

LIST OF PRODUCTS APPROVED FOR NEW REGISTRATION BY THE BRUNEI DARUSSALAM MEDICINES CONTROL AGENCY (BDMCA) IN THE 35TH BDMCA MEETING ON 19 AUGUST 2020

No	Product Licence Number	Product Name	Active Ingredient(s)	Manufacturer(s)	Product Licence Holder	Forensic Classification	Pack size
1	BRU20042823PS1, BRU20042823PS2	Darzalex 100mg/5ml (20mg/ml) Concentrate for Solution for Infusion	Each vial of 5ml concentrate contains 100mg of daratumumab (20mg/ml)	1) Cilag A.G., Switzerland 2) Vetter Pharma Fertigung GmbH & Co. KG, Germany	Zuellig Pharma (B) Sdn Bhd	POM	1 vial of 5ml
2	BRU20042824PS1, BRU2004284PS2	Darzalex 400mg/20ml (20mg/ml) Concentrate for Solution for Infusion	Each vial of 20ml concentrate contains 400mg of daratumumab (20mg/ml)	1) Cilag A.G., Switzerland 2) Vetter Pharma Fertigung GmbH & Co. KG, Germany	Zuellig Pharma (B) Sdn Bhd	POM	1 vial of 20ml
3	BRU20042825P	Malon Injection 2ml Amp	Metoclopramide Hydrochloride 10mg/2ml	Duopharma (M) Sdn Bhd, Malaysia	K-Seri Pharma Sdn Bhd	POM	Packs of 10 x 2ml ampoules
4	BRU20042826P	GC FLU pre-filled syringe inj.	1 pre-filled syringe 0.5mL contains Active ingredient: Purified Inactive Influenza Virus Antigen..... 45µg A/Brisbane/02/2018 IVR-190 (H1N1)..... 15µg A/Kansas/14/2017 NYMC X-	Green Cross Corporation, Republic of Korea	K-Seri Pharma Sdn Bhd	POM	0.5mL pre-filled syringe x 1 & 0.5mL pre-filled syringe x 10
5	BRU20042827P	Thyrosit 100 mcg Tablet	Thyroxine Sodium 100mcg	Sriprasit Pharma Co. Ltd., Thailand	Medicorp Sdn Bhd	POM	20 x 10's
6	BRU20042828P	Lecetam 250 Tablet	Levetiracetam 250mg	Unison Laboratories Co., Ltd, Thailand	K-Seri Pharma Sdn Bhd	POM	3 x 10's
7	BRU20042829P	Pulmicort Respules 0.5mg/ml	Budesonide 0.5mg/ml	AstraZeneca AB, Sweden	Zuellig Pharma (B) Sdn Bhd	POM	30 single dose polyethylene (plastic) units of 2ml
8	BRU20042830NP	Geliga Muscular Balm	i) Methyl Salicylate 29.95% ii) Peppermint Oil 18.50% iii) White Camphor Oil 28.00%	PT Eagle Indo Pharma, Indonesia	SP Setia Sdn Bhd	GSL	10g, 20g & 40g
9	BRU20042831NP	Minyak Urut GPU (Gosok-Pijat- Urut) - Minyak Sereh	ii) Camphor 9.00% iii) Citronella 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
10	BRU20042832P	Ceritec Syrup 1mg/ml	Cetirizine Hydrochloride 1mg/ml	Y.S.P. Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	P	60ml x 20's
11	BRU20042833P	Nexpro Tablets 20mg	Esomeprazole 20mg	Torrent Pharmaceuticals Limited, India	K-Seri Pharma Sdn Bhd	POM	14's & 28's
12	BRU20042834NP	Rexom Potassium Citrate Mixture	Potassium Citrate BP 1.5gm/5ml & Citric Acid Anhydrous BP 250mg/5ml	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	Kingsley Medical Supplies Sdn Bhd	GSL	120ml

13	BRU20042835P	SVOZ (0.5% Ophthalmic Solution)	Moxifloxacin 5mg/ml (as Moxifloxacin Hydrochloride 5.45mg/ml)	Siam Bheasach Co., Ltd, Thailand	K-Seri Pharma Sdn Bhd	POM	1 x 5ml
14	BRU20042836P	Disuf Ointment 2% w/w	Sodium Fusidate (Micronised) 2% w/w	Hovid Bhd., Malaysia	G & H Trading Company	POM	15g
15	BRU20042837P	Allopurinol Tablet 100mg	Allopurinol 100mg	Hovid Bhd., Malaysia	G & H Trading Company	POM	10x10's
16	BRU20042838P	Virest 5% Cream	Aciclovir 5% w/w	Hovid Bhd., Malaysia	G & H Trading Company	POM	1 x 5g tube
17	BRU20052839P	Conpanzole enteric coated tablet 20mg	Pantoprazole 20mg (as pantoprazole sodium)	Y.S.P. Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	POM	14's x 30
18	BRU20052840P	Conpanzole enteric coated tablet 40mg	Pantoprazole 40mg (as pantoprazole sodium)	Y.S.P. Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	POM	14's x 30 and 14's X 2
19	BRU20052841P	Tensiber Film Coated Tablet 150mg	Irbesartan 150mg	Lek Pharmaceuticals d.d., Slovenia	Zuellig Pharma (B) Sdn Bhd	POM	3 x 10's
20	BRU20052842P	Unitrexate Tablet 2.5mg	Methotrexate 2.5mg	Korea United Pharm, Inc., Republic of Korea	K-Seri Pharma Sdn Bhd	POM	10 x 10
21	BRU20052843NP	Hovid-Paracetamol Suspension 250mg/5ml (Sugar Free)	Paracetamol 250mg/5ml	HOVID Bhd., Malaysia	G & H Trading Company	GSL	60ml ; 120ml
22	BRU20052844P	A-Losartan 50mg Tablet	Losartan Potassium 50mg	Pharmathen S.A., Greece	Kingsley Medical Supplies Sdn Bhd	POM	3 x 10's and 10 x 10's
23	BRU20052845P	A-Losartan 100mg Tablet	Losartan Potassium 100mg	Pharmathen S.A., Greece	Kingsley Medical Supplies Sdn Bhd	POM	3 x 10's and 10 x 10's
24	BRU20052846P	Fustadin Cream 2% w/w	Fusidic Acid 2% w/w	Y.S.P. Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	POM	10g x 50 tubes per box; 20g x 40 tubes per box
25	BRU20052847P	Peace DM Syrup	Each 5ml contains: Triprolidine Hydrochloride 1.25mg Pseudoephedrine Hydrochloride 30mg Dextromethorphan	Y.S.P. Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	P	60ml
26	BRU20052848NP	Wintinea Cream	Tolnaftate 1.0% w/w	Winwa Medical Sdn Bhd, Malaysia	Yuh Hua Trading Company	GSL	10g per tube; 20g per tube
27	BRU20052849P	Losartan + HCT Mevon Tablet 100/25mg	Losartan Potassium 100mg & Hydrochlorothiazide 25mg	Pharmathen S.A., Greece	Kingsley Medical Supplies Sdn Bhd	POM	3 x 10's ; 10 x 10's
28	BRU20052850P	Bencodyl Linctus	Ammonium Chloride BP 135mg/5ml & Diphenhydramine Hydrochloride BP 14mg/5ml	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	Kingsley Medical Supplies Sdn Bhd	POM	60ml; 100ml; 120ml
29	BRU20052851P	Defuzin-B Cream	Fusidic Acid 2% w/w & Betamethasone 0.10% w/w (as Betamethasone 17-Valerate)	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	Syarikat Bumimedic	POM	15g
30	BRU20052852P	Pharmaniaga Simvastatin Tablet 20mg	Simvastatin 20mg	Pharmaniaga Manufacturing Berhad, Malaysia	G & H Trading Company	POM	3 x 10's; 12 x 10's
31	BRU20052853P	Torio 40 Tablet	Simvastatin 40mg	Unison Laboratories Co., Ltd., Thailand	K-Seri Pharma Sdn Bhd	POM	10 x 10's
32	BRU20062854P	Basalog Insulin Glargine Injegtion (rDNA origin) 100IU/mL	Insulin Glargine 100 IU/ml	Biocon Limited, India	K-Seri Pharma Sdn Bhd	POM	5 x 3ml cartridge, 1 x 3ml vial, x 5ml vial and x 10ml vial

33	BRU20062855P	Gilenya 0.25mg Hard Capsule	Fingolimod 0.25mg (corresponding to 0.28mg Fingolimod Hydrochloride)	Novartis Pharma Stein AG, Switzerland	Zuellig Pharma (B) Sdn Bhd	POM	2 x 14's
34	BRU20062856P	Zoledronic Acid 5mg/100ml Solution for Infusion	Zoledronic Acid (as Monohydrate) 5mg/100ml	Sichuan Huiyu Pharmaceutical Co. Ltd., China	Kingsley Medical Supplies Sdn Bhd	POM	100ml vial
35	BRU20062857NP	Wellmex Atomic Enema	Each 100ml contains sodium chloride 15g	Health Chemical Pharmaceutical Co., Ltd., Taiwan (R.O.C)	SWL Biomed Sales & Services	GSL	10ml x 2 x 5, 20ml x 2 x 5, 10ml x 2, 20ml x 2
36	BRU20062858P	Vacodil 25mg Tablets	Carvedilol 25mg	Aurobindo Pharma Limited, India	K-Seri Pharma Sdn Bhd	POM	3 x 10's or 10 x 10's
37	BRU20062859P	Mementor Tablets 10mg	Memantine Hydrochloride 10mg equivalent to 8.31mg Memantine	Torrent Pharmaceuticals Limited, India	K-Seri Pharma Sdn Bhd	POM	6 x 10's
38	BRU20062860P	Covastin Tablet 40mg	Simvastatin 40mg	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	Syarikat Bumimedic	POM	3 x 10's
39	BRU20062861P	Myborte 3.5mg (Bortezomib Powder for Solution for Injection 3.5mg/Vial)	Bortezomib 3.5mg	Dr. Reddy's Laboratories Limited, India	G & H Trading Company	POM	1 vial per carton / 10 mL
40	BRU20062862P	Rivasta 1.5mg Capsule	Rivastigmine (as Hydrogen Tartrate) 1.5mg	Siam Bheasach Co., Ltd, Thailand	K-Seri Pharma Sdn Bhd	POM	10 x 10's
41	BRU20062863P	YSP Salbutamol Injection 0.5mg/ml	Salbutamol Sulfate 0.6mg/ml (equivalent to Salbutamol 0.5mg/ml)	Y.S.P. Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	POM	1ml x 100's
42	BRU20062864P	YSP Bufencon Injection	Betamethasone Dipropionate 6.43mg (equivalent to Betamethasone 5.0mg) Betamethasone Sodium Phosphate 2.63mg (equivalent to Betamethasone 2.0mg)	Y.S.P. Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	POM	5ml x 10's
43	BRU20062865P	Finil 16 Tablet	Candesartan Cilexetil 16mg	Unison Laboratories Co., Ltd., Thailand	K-Seri Pharma Sdn Bh	POM	10 x 10's
44	BRU20062866NP	ActiMol Tablet 650mg	Paracetamol 650mg	Pharmaniaga Manufacturing Berhad, Malaysia	G & H Trading Company	P	1 x 10's; 2 x 10's; 3 x 10's; 10 x 10's; 50 x 10's; 100 x 10's
45	BRU20062867NP	Bages Cream	Each 100g contains: Methyl Salicylate 30mg Menthol 10mg Camphor 4mg	Unison Laboratories Co., Ltd., Thailand	K-Seri Pharma Sdn Bhd	GSL	1 x 30g
46	BRU20062868P	Lorsedin Oral Solution 1mg/ml	Loratadine 1mg/ml	Siam Bheasach Co., Ltd, Thailand	K-Seri Pharma Sdn Bhd	P	60ml

47	BRU20052869P	Albumin (Human) U.S.P. Albutein 5%	- Each vial of 250ml contains 12.5g Albumin (Human) in aqueous diluent - Each vial of 500ml contains 25g Albumin (Human) in aqueous diluent	Grifols Biologicals LLC, USA	Hongkiat Trading & Co	POM	250ml & 500ml
48	BRU20062870P	Mico Cream	Miconazole Nitrate 2% w/w	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	K-Seri Pharma Sdn Bhd	GSL	15g, 20g
49	BRU20062871P	Sunvasc 5 Tablet	Amlodipine Besylate 6.934 mg equivalent to Amlodipine 5mg	Sunward Pharmaceutical Sdn Bhd, Malaysia	G & H Trading Company	POM	3 x 10's
50	BRU20062872P	Sensitamine Tablet	Chlorpheniramine Maleate 4mg	SM Pharmaceuticals Sdn Bhd, Malaysia	G & H Trading Company	P	100 x 10's
51	BRU20062873P	Uniflex-N Cream	Betamethasone (as Betamethasone 17-Valerate) 0.10% w/w Neomycin Sulphate 0.50% w/w	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	Syarikat Bumimedic	POM	15g
52	BRU20062874P	Orata 0.5 film coated tablet	Entecavir Monohydrate equivalent to Entecavir 0.5mg	Unison Laboratories Co., Ltd., Thailand	K-Seri Pharma Sdn Bhd	POM	3 x 10's
53	BRU20062875NP	INFUSOL DS Intravenous Infusion	Dextrose Anhydrous BP 50 g/L	Ain Medicare Sdn Bhd, Malaysia	Syarikat Pakatan Indah	GSL	500mL x 20
54	BRU20062876P	Podoxred (Pemetrexed) Powder for Concentrate for Solution for Infusion 100mg	Pemetrexed Disodium equivalent to Pemetrexed 100mg	Dr. Reddy's Laboratories Limited, India	G & H Trading Company	POM	1 vial
55	BRU20062877P	Podoxred (Pemetrexed) Powder for Concentrate for Solution for Infusion 500mg	Pemetrexed Disodium equivalent to Pemetrexed 500mg	Dr. Reddy's Laboratories Limited, India	G & H Trading Company	POM	1 vial
56	BRU20072878NP	Kwan Loong Minyak Angin	Methyl Salicylate BP 21.0% w/w Eucalyptus Oil BP 15.0% w/w Menthol BP 14.0% w/w Camphor BP 10.0% w/w	Tiger Balm (M) Sdn Bhd, Malaysia	Hamitan Marketing	GSL	3 ml, 15 ml, 28 ml & 57 ml
57	BRU20072879P	Nifecard XL Tablet 30mg	Nifedipine, USP 30mg	Lek Pharmaceutical D.D., Italy	Zuellig Pharma (B) Sdn Bhd	POM	3 X 10's
58	BRU20072880P	Tirlor 10mg tablet	Loratadine 10mg	Novartis (Bangladesh) Limited, Bangladesh	Zuellig Pharma (B) Sdn Bhd	P	1 x 10's; 2 x 10's; 3 x 10's; 10 x 10'S
59	BRU20072881P	Alecensa 150mg hard capsule	Alectinib 150mg (equivalent to Alectinib Hydrochloride 161.3mg)	Excella GmbH & Co. KG, Germany	Hong Kiat Trading Company	POM	Multipack: 224 (4 packs of 56 (7 x 8's))
60	BRU20072882NP	Dermoplex Burn-Aid Cream	Acridlavine 0.1% w/w	Duopharma Sdn Bhd, Malaysia	Bintang Ria Sdn Bhd	GSL	25g tube
61	BRU20072883P	Avoxred (Azacitidine) Powder for Suspension for injection 100mg/vial	Azacitidine 100mg	Dr Reddy's Laboratories Limited, India	G & H Trading Company	POM	1 vial per carton
62	BRU20072884P	Redtibin (Decitabine) Powder for Injection 50mg/vial	Decitabine 50mg	Dr Reddy's Laboratories Limited, India	G & H Trading Company	POM	1 vial per carton

63	BRU20072885P	Stelara 130mg/26ml Concentrate for solution for infusion	Ustekinumab 130mg/26ml	Cilag AG, Switzerland	Zuellig Pharma (B) Sdn Bhd	POM	1 vial per box / 30 MI
64	BRU20072886P	Besomid 100mcg/actuation HFA-Metered Dose Inhaler	Beclometasone Dipropionate 100mcg/Actuation	Midas Pharmaceuticals Pvt.Ltd., India	K-Seri Pharma Sdn Bhd	POM	1 x 200 metered dose aerosol inhalation spray
65	BRU20072887P	Timo-COMOD 0.5% eyedrops	1ml solution contains: Timolol Maleate 6.84mg (equivalent to 5.0mg of	Ursapharm Arzneimittel GmbH, Germany	Medicorp Sdn Bhd	POM	1 x 10ml
66	BRU20072888P	Granisetron Kabi 1mg/ml concentrate solution injection / infusion	Granisetron (as Granisetron Hydrochloride) 1mg/ml	Labesfal-Laboratories Almiro, Portugal	Zuellig Pharma (B) Sdn Bhd	POM	5 x 1ml ampoules per box; 5 x 3ml ampoules per box
67	BRU20072889NP	Unidine Povidone Iodine Solution 10% w/v	Povidone Iodine 10% w/v (equivalent to 1% w/v Available Iodine)	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	Kingsley Medical Supplies Sdn Bhd	GSL	1 x 100ml; 1 x 500ml; 1 x 1000ml
68	BRU20072890P	Ikervis 1mg/ml eyedrops, emulsion	Ciclosporin 1mg/ml	Excelvision, France	Medipharm Sdn Bhd	POM	0.3mL x 30
69	BRU20072891P	Dezor Plus Shampoo	Ketoconazole 2.0% w/w Zinc Pyrithione 1.0% w/w	Hoe Pharmaceuticals Sdn Bhd, Malaysia	G & H Trading Company	GSL	60ml and 120ml
70	BRU20072892P	Atorvin 40 Film-coated tablet	Atorvastatin Calcium equivalent to Atorvastatin 40mg	Unison Laboratories Co., Ltd., 39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000, Thailand	K-Seri Pharma Sdn Bhd	POM	3 x 10's; 10 x 10's
71	BRU20072893P	Vitraq Film-coated tablet 75mg	Clopidogrel 75mg (as Clopidogrel Bisulfate)	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	Syarikat Bumimedic	POM	3 x 10's (30's)
72	BRU20072894P	Abiratred Abiraterone Acetate Tablets 250mg	Abiraterone Acetate 250mg	Dr Reddy's Laboratories Limited, India	G & H Trading Company	POM	120 tablets per bottle
73	BRU20072895P	A-Lices Lotion 1% w/w	Permethrin 1% w/w	HOE Pharmaceuticals Pvt Ltd, Malaysia	G & H Trading Company	GSL	1 x 60ml
74	BRU20072896P	Fusidasol cream	Each gram contains: Fusidic Acid 2% w/w Betamethasone Dipropionate 0.05% w/w	Y.S.P. Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	POM	15g x 40 tubes per box
75	BRU20072897NP	Actimol tablet 500mg	Paracetamol 500mg	Pharmaniaga Manufacturing Berhad, Malaysia	G & H Trading Company	GSL -10'S, 20'S & 30'S P - 100'S & 1000'S	1 x 10's; 2 x 10's; 3 x 10's; 10 x 10's; 100 x 10's
76	BRU20072898P	Proglutrol G2 Sustained Release tablet 2/500mg	Glimepiride 2mg & Metformin Hydrochloride 500mg	Inventia Healthcare Ltd, India	Medicorp Sdn Bhd	POM	5 x 20's (20 tablets / blister)

