

## SENARAI PRODUK UBAT BARU YANG DIDAFTARKAN OLEH PBKD PADA TAHUN 2021

### PBKD 353 (5 FEBRUARI 2021)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1.	201912063118A	MAL21026001ARZ	Lixiana 15mg Film-Coated Tablets	Edoxaban tosilate 20.205 mg (as edoxaban free base 15 mg)	A. Menarini Singapore Pte. Ltd
2.	201912063119A	MAL21026002ARZ	Lixiana 30mg Film-Coated Tablets	Edoxaban tosilate 40.410 mg (as edoxaban free base 30 mg)	
3.	201912063120A	MAL21026003ARZ	Lixiana 60mg Film-Coated Tablets	Edoxaban tosilate 80.820 mg (as edoxaban free base 60 mg)	
4.	201903251952A	MAL21026004AZ	Carivalan (Carvedilol 6.25mg/Ivabradine 5mg) film-coated tablets	Carvedilol 6.25mg/Ivabradine 5mg (equivalent to 5.390mg ivabradine as hydrochloride)	Servier Malaysia Sdn Bhd
5.	201903251949A	MAL21026005AZ	Carivalan (Carvedilol 6.25mg/Ivabradine 7.5mg) film-coated tablets	Carvedilol 6.25mg/Ivabradine 7.5mg (equivalent to 8.085mg ivabradine as hydrochloride)	
6.	201903251953A	MAL21026006AZ	Carivalan (Carvedilol 12.5mg/Ivabradine 5mg) film-coated tablets	Carvedilol 12.5mg/Ivabradine 5mg (equivalent to 5.390mg ivabradine as hydrochloride)	

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<b>Bil.</b>	<b>No. Rujukan</b>	<b>No. Pendaftaran</b>	<b>Nama Produk</b>	<b>Bahan Aktif</b>	<b>Pemegang Pendaftaran Produk (PRH)</b>
7.	201903251950A	MAL21026007AZ	Carivalan (Carvedilol 12.5mg/Ivabradine 7.5mg) film-coated tablets	Carvedilol 12.5mg/Ivabradine 7.5mg (equivalent to 8.085mg ivabradine as hydrochloride)	
8.	201903251954A	MAL21026008AZ	Carivalan (Carvedilol 25mg/Ivabradine 5mg) film-coated tablets	Carvedilol 25mg/Ivabradine 5mg (equivalent to 5.390mg ivabradine as hydrochloride)	
9.	201903251951A	MAL21026009AZ	Carivalan (Carvedilol 25mg/Ivabradine 7.5mg) film-coated tablets	Carvedilol 25mg/Ivabradine 7.5mg (equivalent to 8.085mg ivabradine as hydrochloride)	

**PBKD 354 (2 MAC 2021)**

<b>Bil.</b>	<b>No. Rujukan</b>	<b>No. Pendaftaran</b>	<b>Nama Produk</b>	<b>Bahan Aktif</b>	<b>Pemegang Pendaftaran Produk (PRH)</b>
1.	202101074755A	MAL21036045AZ	Fabiflu 200mg Tablets	Favipiravir 200mg	Glenmark Pharmaceuticals (Malaysia) Sdn. Bhd.
2.	201902071798A	MAL21036001AZ	Caliberi® Orodispersible Film 5mg	Tadalafil 5mg	Abbot Laboratories Malaysia Sdn. Bhd.

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3.	201912063119A	MAL21036002AZ	Caliberi® Orodispersible Film 20mg	Tadalafil 20mg	Abbot Laboratories Malaysia Sdn. Bhd.
4.	202001063208A	MAL21036003ACZ	SPRAVATO 28mg Nasal Spray	Esketamine Hydrochloride 28mg	Johnson & Johnson Sdn Bhd
5.	201912233201A	MAL21036004ACZ	Lanoxin Injection 0.5mg/2ml	Digoxin 0.5mg/2ml	Aspen Medical Products Malaysia Sdn Bhd

**PBKD 355 (2 APRIL 2021)**

<b>Bil.</b>	<b>No. Rujukan</b>	<b>No. Pendaftaran</b>	<b>Nama Produk</b>	<b>Bahan Aktif</b>	<b>Pemegang Pendaftaran Produk (PRH)</b>
1.	201904302080A	MAL21046009AZ	Bilaxten 10mg Orodispersible Tablets	Bilastine 10mg	A. MENARINI SINGAPORE PTE. LTD.
2.	201904302079A	MAL21046008AZ	Bilaxten 2.5 mg/ml Oral Solution	Bilastine 2.5 mg/mL	A. MENARINI SINGAPORE PTE. LTD.
3.	201909052642A	MAL21046002ACZ	CABOMETYX 20mg film-coated tablets	Cabozantinib 20mg	ZUELLIG PHARMA SDN BHD

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<b>Bil.</b>	<b>No. Rujukan</b>	<b>No. Pendaftaran</b>	<b>Nama Produk</b>	<b>Bahan Aktif</b>	<b>Pemegang Pendaftaran Produk (PRH)</b>
4.	201909052643A	MAL21046003ACZ	CABOMETRYX 40mg film-coated tablets	Cabozantinib 40mg	ZUELLIG PHARMA SDN BHD
5.	201909052644A	MAL21046004ACZ	CABOMETRYX 60mg film-coated tablets	Cabozantinib 50mg	ZUELLIG PHARMA SDN BHD
6.	201908202538A	MAL21046005ACZ	Alunbrig (Brigatinib) 30mg Film-Coated Tablet	Brigatinib 30mg	Takeda Malaysia Sdn Bhd
7.	201908202539A	MAL21046006ACZ	Alunbrig (Brigatinib) 90mg Film-Coated Tablet	Brigatinib 90mg	Takeda Malaysia Sdn Bhd
8.	201908202540A	MAL21046007ACZ	Alunbrig (Brigatinib) 180mg Film-Coated Tablet	Brigatinib 180mg	Takeda Malaysia Sdn Bhd

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**PBKD 357 (7 MEI 2021)**

<b>Bil.</b>	<b>No. Rujukan</b>	<b>No. Pendaftaran</b>	<b>Nama Produk</b>	<b>Bahan Aktif</b>	<b>Pemegang Pendaftaran Produk (PRH)</b>
1.	201911142963A	MAL21056003ACZ	Ferinject® 50 mg iron/mL solution for injection/infusion	Ferric Carboxymaltose 50mg iron/ml	ZUELLIG PHARMA SDN BHD
2.	201908052458A	MAL21056004AZ	Triveram 10mg/5mg/5mg (atorvastatin/perindopril arginine/amlodipine) film-coated tablets	Atorvastatin 10 mg/ perindopril arginine 5 mg/ amlodipine 5 mg	SERVIER MALAYSIA SDN BHD
3.	201908052459A	MAL21056005AZ	Triveram 20mg/5mg/5mg (atorvastatin/perindopril arginine/amlodipine) film-coated tablets	Atorvastatin 20 mg/ perindopril arginine 5 mg/ amlodipine 5 mg	SERVIER MALAYSIA SDN BHD
4.	201908052460A	MAL21056006AZ	Triveram 20mg/10mg/5mg (atorvastatin/perindopril arginine/amlodipine) film-coated tablets	Atorvastatin 20 mg/ perindopril arginine 10 mg/ amlodipine 5 mg	SERVIER MALAYSIA SDN BHD
5.	201908052461A	MAL21056007AZ	Triveram 20mg/10mg/10mg (atorvastatin/perindopril arginine/amlodipine) film-coated tablets	Atorvastatin 20 mg/ perindopril arginine 10 mg/ amlodipine 10 mg	SERVIER MALAYSIA SDN BHD

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<b>Bil.</b>	<b>No. Rujukan</b>	<b>No. Pendaftaran</b>	<b>Nama Produk</b>	<b>Bahan Aktif</b>	<b>Pemegang Pendaftaran Produk (PRH)</b>
6.	201908052462A	MAL21056008AZ	Triveram 40mg/10mg/10mg (atorvastatin/perindopril arginine/amlodipine) film-coated tablets	Atorvastatin 40 mg/ perindopril arginine 10 mg/ amlodipine 10 mg	SERVIER MALAYSIA SDN BHD

**PBKD 358 (4 JUN 2021)**

<b>Bil.</b>	<b>No. Rujukan</b>	<b>No. Pendaftaran</b>	<b>Nama Produk</b>	<b>Bahan Aktif</b>	<b>Pemegang Pendaftaran Produk (PRH)</b>
1.	202103125061A	MAL21066002ACZ	RAVIDA TABLET 200MG	Ravidasvir Hydrochloride 200mg	PHARMANIAGA MANUFACTURING BERHAD
2.	201910262859A	MAL21066005ACZ	Puroxan (Doxofylline 400mg) Tablet	Doxofylline 400mg	EURODRUG LABORATORIES (M) SDN BHD
3.	201902201830A	MAL21066006AZ	TRIMBOW (BECLOMETASONE DIPROPIONATE/FORMOTERO L FUMARATE/GLYCOPYRRONIUM BROMIDE 100/6/12.5 MICROGRAMS PRESSURISED INHALATION SOLUTION)	Beclometasone Dipropionate 100mcg/Formoterol Fumarate Dihydrate 6mcg/Glycopyrronium Bromide12.5mcg	Orient Europharma (M) Sdn Bhd

## SENARAI PRODUK UBAT BARU YANG DIDAFTARKAN OLEH PBKD PADA TAHUN 2021

### PBKD 360 (1 JULAI 2021)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1.	201908212548A	MAL21076002ACRZ	Cresemba powder for concentrate for solution for infusion 200mg	Isavuconazonium sulfate (equivalent to isavuconazole 200mg)	PFIZER (MALAYSIA) SDN. BHD.
2.	201908212549A	MAL21076003ACRZ	Cresemba 100mg Capsule	Isavuconazonium sulfate (equivalent to isavuconazole 100mg)	PFIZER (MALAYSIA) SDN. BHD.
3.	201912103132A	MAL21076001ARZ	Eybelis ophthalmic solution 0.002%	Omidenepag isopropyl 0.002%	SANTEN PHARMA MALAYSIA SDN. BHD.

### PBKD 362 (5 OGOS 2021)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1.	202010054317A	MAL21086002ARZ	Evrysdi Powder for oral solution 0.75 mg/mL	Risdiplam 0.75 mg/mL	ROCHE (MALAYSIA) SDN. BHD.
2.	202101114772A	MAL21086003ACRZ	Talzenna 0.25mg Hard Capsules	Talazoparib Tosylate 0.363 mg (equivalent to 0.25 mg of talazoparib active moiety [free base])	PFIZER (MALAYSIA) SDN. BHD.

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<b>Bil.</b>	<b>No. Rujukan</b>	<b>No. Pendaftaran</b>	<b>Nama Produk</b>	<b>Bahan Aktif</b>	<b>Pemegang Pendaftaran Produk (PRH)</b>
3.	202101114773A	MAL21086004ACRZ	Talzenna 1mg Hard Capsules	Talazoparib Tosylate 1.453 mg (equivalent to 1 mg of talazoparib active moiety [free base])	PFIZER (MALAYSIA) SDN. BHD.

**PBKD 365 (8 OKTOBER 2021)**

<b>Bil.</b>	<b>No. Rujukan</b>	<b>No. Pendaftaran</b>	<b>Nama Produk</b>	<b>Bahan Aktif</b>	<b>Pemegang Pendaftaran Produk (PRH)</b>
1.	202101264847A	MAL21106001ARZ	Aectura Breezhaler (Indacaterol Acetate/Mometasone Furoate) 150/80mcg Inhalation Powder Hard Capsules	Indacaterol acetate 150mcg and mometasone furoate 50mcg	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
2.	202101264848A	MAL21106002ARZ	Aectura Breezhaler (Indacaterol Acetate/Mometasone Furoate) 150/160mcg Inhalation Powder Hard Capsules	Indacaterol acetate 150mcg and mometasone furoate 160mcg	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.



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<b>Bil.</b>	<b>No. Rujukan</b>	<b>No. Pendaftaran</b>	<b>Nama Produk</b>	<b>Bahan Aktif</b>	<b>Pemegang Pendaftaran Produk (PRH)</b>
3.	202101264849A	MAL21106003ARZ	Aectura Breezhaler (Indacaterol Acetate/Mometasone Furoate) 150/320mcg Inhalation Powder Hard Capsules	Indacaterol acetate 150mcg and mometasone furoate 320mcg	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
4.	202101264846A	MAL21106004ARZ	Energair Breezhaler (Indacaterol Acetate/Glycopyrronium Bromide/Mometasone Furoate) 150/50/160mcg Inhalation Powder Hard Capsules	Indacaterol acetate 150mcg, glycopyrronium bromide 50mcg and mometasone furoate 160mcg	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
5.	202010194378A	MAL21106005AZ	Calquence Hard Capsules 100mg	Acalabrutinib 100mg	ASTRAZENECA SDN. BHD.
6.	202005203742A	MAL21106006AZ	Euvalcor (10mg Atorvastatin / 5mg Perindopril) hard capsules	Atorvastatin 10 mg/Perindopril arginine 5 mg	SERVIER MALAYSIA SDN BHD
7.	202005203743A	MAL21106007AZ	Euvalcor (10mg Atorvastatin / 10mg Perindopril) hard capsules	Atorvastatin 10 mg/Perindopril arginine 10 mg	SERVIER MALAYSIA SDN BHD

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<b>8.</b>	202005203744A	MAL21106008AZ	Euvalcor (20mg Atorvastatin / 5mg Perindopril) hard capsules	Atorvastatin 20 mg/ Perindopril arginine 5 mg	SERVIER MALAYSIA SDN BHD
<b>9.</b>	202005203746A	MAL21106009AZ	Euvalcor (40mg Atorvastatin / 5mg Perindopril) hard capsules	Atorvastatin 40 mg/ Perindopril arginine 5 mg	SERVIER MALAYSIA SDN BHD
<b>10.</b>	202005203745A	MAL21106010AZ	Euvalcor (20mg Atorvastatin / 10mg Perindopril) hard capsules	Atorvastatin 20 mg/ Perindopril arginine 10 mg	SERVIER MALAYSIA SDN BHD
<b>11.</b>	202005203747A	MAL21106011AZ	Euvalcor (40mg Atorvastatin / 10mg Perindopril) hard capsules	Atorvastatin 40 mg/ Perindopril arginine 10 mg	SERVIER MALAYSIA SDN BHD
<b>12.</b>	202008124111A	MAL21106012ACZ	TAMBOCOR TABLET 100MG	Flecainide Acetate 100mg	iNova Pharmaceuticals (Singapore) Pte Ltd (incorporated In Singapore) Malaysia Branch
<b>13.</b>	202006253898A	MAL21106013ACRZ	Velcade 3.5mg for Injection (sterile lyophilized powder)	Bortezomib 3.5mg	JOHNSON & JOHNSON SDN BHD

## SENARAI PRODUK UBAT BARU YANG DIDAFTARKAN OLEH PBKD PADA TAHUN 2021

### PBKD 366 (17 NOVEMBER 2021)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1.	202006023783A	MAL21116005ARZ	Kiendra 0.25mg film-coated tablet	Siponimod 0.25mg (as siponimod fumaric acid)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
2.	202006023784A	MAL21116006ARZ	Kiendra 2mg film-coated tablet	Siponimod 2 mg (as siponimod fumaric acid)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
3.	201911132961A	MAL21116009ACSZ	Afrin Nasal Spray 0.05%	Oxymetazoline Hydrochloride 0.05%w/v	BAYER CO. (MALAYSIA) SDN. BHD.
4.	202003273589A	MAL21116007ACRZ	Nitroderm TTS 5 (5mg/24hr) transdermal patch	Nitroglycerin, diluted 25mg	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
5.	202003273590A	MAL21116008ACRZ	Nitroderm TTS 10 (10mg/24hr) transdermal patch	Nitroglycerin, diluted 50mg	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
6.	202006193860A	MAL21116010ACZ	MIACALCIC 50IU AMPOULES	Calcitonin Salmon 50IU	ZUELLIG PHARMA SDN BHD

## SENARAI PRODUK UBAT BARU YANG DIDAFTARKAN OLEH PBKD PADA TAHUN 2021

### PBKD 367 (13 DISEMBER 2021)

Bil.	No. Rujukan	No. Pendaftaran	Nama Produk	Bahan Aktif	Pemegang Pendaftaran Produk (PRH)
1.	202006113827A	MAL21126002ACZ	RADICAVA™ IV Concentrate Solution for Infusion 30mg/20mL	Edaravone 30mg/20mL	Mitsubishi Tanabe Pharma Malaysia Sdn. Bhd.