

SENARAI PRODUK UBAT BARU YANG DIDAFTARKAN OLEH PBKD PADA TAHUN 2022

PBKD 368 (6 JANUARI 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202003053513A	MAL22016001ACZ	Spedra 50mg Tablets	Avanafil 50 mg	A. MENARINI SINGAPORE PTE. LTD.
2	202003053514A	MAL22016002ACZ	Spedra 100mg Tablets	Avanafil 100 mg	A. MENARINI SINGAPORE PTE. LTD.
3	202003053515A	MAL22016003ACZ	Spedra 200mg Tablets	Avanafil 200 mg	A. MENARINI SINGAPORE PTE. LTD.
4	202008144118A	MAL22016004AZ	Velphoro Chewable Tablet 500mg	Sucroferric Oxyhydroxide 2500mg (equivalent to 500mg iron)	FRESENIUS KABI MALAYSIA SDN. BHD

PBKD 370 (3 MAC 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202008184140A	MAL22036006AZ	Amopril 5mg/4mg Tablet	Amlodipine Besilate/ Perindopril tert-butylamine 5mg/4mg Tablet	Pharmaniaga Marketing Sdn Bhd
2	202008264169A	MAL22036005AZ	Amopril 5mg/8mg Tablet	Amlodipine Besilate/ Perindopril tert-butylamine 5mg/8mg Tablet	Pharmaniaga Marketing Sdn Bhd
3	202009034206A	MAL22036004AZ	Amopril 10mg/4mg Tablet	Amlodipine Besilate/ Perindopril tert-butylamine 10mg/4mg Tablet	Pharmaniaga Marketing Sdn Bhd
4	202009034207A	MAL22036003AZ	Amopril 10mg/8mg Tablet	Amlodipine Besilate/ Perindopril tert-butylamine 10mg/8mg Tablet	Pharmaniaga Marketing Sdn Bhd
5	202201046462A	MAL22036001ACRZ	PAXLOVID (PF-07321332 150 MG FILM-COATED TABLETS AND RITONAVIR 100 MG FILM-COATED TABLETS)	PF-07321332/ Ritonavir	PFIZER (MALAYSIA) SDN. BHD.
6	202202186938A	MAL22036002ACRSZ	PAXLOVID (PF-07321332 150 MG FILM-COATED TABLETS AND RITONAVIR 100 MG FILM-COATED TABLETS)	PF-07321332/ Ritonavir	PFIZER (MALAYSIA) SDN. BHD.

7	202101224839A	MAL22036009ACZ	ALDARA CREAM 5% w/w	ALDARA CREAM 5% w/w	iNova Pharmaceuticals (Singapore) Pte Ltd (incorporated In Singapore) Malaysia Branch
8	202101124779A	MAL22036007ACZ	BLOPRESS TABLET 8MG	Candesartan Cilexetil 8mg	Takeda Malaysia Sdn Bhd
9	202101124780A	MAL22036008ACZ	BLOPRESS TABLET 16MG	Candesartan Cilexetil 16mg	Takeda Malaysia Sdn Bhd

PBKD 371 (7 APRIL 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202104145245A	MAL22046004ARZ	Rahika 150mg Film-coated Tablet	Capmatinib dihydrochloride monohydrate 183 mg (equivalent to 150 mg of capmatinib free base)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
2	202104145246A	MAL22046005ARZ	Rahika 200mg Film-coated Tablet	Capmatinib dihydrochloride monohydrate 244 mg (equivalent to 200 mg of capmatinib free base)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
3	202109105990A	MAL22046007ACRZ	Sybrava 284mg/1.5ml Solution for Injection in Pre-filled Syringe	Inclisiran sodium 300mg (corresponds to Inclisiran 284mg)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
4	202202226960A	MAL22046001ACRZ	Lagevrio 200mg Hard Capsule	Molnupiravir 200mg	MERCK SHARP & DOHME (MALAYSIA) SDN BHD
5	202202226961A	MAL22046002ACRSZ	Lagevrio 200mg Hard capsule	Molnupiravir 200mg	MERCK SHARP & DOHME (MALAYSIA) SDN BHD
6	202202226962A	MAL22046003ARSZ	Lagevrio 200mg Hard Capsule	Molnupiravir 200mg	MERCK SHARP & DOHME (MALAYSIA) SDN BHD
7	202105215396A	MAL22046006ACRZ	Mictonorm 15mg film coated tablets	Propiverine hydrochloride 15mg	PHARMAFORTE (MALAYSIA) SDN. BHD.

PBKD 372 (12 MEI 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
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1	202012184638A	MAL22056043ACRZ	ONIVYDE pegylated liposomal 4.3 mg/ml concentrate for solution for infusion (Irinotecan anhydrous free base)	Irinotecan Hydrochloride Trihydrate 5.0 mg/ml (equivalent to 4.3 mg/ml of irinotecan anhydrous free base)	SERVIER MALAYSIA SDN BHD
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PBKD 373 (3 JUN 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202010274422A	MAL22066003ACZ	NALDEBAIN (dinalbuphine sebacate) Extended Release Injection 75 mg/ mL.	Dinalbuphine sebacate 75 mg/ml	Intega Sdn. Bhd.
2	202103295139A	MAL22066001ACZ	Samsca Tolvaptan Tablet 15mg	Tolvaptan 15mg	OTSUKA PHARMACEUTICALS (MALAYSIA) SDN. BHD.
3	202103195087A	MAL22066002AZ	Takipril 20mg/ml Solution for Injection	Prilocaine Hydrochloride 20mg/ml	B.BRAUN MEDICAL INDUSTRIES SDN BHD

PBKD 374 (7 JULAI 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202101074749A	MAL22076003ACZ	REMLEAS™ hard capsules 40mg	Valbenazine tosylate 73mg (eq. to Valbenazine 40mg)	Mitsubishi Tanabe Pharma Malaysia Sdn. Bhd.
2	202204137444A	MAL22076001ACRZ	Veklury lyophilized powder for injection (remdesivir 100 mg/vial)	Remdesivir 100mg	Gilead Sciences Malaysia Sdn. Bhd.
3	202111176274A	MAL22076002AZ	TELDY (Dolutegravir 50mg/Lamivudine 300mg/Tenofovir Disoproxil Fumarate 300mg) Film-Coated Tablets	Dolutegravir 50mg/Lamivudine 300mg/Tenofovir Disoproxil Fumarate 300mg	CAMBER LABORATORIES SDN. BHD.

PBKD 375 (4 OGOS 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
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1	202101294872A	MAL22086002ACRZ	Spinraza 12 mg Solution for Injection	Nusinersen Sodium 2.52 mg/mL	ZUELLIG PHARMA SDN BHD
2	202103265120A	MAL22086003ARZ	Zinnat Tablets 500mg	Cefuroxime Axetil 601.44 mg (equivalent to cefuroxime 500 mg)	GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.
3	202108205887A	MAL22086001ACRZ	Vyndamax 61 mg Soft Capsules	Tafamidis 61 mg	PFIZER (MALAYSIA) SDN. BHD.
4	202105215394A	MAL22086004ACZ	MIACALCIC 100IU AMPOULES	Calcitonin Salmon 100IU	ZUELLIG PHARMA SDN BHD

PBKD 376 (1 SEPTEMBER 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202011274527A	MAL22096001AZ	AIKENING (Albuvirtide for Injection 160 mg/vial)	Albuvirtide 160mg	PAHANG PHARMACY SDN. BHD.
2	202102044903A	MAL22096003ACZ	CONTRAIVE Prolonged-Release Tablet Naltrexone Hydrochloride 8mg/ Bupropion Hydrochloride 90mg	Naltrexone hydrochloride 8mg Bupropion hydrochloride 90mg	iNova Pharmaceuticals (Singapore) Pte Ltd (incorporated In Singapore) Malaysia Branch
3	202103014990A	MAL22096002AZ	Ryaltris (Olopatadine hydrochloride 600mcg/Mometasone furoate 25mcg) Nasal Spray	Olopatadine hydrochloride 600 mcg/ Mometasone furoate 25 mcg	Glenmark Pharmaceuticals (Malaysia) Sdn. Bhd.
4	202108095824A	MAL22096005ACRZ	ALIMTA 100 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	Pemetrexed Disodium Heptahydrate 151.7 mg (equivalent to 100 mg Pemetrexed Free Acid)	ZUELLIG PHARMA SDN BHD
5	202108095825A	MAL22096006ACRZ	ALIMTA 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	Pemetrexed Disodium Heptahydrate 713.0 mg (equivalent to 500 mg Pemetrexed Free Acid)	ZUELLIG PHARMA SDN BHD
6	202103175076A	MAL22096004ACZ	Dolofast Sachets 50mg Powder for Oral Solution	Diclofenac Potassium 50mg	DKSH MALAYSIA SDN BHD

PBKD 377 (6 OKTOBER 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
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1	202107165723A	MAL22106001ARZ	IMBRUVICA 140 mg film-coated tablets	Ibrutinib 140 mg	JOHNSON & JOHNSON SDN BHD
2	202107165724A	MAL22106002ARZ	IMBRUVICA 280 mg film-coated tablets	Ibrutinib 280 mg	JOHNSON & JOHNSON SDN BHD
3	202107165725A	MAL22106003ARZ	IMBRUVICA 420 mg film-coated tablets	Ibrutinib 420 mg	JOHNSON & JOHNSON SDN BHD

PBKD 378 (3 NOVEMBER 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202107295796A	MAL22116002AZ	Simdax 2.5 mg/ml concentrate for solution for infusion.	Levosimendan 2.5mg/ml (Each ml of concentrate contains 2.5mg of levosimendan. One 5ml vial contains 12.5mg of levosimendan)	ORION PHARMA (MY) SDN. BHD.
2	202008104095A	MAL22116001AZ	Prezcobix® (darunavir/cobicistat) 800mg/150mg Film-Coated Tablet	Darunavir ethanolate (equivalent to darunavir 800mg) and cobicistat 150mg	JOHNSON & JOHNSON SDN BHD

PBKD 379 (13 DISEMBER 2022)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202101204826A	MAL22126001ACRZ	Latuda Film-Coated Tablets 20mg	Lurasidone hydrochloride 20mg	Zuellig Pharma Sdn. Bhd.
2	202101204827A	MAL22126002ACRZ	Latuda Film-Coated Tablets 40mg	Lurasidone hydrochloride 40MG	Zuellig Pharma Sdn. Bhd.
3	202101204828A	MAL22126003ACRZ	Latuda Film-Coated Tablets 80mg	Lurasidone hydrochloride 80MG	Zuellig Pharma Sdn. Bhd.
4	202110076113A	MAL22126004AZ	Verquvo Film Coated Tablet 2.5mg	Vericiguat micronized 2.5mg	Bayer Co. (Malaysia) Sdn. Bhd.
5	202110076114A	MAL22126005AZ	Verquvo Film Coated Tablet 5mg	Vericiguat micronized 5mg	Bayer Co. (Malaysia) Sdn. Bhd.
6	202110076115A	MAL22126006AZ	Verquvo Film Coated Tablet 10mg	Vericiguat micronized 10mg	Bayer Co. (Malaysia) Sdn. Bhd.
7	202107075674A	MAL22126007AZ	Ibuprofen B. Braun 4 mg/ml Solution for Infusion	Ibuprofen 4 mg/ml	B. Braun Medical Industries Sdn. Bhd.

8	202107075675A	MAL22126008AZ	Ibuprofen B. Braun 6 mg/ml Solution for Infusion	Ibuprofen 6 mg/ml	B. Braun Medical Industries Sdn. Bhd.
9	202110206154A	MAL22126009ACZ	Fentanyl-Piramal 0.05mg/ml injectable solution	Fentanyl 0.05mg/ml (as fentanyl citrate 0.0785 mg)	DKSH Malaysia Sdn. Bhd.
10	202110126139A	MAL22126010AZ	Dicloxy AQ (Diclofenac Sodium Injection 75mg/mL)	Diclofenac Sodium	UNIMED SDN BHD
11	202112076362A	MAL22126011ACZ	RAPIFEN 0.5mg/ml Injection	Alfentanil Hydrochloride	DKSH Malaysia Sdn. Bhd.