

SENARAI PRODUK UBAT BARU YANG DIDAFTARKAN OLEH PBKD PADA TAHUN 2023

PBKD 380 (5 JANUARI 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202204057380A	MAL23016001ACZ	Proveblue 5mg/ml Solution for Injection	Methylene Blue (Methylthioninium Chloride) 5 mg/mL	PHARM-D SDN. BHD.
2	202112136395A	MAL23016002ACZ	HOVID ERETAF ORODISPERSIBLE FILMS 10MG	Tadalafil 10mg	HOVID BERHAD
3	202112136396A	MAL23016003ACZ	HOVID ERETAF ORODISPERSIBLE FILMS 20MG	Tadalafil 20mg	HOVID BERHAD

PBKD 381 (2 FEBRUARI 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202110296206A	MAL23026001ACZ	Lokelma 5g Powder for Oral Suspension	Sodium Zirconium Cyclosilicate	ASTRAZENECA SDN. BHD.
2	202110296207A	MAL23026002ACZ	Lokelma 10g Powder for Oral Suspension	Sodium Zirconium Cyclosilicate	ASTRAZENECA SDN. BHD.
3	202109146015A	MAL23026005ACRSZ	Suboxone Film 2mg/0.5mg	Buprenorphine 2mg (as hydrochloride) / naloxone 0.5mg (as hydrochloride dihydrate)	ZUELLIG PHARMA SDN BHD
4	202109146016A	MAL23026006ACRSZ	Suboxone Film 8mg/2mg	Buprenorphine 8mg (as hydrochloride) / naloxone 2mg (as hydrochloride dihydrate)	ZUELLIG PHARMA SDN BHD
5	201903071898A	MAL23026004AZ	DICLOTROY (Diclofenac Diethylamine Topical Solution 4.64% w/v)	Diclofenac Diethylamine	UNIMED SDN BHD
6	202201046455A	MAL23026003ARZ	Nicorette QuickMist Freshmint 1mg/spray Mouthspray	Nicotine 13.6mg/MI	JOHNSON & JOHNSON SDN BHD

PBKD 382 (2 MAC 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202109025946A	MAL23036001AZ	COSOPT-S Ophthalmic Solution	Dorzolamide HCl 22.26mg/ml and Timolol Maleate 6.83mg/ml (equivalent to 20mg dorzolamide and 5mg timolol)	SANTEN PHARMA MALAYSIA SDN. BHD.
2	202103175070X	MAL23036002XZ	Fluimucil 100mg/5 ml Oral Solution	Acetylcysteine 2 gram/100 ml	EP PLUS GROUP SDN. BHD.

PBKD 383 (6 APRIL 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202202287026A	MAL23046001ACRZ	Rozlytrek (Entrectinib) 100mg Hard Capsules	Entrectinib 100 mg	ROCHE (MALAYSIA) SDN. BHD.
2	202202287027A	MAL23046002ACRZ	Rozlytrek (Entrectinib) 200mg Hard Capsules	Entrectinib 200 mg	ROCHE (MALAYSIA) SDN. BHD.
3	202205107693A	MAL23046003ACRZ	Koselugo Hard Capsules 10 mg	Selumetinib 10mg	ASTRAZENECA SDN. BHD.
4	202205107694A	MAL23046004ACRZ	Koselugo Hard Capsules 25 mg	Selumetinib 25mg	ASTRAZENECA SDN. BHD.
5	202201286702A	MAL23046005AZ	Glencet M (Montelukast 10mg/ Levocetirizine dihydrochloride 5mg) Film-Coated Tablet	Montelukast 10mg/ Levocetirizine dihydrochloride 5mg	Glenmark Pharmaceuticals (Malaysia) Sdn. Bhd.

PBKD 384 (11 MEI 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202106155540A	MAL23056003AZ	PARMODIA Film-coated Tablets 0.1 mg	Pemafibrate 0.1mg	DKSH MALAYSIA SDN BHD
2	202211169565A	MAL23056001ARZ	Scemblix 20mg film-coated tablet	Asciminib 20mg (corresponds to Asciminib hydrochloride 21.620mg)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
3	202211169566A	MAL23056002ARZ	Scemblix 40mg film-coated tablet	Asciminib 40mg (corresponds to Asciminib hydrochloride 43.240mg)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
4	202204127435A	MAL23056007ACZ	Maxigesic IV Paracetamol 1000mg and Ibuprofen (as sodium dihydrate) 300mg in 100ml Solution for Infusion	Paracetamol 1000mg and Ibuprofen (as sodium dehydrate) 300mg	PAHANG PHARMACY SDN. BHD.
5	202010174373A	MAL23056004AZ	Arisa 5 mg tablets	Aripiprazole 5mg	Mansa Healthcare Sdn Bhd
6	202010174374A	MAL23056005AZ	Arisa 10 mg orodispersible tablets	Aripiprazole 10mg	Mansa Healthcare Sdn Bhd
7	202010174375A	MAL23056006AZ	Arisa 15 mg orodispersible tablets	Aripiprazole 15mg	Mansa Healthcare Sdn Bhd

PBKD 385 (8 JUN 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202207228325A	MAL23066001ACZ	TEPADINA 15 mg powder for concentrate for solution for infusion	Thiotepa 15 mg	DKSH MALAYSIA SDN BHD
2	202207228326A	MAL23066002ACZ	TEPADINA 100 mg powder for concentrate for solution for infusion	Thiotepa 100 mg	DKSH MALAYSIA SDN BHD
3	202207228327A	MAL23066003ACZ	TEPADINA 400 mg powder and solvent for solution for infusion	Thiotepa 400 mg	DKSH MALAYSIA SDN BHD

PBKD 386 (6 JULAI 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	2023020210328A	MAL23076001ACRZ	Nurtec 75mg Oral Lyophilisate	Rimegepant	PFIZER (MALAYSIA) SDN. BHD.
2	202104165258A	MAL23076002AZ	ProHance 279.3 mg/ml solution for injection	279.3 mg of gadoteridol (equivalent to 0.5 mmol/mL of gadoteridol)	DCH AURIGA (MALAYSIA) SDN. BHD.
3	202206178043A	MAL23076003ACZ	Ducessa (Dexamethasone 1mg/ml + Levofloxacin 5mg/ml) eye drops, solution	Dexamethasone 1mg/ml and Levofloxacin 5mg/ml	SANTEN PHARMA MALAYSIA SDN. BHD.
4	202204277606A	MAL23076004ACRZ	Energair Breezhaler (Indacaterol Acetate/Glycopyrronium Bromide/Mometasone Furoate) 150/50/80mcg Inhalation Powder Hard Capsules	Indacaterol Acetate/ Glycopyrronium Bromide/ Mometasone Furoate	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.

PBKD 387 (3 OGOS 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202212159850A	MAL23086003ACRZ	BRUKINSA 80 mg capsules	Zanubrutinib 80mg	ZUELLIG PHARMA SDN BHD
2	2023032010772A	MAL23086001ACRZ	TUKYSA 50 mg film-coated tablets	Tucatinib 50 mg	MERCK SHARP & DOHME (MALAYSIA) SDN BHD
3	2023032010773A	MAL23086002ACRZ	TUKYSA 150 mg film-coated tablets	Tucatinib 150 mg	MERCK SHARP & DOHME (MALAYSIA) SDN BHD
4	202101084758X	MAL23086005X	Gaviscon Infant Powder for Oral Suspension	Sodium Alginate 225 mg & Magnesium Alginate 87.5 mg	RB (HEALTH) MALAYSIA SDN BHD

5	202201206613A	MAL23086004ARZ	RINVOQ 30 mg extended-release film coated tablets	Upadacitinib hemihydrate 30.7 mg (corresponds to 30 mg of upadacitinib on an anhydrous basis)	ABBVIE SDN BHD
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PBKD 388 (14 SEPTEMBER 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	2023081412197A	MAL23096001ACRZ	Apretude 30mg Film-Coated Tablet	Cabotegravir Sodium 31.62mg (equivalent to 30mg cabotegravir)	GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.
2	2023081412196A	MAL23096002ACZ	Apretude 600mg Prolonged-release suspension for injection	Cabotegravir 600mg	GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.
3	202209078742A	MAL23096003ACRZ	LUMAKRAS FILM-COATED TABLET 120MG	Sotorasib 120 mg	Amgen Biopharmaceuticals Malaysia Sdn Bhd
4	202204087406A	MAL23096006AZ	Miron 10mg Tablets	Midodrine Hydrochloride 10mg	NOVUGEN PHARMA SDN. BHD.
5	202204087404A	MAL23096004AZ	Miron 2.5mg Tablets	Midodrine Hydrochloride 2.5mg	NOVUGEN PHARMA SDN. BHD.
6	202204087405A	MAL23096005AZ	Miron 5mg Tablets	Midodrine Hydrochloride 5mg	NOVUGEN PHARMA SDN. BHD.
7	202208298675A	MAL23096007AZ	Glenmark Airz F (Glycopyrronium 12.5mcg and Formoterol Fumarate 12mcg) Powder for Inhalation	Glycopyrronium Bromide 12.5mcg and Formoterol Fumarate 12mcg	Glenmark Pharmaceuticals (Malaysia) Sdn. Bhd.
8	202208298673A	MAL23096013ACRZ	Ferriprox 1000 mg Delayed-Release Tablets	Deferiprone 1000 mg	PHARMAFORTE (MALAYSIA) SDN. BHD.
9	202201056474A	MAL23096012ACZ	Hovid Erecor Orodispersible Films 50mg	Sildenafil 50mg	HOVID BERHAD
10	202204237555A	MAL23096009AZ	Ibrance Film-Coated Tablets 100mg	Palbociclib 100 mg	PFIZER (MALAYSIA) SDN. BHD.
11	202204237556A	MAL23096010AZ	Ibrance Film-Coated Tablets 125mg	Palbociclib 125 mg	PFIZER (MALAYSIA) SDN. BHD.
12	202204237554A	MAL23096008AZ	Ibrance Film-Coated Tablets 75mg	Palbociclib 75 mg	PFIZER (MALAYSIA) SDN. BHD.
13	202207278370A	MAL23096011ACZ	MANFORM ODS-20 Tadalafil Orally Disintegrating Strips 20 mg	Tadalafil 20mg	MEGA LIFESCIENCES SDN. BHD.

PBKD 389 (5 OKTOBER 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202011144480A	MAL23106003AZ	LURATA 40 mg Film-Coated Tablet	Lurasidone hydrochloride 40 mg	Mansa Healthcare Sdn Bhd
2	202011144481A	MAL23106004AZ	LURATA 80 mg Film-Coated Tablet	Lurasidone hydrochloride 80 mg	Mansa Healthcare Sdn Bhd

PBKD 391 (7 DISEMBER 2023)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1	202109206042A	MAL23126005ACRZ	Equfina Film coated Tablets 50 mg	Safinamide mesylate 65.88mg (equivalent to 50 mg safinamide free base)	EISAI (MALAYSIA) SDN BHD (18039-D)
2	202211299674A	MAL23126004ACZ	Inrebic 100 mg capsules	Fedratinib 100mg (Fedratinib dihydrochloride monohydrate 117.30mg)	DKSH MALAYSIA SDN BHD
3	202210139134A	MAL23126003ARZ	Xospata 40mg Film Coated Tablets	Gilteritinib fumarate 44.2mg (salt-free Gilteritinib 40mg)	Astellas Pharma Malaysia Sdn Bhd

4	202206218061A	MAL23126008ACZ	ROSUZET (EZETIMIBE 10MG/ ROSUVASTATIN 10MG) FILM COATED TABLET	Ezetimibe 10mg and Rosuvastatin Calcium 10.4mg (equivalent to 10mg rosuvastatin free acid)	ORGANON MALAYSIA SDN. BHD.
5	202206218062A	MAL23126009ACZ	ROSUZET (EZETIMIBE 10MG/ ROSUVASTATIN 20MG) FILM COATED TABLET	Ezetimibe 10mg and Rosuvastatin Calcium 20.8mg (equivalent to 20mg rosuvastatin free acid)	ORGANON MALAYSIA SDN. BHD.
6	202209078735A	MAL23126007AZ	INVEGA HAFYERA 700 mg/3.5 mL Prolonged-Release Suspension for Intramuscular Injection	Paliperidone palmitate 1092 mg (equivalent to 700 mg paliperidone)	JOHNSON & JOHNSON SDN BHD
7	202207278364A	MAL23126006AZ	INVEGA HAFYERA 1000 mg/5.0 mL Prolonged-Release Suspension for Intramuscular Injection	Paliperidone palmitate 1560 mg (equivalent to 1000 mg paliperidone)	JOHNSON & JOHNSON SDN BHD