

PRODUK UBAT BARU YANG DIDAFTARKAN PADA 2017

Senarai produk yang didaftarkan pada 24 Februari 2017 (DCA 309)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201605032016A/ MAL17025022AC Z	Genvoya (Elvitegravir 150mg/Cobicistat 150mg/Emtricitabi ne 200mg/Tenofovir alafenamide10m) Film-Coated Tablets	Elvitegravir 150mg, Cobicistat on silicon dioxide 288.5 mg (corresponds to 150 mg of cobicistat), Emtricitabine 200mg and Tenofovir alafenamide 11.2 mg (corresponds to 10 mg of tenofovir alafenamide)	Gilead Sciences Malaysia Sdn. Bhd.
2.	201509172012A/ MAL17025019AR Z	Farydak 10mg Hard Capsules	Panobinostat lactate anhydrous 12.576 mg (corresponding to 10 mg of panobinostat)	Novartis Corporation (Malaysia) Sdn. Bhd.
3.	201509172013A/ MAL17025020AR Z	Farydak 15mg Hard Capsules	Panobinostat lactate anhydrous 18.864 mg (corresponding to 15 mg of panobinostat)	Novartis Corporation (Malaysia) Sdn. Bhd.
4.	201509172014A/ MAL17025021AR Z	Farydak 20mg Hard Capsules	Panobinostat lactate anhydrous 25.152 mg (corresponding to 20 mg of panobinostat)	Novartis Corporation (Malaysia) Sdn. Bhd.
5.	201402062012A/ MAL17025017AC RZ	Monofer 100mg/ml solution for injection/infusion in ampoules	Iron (III) isomaltoside, 100mg/ml	Zuellig Pharma Sdn. Bhd.

6.	201402062014A/ MAL17025018AC RZ	Monofer 100 mg/ml solution for injection/infu sion in vials	Iron (III) isomaltoside, 100mg/ml	Zuellig Pharma Sdn. Bhd.
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Senarai produk yang didaftarkan pada 29 Mac 2017 (DCA310)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201508250001A/ MAL17035024AC Z	ENDOMETRIN 100mg Vaginal Tablet	Micronised progesterone 100 mg	Ferring Sdn. Bhd.
2.	201511102017A/ MAL17035025AZ	Atozet 10mg/10mg film- coated tablets	Ezetimibe 10mg and atorvastatin calcium trihydrate 10.9mg (equivalent to free acid 10mg)	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.
3.	201511102016A/ MAL17035022AZ	Atozet 10mg/20mg film- coated tablets	Ezetimibe 10mg and atorvastatin calcium trihydrate 21.7mg (equivalent to free acid 20mg)	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.
4.	201511102015A/ MAL17035021AZ	Atozet 10mg/40mg film- coated tablets	Ezetimibe 10mg and atorvastatin calcium trihydrate 43.3mg (equivalent to free acid 40mg)	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.
5.	201511102018A/ MAL17035026AZ	Atozet 10mg/80mg film- coated tablets	Ezetimibe 10mg and atorvastatin calcium trihydrate 86.8 mg (equivalent to free acid 80mg)	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.
6.	201512072017A/ MAL17035023AC Z	TAPCOM-S ophthalmic solution 15 micrograms/ml+ 5 mg/ml, solution in single-dose	Taf luprost 0.0015mg/ml + Timolol maleate 6.84mg/ml (corresponding to timolol 5mg/ml)	Santen Pharma Malaysia Sdn. Bhd.

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Senarai produk yang didaftarkan pada 2 Mei 2017 (DCA 311)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	20160906877A/ MAL20172807AZ	Tagrisso Film-Coated Tablet 40mg	Osimertinib mesylate 47.7mg (equivalent to 40mg osimertinib)	Astrazeneca Sdn. Bhd.
2.	20160906878A/ MAL20172808AZ	Tagrisso Film-Coated Tablet 80mg	Osimertinib mesylate 95.4mg (equivalent to 80mg osimertinib)	Astrazeneca Sdn. Bhd.
3.	201507100001A MAL17055020AZ	MISODEL 200mcg Vaginal Pessary	Misoprostol 200 mcg	Ferring Sdn. Bhd.

Senarai produk yang didaftarkan pada 4 Julai 2017 (DCA 313)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201603022014A/ MAL17075001AZ	Spiolto Respimat Inhalation Solution 2.5mcg/2.5mcg per actuation	Olodaterol hydrochloride 2.736mcg (equivalent to olodaterol 2.5mcg per actuation) and tiotropium bromide monohydrate 3.124mcg (equivalent to tiotropium 2.5mcg per actuation)	Boehringer Ingelheim (Malaysia) Sdn. Bhd.
2.	201503162012A/ MAL17075002AZ	Factive film-coated tablet 320 mg	Gemifloxacin mesylate 426.39 mg (Gemifloxacin mesylate is the	Pahang Pharmacy Sdn. Bhd.

			sesquihydrate form. 426.39mg is equivalent to 320 mg pure free base)	
3.	201502052017A/ MAL17075003AR Z	Nesina Met 12.5mg/500mg Film-Coated Tablet	Alogliptin benzoate 12.5 mg (equivalent to 8.5 mg alogliptin free base) & metformin hydrochloride 500 mg	Takeda Malaysia Sdn Bhd
4.	201502052018A/ MAL17075004AR Z	Nesina Met 12.5mg/1000mg Film-Coated Tablet	Alogliptin benzoate 12.5 mg (equivalent to 8.5 mg alogliptin free base) & metformin hydrochloride 1000 mg	Takeda Malaysia Sdn Bhd

Senarai produk yang didaftarkan pada 3 Ogos 2017 (DCA 314)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	20161207212A/ MAL20172943AZ	ZEPATIER (Grazoprevir 100mg/Elbasvir 50mg) Film-coated Tablets	Grazoprevir hydrate 102.3mg (equivalent to 100.0 mg grazoprevir) and elbasvir 50mg	Merck Sharp & Dohme (Malaysia) Sdn Bhd

Senarai produk yang didaftarkan pada 29 Ogos 2017 (DCA 315)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201506292012A/ MAL17085069AZ	IZBA 30 micrograms/mL eye drops, solution	Travoprost 0.003% w/v	Alcon Laboratories (Malaysia) Sdn. Bhd.
2.	201603022016A/ MAL17085067AC Z	Mezavant XI 1200mg, Gastro-Resistant, Prolonged	MESALAZINE 1200MG	LF Asia (Malaysia) Sdn Bhd

		Release Tablets		
3.	201504202013A/ MAL17085068AZ	Foster® Nexthaler® 100 micrograms/6 micrograms per dose inhalation powder	Beclomethasone dipropionate 100 µg (corresponding to delivered dose of 81.9 micrograms of beclomethasone propionate anhydrous) and formoterol fumarate 6 µg (corresponding to delivered dose of 5.0 micrograms of formoterol fumarate dihydrate)	Orient Europharma (M) Sdn Bhd

Senarai produk yang didaftarkan pada 3 Oktober 2017 (DCA 316)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201505202013A/ MAL17107003AC RZ	Cholib 145mg/20mg Film-Coated Tablet	145 mg of fenofibrate and 20 mg of simvastatin	Abbott Laboratories (M) Sdn. Bhd.
2.	201505202012A/ MAL17107004AC RZ	Cholib 145mg/40mg Film-Coated Tablet	145 mg of fenofibrate and 40 mg of simvastatin	Abbott Laboratories (M) Sdn. Bhd.
3.	201511232015A/ MAL17107002AC Z	Duaklir Genuair 340/12 mcg Inhalation Powder	Acclidinium bromide 400 mcg (the delivered dose is 396 mcg acclidinium bromide equivalent to 340 mcg of aclidinium) and formoterol fumarate dihydrate 12 mcg (the delivered dose is 11.8 mcg formoterol fumarate dihydrate)	Astrazeneca Sdn. Bhd.
4.	201511232016A/ MAL17107001AC Z	Eklira Genuair 322 mcg Inhalation Powder	Acclidinium bromide 400 mcg (Equivalents to 343 mcg)	Astrazeneca Sdn. Bhd.

			equivalents to 322 mcg acridinium)	
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Senarai produk yang didaftarkan pada 30 Oktober 2017 (DCA 317)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201601102013A/ MAL17107075AC RZ	MINIRIN Oral Lyophilisate for Sublingual 60 mcg	Desmopressin acetate 67 mcg (equivalent to 60 mcg desmopressin free base)	Ferring Sdn. Bhd.
2.	201601102014A/ MAL17107076AC RZ	MINIRIN Oral Lyophilisate for Sublingual 120 mcg	Desmopressin acetate 135 mcg (equivalent to 120 mcg desmopressin free base)	Ferring Sdn. Bhd.
3.	201604260001A/ MAL17107074AR Z	ALOXI 500mcg Soft Capsules	Palonosetron Hydrochloride	Mundipharma Pharmaceuticals Sdn. Bhd.
4.	201506222014A/ MAL17107077AZ	Cravit 1.5% Ophthalmic Solution	Levofloxacin 1.5% w/v	Santen Pharma Malaysia Sdn. Bhd.

Senarai produk yang didaftarkan pada 27 November 2017 (DCA 318)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201511170001A/ MAL17117022AR Z	URIEF FILM- COATED TABLETS 4MG	SILODOSIN 4MG	Eisai (Malaysia) Sdn. Bhd.