals Ltd, Cyprus	Zuellig Pharma (B) Sdn Bhd	GSL	1 x 15gm & 1 x 40gm
51	BRU20032804P	Kytron Solution for Injection/Infusion 3mg/3ml	Granisetron Hydrochloride equivalent to Granisetron 3mg/3ml	Duopharma (M) Sdn Bhd, Malaysia	K-Seri Pharma Sdn Bhd	POM	10 x 3ml
52	BRU20032805P	Nerlynx 40mg Film-Coated Tablet	Neratinib (as Maleate) 40mg	Excella GmbH & Co. KG, Germany	Hongkiat Trading & Company	POM	180's
53	BRU20032806P	Penrazol Powder for Solution for Infusion 40mg/Vial	Omeprazole 40mg (equivalent to Omeprazole Sodium 42.60mg)	Elpen Pharmaceutical Co. Inc, Greece	G&H Trading Company	POM	1 X 12ml
54	BRU20032807P	Pospenem Powder for Solution for Injection 500mg	Meropenem 500mg (as Meropenem Trihydrate 570mg)	JW Pharmaceutical Corporation, South Korea	Kingsley Medical Supplies Sdn Bhd	POM	10 x 20ml
55	BRU20032808P	Pospenem Powder for Solution for Injection 1g	Meropenem trihydrate 1,141mg equivalent to Meropenem 1g	JW Pharmaceutical Corporation, South Korea	Kingsley Medical Supplies Sdn Bhd	POM	10x 30ml
56	BRU20032809P	Ebetaxel Injection 6mg/ml	Paclitaxel 6mg/ml	Ebewe Pharma Ges.m.b.H Ngf.KG, Austria	Zuellig Pharma (B) Sdn Bhd	POM	1 x 5ml, 1 x 16.7ml, 1 x 25ml, 1 x 50ml
57	BRU20032810P	Imarem 400mg Tablet	Imatinib 400 mg (as mesilate)	Remedica Limited, Cyprus	Kingsley Medical Supplies Sdn Bhd	POM	3 X 10's
58	BRU20032811P	Imarem 100mg Tablet	Imatinib 100 mg (as mesilate)	Remedica Limited, Cyprus	Kingsley Medical Supplies Sdn Bhd	POM	3 X 10's
59	BRU20032812P	Pharmidea Carbetocin 100mcg/ml	Carbetocin 100mcg/ml	Pharmidea Sia, Latvia	Kingsley Medical Supplies Sdn Bhd	POM	5 X 1ml
60	BRU20032813P	Aurasert Tablet 50mg	Sertraline Hydrochloride eq. to Sertraline 50mg	Aurobindo Pharma Limited, India	Kingsley Medical Supplies Sdn Bhd	POM	2 x 14's (28's) & 10 x 10's (100's)
61	BRU20032814P	Aurasert Tablet 100mg	Sertraline Hydrochloride eq. to Sertraline 100mg	Aurobindo Pharma Limited, India	Kingsley Medical Supplies Sdn Bhd	POM	2 x 14's (28's) & 10 x 10's (100's)
62	BRU20032815NP	Septidin 10% Solution	Povidone Iodine 10% w/v	Pahang Pharmacy Sdn Bhd, Malaysia	G & H Trading Company	GSL	500ml, 1L or 4L
63	BRU20032816P	Prepenem 500mg Injection	Imipenem 530mg (equivalent to Imipenem Anhydrous 500mg) Cilastatin Sodium 532mg (equivalent to Cilastatin 500mg)	JW Pharmaceutical Corporation, South Korea	Kingsley Medical Supplies Sdn Bhd	POM	10's
64	BRU20032817P	Betaloc ZOK 25mg Tablet	Metoprolol Succinate 23.75mg corresponding to Metoprolol Tartrate 25mg	AstraZeneca AB, Sweden	Zuellig Pharma (B) Sdn Bhd	POM	1 x 14's
65	BRU20032818P	Betaloc ZOK 50mg Tablet	Metoprolol Succinate 47.5mg corresponding to Metoprolol Tartrate 50mg	AstraZeneca AB, Sweden	Zuellig Pharma (B) Sdn Bhd	POM	30's
66	BRU20032819P	MYODEEN Adenosine Injection USP 3mg/ml	Adenosine USP 3mg/ml	Gland Pharma Limited, India	Kingsley Medical Supplies Sdn Bhd	POM	10 x 1's x 2ml
67	BRU20032820P	Cravit Ophthalmic Solution 1.5% w/v	Levofloxacin Hydrate 1.5% w/v	Santen Pharmaceutical Co., Ltd, Japan	MediPharm Sdn Bhd	POM	1 x 5mL
68	BRU20032821P	Supirocin Ointment 2% w/w	Mupirocin USP 2% w/w	Glenmark Pharmaceuticals Limited, India	Kingsley Medical Supplies Sdn Bhd	POM	5g and 15g

69	BRU20032822NP	Minyak Urut GPU (Gosok-Pijat-Urut) - Minyak Jahe	i) Methyl Salicylate 20.00% ii) Camphor 9.00% iii) Ginger Oil 7.50% iv) Menthol 3.00% v) Eucalyptus Oil 2.50%	PT Eagle Indo Pharma, Indonesia	SP Setia Sdn Bhd	GSL	30ml, 60ml & 100ml
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