

PRODUK UBAT BARU YANG DIDAFTARKAN PADA 2018

Senarai produk yang didaftarkan pada 4 Januari 2018 (DCA 319)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201603212017A/ MAL18016070AR Z	Uritos Film Coated Tablets 0.1mg	Imidafenacin 0.1mg	Eisai (Malaysia) Sdn. Bhd.
2.	201605232045A/ MAL18016074AR Z	EXJADE 90 mg Film-Coated Tablets	Deferasirox 90mg	Novartis Corporation (Malaysia) Sdn. Bhd.
3.	201605232046A/ MAL18016073AR Z	EXJADE 180 mg Film-Coated Tablets	Deferasirox 180 mg	Novartis Corporation (Malaysia) Sdn. Bhd.
4.	201605232047A/ MAL18016071AR Z	EXJADE 360 mg Film-Coated Tablets	Deferasirox 360mg	Novartis Corporation (Malaysia) Sdn. Bhd.

Senarai produk yang didaftarkan pada 30 Januari 2018 (DCA 320)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201605232040A/ MAL18016005AZ	Glyxambi Film- Coated Tablets 10mg/5mg	Empagliflozin 10mg & linagliptin 5mg	Boehringer Ingelheim (Malaysia) Sdn. Bhd.
2.	201605232039A/ MAL18016004AZ	Glyxambi Film- Coated Tablets 25mg/5mg	Empagliflozin 25mg & linagliptin 5mg	Boehringer Ingelheim (Malaysia) Sdn. Bhd.
3.	201603302019A/ MAL18016055AZ	Jardiance Duo 5mg/ 500mg Film-coated tablets	Empagliflozin 5mg & metformin hydrochloride 500mg	Boehringer Ingelheim (Malaysia) Sdn. Bhd.
4.	201603302018A/ MAL18016056AZ	Jardiance Duo 12.5mg/ 500mg Film-coated tablets	Empagliflozin 12.5mg & metformin hydrochloride 500mg	Boehringer Ingelheim (Malaysia) Sdn. Bhd.
5.	201603302017A/ MAL18016057AZ	Jardiance Duo 12.5mg/ 850mg Film-coated tablets	Empagliflozin 12.5mg & metformin hydrochloride 850mg	Boehringer Ingelheim (Malaysia) Sdn. Bhd.
6.	201603302016A/	Jardiance Duo	Empagliflozin	Boehringer Ingelheim

	MAL18016058AZ	12.5mg/ 1000mg Film-coated tablets	12.5mg & metformin hydrochloride 1000mg	(Malaysia) Sdn. Bhd.
7.	201605242021A/ MAL18016012AC Z	Transtec 35 micrograms/h Transdermal Patch	Buprenorphine 20mg	Mundipharma Pharmaceuticals Sdn. Bhd.
8.	201605242022A/ MAL18016011AC Z	Transtec 52.5 micrograms/h Transdermal Patch	Buprenorphine 30mg	Mundipharma Pharmaceuticals Sdn. Bhd.
9.	201605242020A/ MAL18016010AC Z	Transtec 70 micrograms/h Transdermal Patch	Buprenorphine 40mg	Mundipharma Pharmaceuticals Sdn. Bhd.
10.	201605032012A/ MAL18016015AC RZ	Nurofen Express 200mg Liquid Capsules	Ibuprofen 200mg	Reckitt Benckiser (Malaysia) Sdn. Bhd.
11.	201512092013A/ MAL18016016AC RZ	Nurofen Express 400mg Liquid Capsules	Ibuprofen 400mg	Reckitt Benckiser (Malaysia) Sdn. Bhd.
12.	201601092015A/ MAL18016013AC Z	Sancuso® (Granisetron Transdermal System) 3.1mg/24hours	Granisetron 34.3mg per patch	Smart Medicine Sdn. Bhd.

Senarai produk yang didaftarkan pada 28 Februari 2018 (DCA321)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201603290001A/ MAL18026186AZ	Abilify Maintena 400 mg powder and solvent for prolonged- release suspension for injection	Aripiprazole monohydrate 475mg equivalent to 400mg aripiprazole	Lundbeck Malaysia Sdn. Bhd.
2.	201605242040A/ MAL18026001AC Z	IKERVIS 1 mg/mL eye drops, emulsion	Ciclosporin A (CsA)	Santen Pharma Malaysia Sdn. Bhd.
3.	201605192018A/ MAL18026073AZ	Implicor 25mg/5mg Film-	Metoprolol tartrate 25 mg & ivabradine hydrochloride 5.390	Servier Malaysia Sdn. Bhd.

		Coated Tablets	mg (equivalent to 5 mg ivabradine).	
4.	201605192015A/ MAL18026072AZ	Implicor 25mg/7.5mg Film-Coated Tablets	Metoprolol tartrate 25 mg & ivabradine hydrochloride 8.085 mg (equivalent to 7.5 mg ivabradine).	Servier Malaysia Sdn. Bhd.
5.	201605192016A/ MAL18026075AZ	Implicor 50mg/5mg Film- Coated Tablets	Metoprolol tartrate 50 mg & ivabradine hydrochloride 5.390 mg (equivalent to 5 mg ivabradine).	Servier Malaysia Sdn. Bhd.
6.	201605192017A/ MAL18026074AZ	Implicor 50mg/7.5mg Film-Coated Tablets	Metoprolol tartrate 50 mg & ivabradine hydrochloride 8.085 mg (equivalent to 7.5 mg ivabradine)	Servier Malaysia Sdn. Bhd.
7.	201601102016A/ MAL18026063AR Z	Kanarb [®] Film- Coated Tablets 60mg	Fimasartan Potassium Trihydrate 66.01 mg (equivalent to 60 mg fimasartan potassium)	Zuellig Pharma Sdn. Bhd.
8.	201601102017A/ MAL18026065AR Z	Kanarb [®] Film- Coated Tablets 120 mg	Fimasartan Potassium Trihydrate 132.02 mg (equivalent to 120 mg fimasartan potassium)	Zuellig Pharma Sdn. Bhd.

Senarai produk yang didaftarkan pada 2 April 2018 (DCA 322)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201601102012A/ MAL18046005AC Z	Selexid 400mg Film-Coated Tablets	Pivmecillinam hydrochloride 400mg	DKSH Malaysia Sdn Bhd
2.	201605162023A/ MAL18046016AC Z	Inovelon 200mg Film-Coated Tablets	Rufinamide 200mg	Eisai (Malaysia) Sdn Bhd (18039-D)

3.	201707170550A/ MAL18046002AZ	Epclusa (sofosbuvir 400mg/ velpatasvir 100mg) Film- Coated Tablets	Sofosbuvir 400mg and velpatasvir 100mg	Gilead Sciences Malaysia Sdn. Bhd.
4.	201707170539A/ MAL18046001AR Z	Kryxana 200mg Film-coated Tablets	Ribociclib succinate 254.4mg (equivalent to 200mg of ribociclib free base)	Novartis Corporation (Malaysia) Sdn. Bhd.
5.	201605232033A/ MAL18046007AR Z	Cotellic Film Coated Tablet 20mg	Cobimetinib hemifumarate 22.2mg (corresponds to 20 mg cobimetinib free base)	Roche (Malaysia) Sdn. Bhd.

Senarai produk yang didaftarkan pada 23 April 2018 (DCA 323)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201605302073A/ MAL18046146AZ	Ajenafil 25 mg Chewable Tablet	Sildenafil citrate 35.12mg (equivalent to sildenafil 25mg)	AJ Research & Pharma Sdn. Bhd.
2.	201605302075A/ MAL18046145AZ	Ajenafil 50 mg Chewable Tablet	Sildenafil citrate 70.24mg (equivalent to sildenafil 50mg)	AJ Research & Pharma Sdn. Bhd.
3.	201605302074A/ MAL18046144AZ	Ajenafil 100 mg Chewable Tablet	Sildenafil citrate 140.48mg (equivalent to sildenafil 100mg)	AJ Research & Pharma Sdn. Bhd.
4.	20160906944A/ MAL18046135AZ	Brilinta 60 mg Film-Coated Tablet	Ticagrelor 60 mg	Astrazeneca Sdn. Bhd.
5.	201602190001A/ MAL18046136AZ	Belara 0.03 mg/2 mg film-coated tablets	0.030 mg ethinylestradiol and 2 mg chlormadinone acetate (corresponding to 1.71 mg chlormadinone)	Pahang Pharmacy Sdn. Bhd.

Senarai produk yang didaftarkan pada 31 Mei 2018 (DCA 324)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201706220475A/ MAL18056111AC Z	Vemlidy (Tenofovir Alafenamide 25mg) Film- Coated Tablets	Tenofovir alafenamide fumarate 28.04mg (corresponds to 25 mg of tenofovir alafenamide free base)	Gilead Sciences Malaysia Sdn. Bhd.
2.	201605312026A/ MAL18056067AZ	Poly-MXB for Injection U.S.P. 500,000 Units (Lyophilized)	Polymyxin B Sulphate 500,000 Unit	Pahang Pharmacy Sdn. Bhd.
3.	20170107318A/ MAL18056065AC Z	Dymista Nasal Spray 137mcg/50mcg	Azelastine hydrochloride 137mcg (equivalent to 125 micrograms azelastine) + fluticasone propionate 50mcg	Meda Healthcare Sdn. Bhd.
4.	201605242039A/ MAL18056066AC RZ	Buffered Binosto 70 mg Effervescent Tablets	Alendronate monosodium salt trihydrate 91.37mg (equivalent to alendronic acid 70mg)	Zuellig Pharma Sdn Bhd
5.	201601102015A/ MAL18056094AZ	Dienille 2mg/ 0.03mg film coated tablets	Dienogest 2 mg/ ethinylestradiol 0.03 mg	Exeltis Pharma Sdn Bhd

Senarai produk yang didaftarkan pada 25 Jun 2018 (DCA 325)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	20161006957A/ MAL18066050AC Z	Cortiment Prolonged Release Tablets 9mg	Budesonide 9mg	Ferring Sdn. Bhd.

Senarai produk yang didaftarkan pada 28 Ogos 2018 (DCA 326)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	20161207215 A/ MAL1808610 5AZ	Ajalopram 5mg Orodispersible Tablet	Escitalopram Oxalate 6.3875mg equivalent to Escitalopram 5mg	AJ Research & Pharma Sdn. Bhd.
2.	20161207214A/ MAL18086106AZ	Ajalopram 10mg Orodispersible Tablet	Escitalopram Oxalate 12.775mg equivalent to Escitalopram 10mg	AJ Research & Pharma Sdn. Bhd.
3.	20170107343A/ MAL18086104AZ	Ajalopram 15mg Orodispersible Tablet	Escitalopram Oxalate 19.1625mg equivalent to Escitalopram 15mg	AJ Research & Pharma Sdn. Bhd.
4.	20170107344A/ MAL18086103AZ	Ajalopram 20mg Orodispersible Tablet	Escitalopram Oxalate 25.55mg equivalent to Escitalopram 20mg	AJ Research & Pharma Sdn. Bhd.
5.	201605302070A/ MAL18086137AC Z	Kyprolis (carfilzomib) for Injection 60mg/vial	Carfilzomib 61.6mg	ARC Pharma Consulting Sdn Bhd
6.	201711241093A/ MAL18086114AC RZ	Uptravi 200 microgram film- coated tablets	Selexipag 200mcg	DKSH Malaysia Sdn Bhd.
7.	201711241094A/ MAL18086113AC RZ	Uptravi 400 microgram film	Selexipag 400mcg	DKSH Malaysia Sdn Bhd.
8.	20171124109 5A/ MAL1808611 2ACRZ	Uptravi 600 microgram film	Selexipag 600mcg	DKSH Malaysia Sdn Bhd.
9.	201711241096A/ MAL18086111AC RZ	Uptravi 800 microgram film	Selexipag 800mcg	DKSH Malaysia Sdn Bhd.
10.	201711241097A/ MAL18086110AC RZ	Uptravi 1000 microgram film	Selexipag 1000mcg	DKSH Malaysia Sdn Bhd.
11.	201711241098A/ MAL18086109AC RZ	Uptravi 1200 microgram film	Selexipag 1200mcg	DKSH Malaysia Sdn Bhd.
12.	201711241099A/ MAL18086108AC RZ	Uptravi 1400 microgram film	Selexipag 1400mcg	DKSH Malaysia Sdn Bhd.
13.	201711241100A/ MAL18086107AC	Uptravi 1600 microgram film	Selexipag 1600mcg	DKSH Malaysia Sdn Bhd.

	RZ			
14.	201706210455A/ MAL18086128AR Z	Olumiant 2mg Film-Coated Tablets	Baricitinib 2mg	Eli Lilly (Malaysia) Sdn Bhd.
15.	201706210456A/ MAL18086127AR Z	Olumiant 4mg Film-Coated Tablets	Baricitinib 4mg	Eli Lilly (Malaysia) Sdn Bhd.
16.	201605300001A/ MAL18086115AZ	Tenolam (Tenofovir Disoproxil Fumarate 300 mg and Lamivudine 300 mg) Film- coated Tablet	Tenofovir Disoproxil Fumarate 300mg (equivalent to 245mg Tenofovir Disoproxil) and Lamivudine 300 mg	Pharmamode (M) Sdn Bhd
17.	201705230340A/ MAL18086130AC RZ	Alecensa (Alectinib) Hard Capsules 150mg	Alectinib hydrochloride 161.3mg (equivalent to 150mg alectinib)	Roche (Malaysia) Sdn. Bhd.
18.	20161007045A/ MAL18086135AZ	Aprovasc Film Coated Tablet 150mg/5mg	Irbesartan 150mg / Amlodipine Besilate 5mg	Sanofi-Aventis (Malaysia) Sdn. Bhd
19.	20161107141A/ MAL18086133AZ	Aprovasc Film Coated Tablet 150mg/10mg	Irbesartan 150mg / Amlodipine Besilate 10mg	Sanofi-Aventis (Malaysia) Sdn. Bhd.
20.	20161107142A/ MAL18086132AZ	Aprovasc Film Coated Tablet 300mg/5mg	Irbesartan 300mg / Amlodipine Besilate 5mg	Sanofi-Aventis (Malaysia) Sdn. Bhd.
21.	20161007046A/ MAL18086134AZ	Aprovasc Film Coated Tablet 300mg/10mg	Irbesartan 300mg / Amlodipine Besilate 10mg	Sanofi-Aventis (Malaysia) Sdn. Bhd.

Senarai produk yang didaftarkan pada 15 Oktober 2018 (DCA 327)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201605162014A/ MAL18106136AZ	Medikinet MR 5mg Hard Capsules	Methylphenidate hydrochloride 5 mg, corresponding to 4.35 mg methylphenidate.	Hyphens Pharma Sdn. Bhd.
2.	201605162015A/ MAL18106134AZ	Medikinet MR 10mg Hard Capsules	Methylphenidate hydrochloride 10 mg, corresponding to 8.65 mg methylphenidate.	Hyphens Pharma Sdn. Bhd.
3.	201605162016A/ MAL18106133AZ	Medikinet MR 20mg Hard Capsules	Methylphenidate hydrochloride 20 mg, corresponding to 17.30 mg methylphenidate.	Hyphens Pharma Sdn. Bhd.
4.	201605092021A/ MAL18106137AZ	Medikinet MR 30mg Hard Capsules	Methylphenidate hydrochloride 30 mg, corresponding to 25.95 mg methylphenidate.	Hyphens Pharma Sdn. Bhd.
5.	201605092022A/ MAL18106139AZ	Medikinet MR 40mg Hard Capsules	Methylphenidate hydrochloride 40 mg, corresponding to 34.60 mg methylphenidate	Hyphens Pharma Sdn. Bhd.
6.	201602242012X/ MAL18106050XC	Hepa-Merz 3000mg Granulate/sachet for oral solution	L-ornithine-L- aspartate 3000mg	MERZ Malaysia Sdn. Bhd.
7.	20161207213A/ MAL18106051AZ	Diquas Ophthalmic Solution 3%	Diquafosol Sodium 30mg/ml	Santen Pharma Malaysia Sdn. Bhd.

Senarai produk yang didaftarkan pada 15 November 2018 (DCA 328)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201606012013A/ MAL18116081AZ	BLES (bovine lipid extract surfactant) 27 mg/ml Suspension for Intratracheal Instillation	Phospholipid 27mg/ml & surfactant associated proteins SP-B and SP-C 176 - 500µg	Averroes Pharmaceuticals Sdn. Bhd.
2.	201708250712A/ MAL18116086AR Z	Otezla Film-Coated Tablets 10mg	Apremilast 10mg	Celgene Sdn. Bhd.
3.	201708250711A/ MAL18116085AR Z	Otezla Film-Coated Tablets 20mg	Apremilast 20mg	Celgene Sdn. Bhd.
4.	201708250710A/ MAL18116084AR Z	Otezla Film-Coated Tablets 30mg	Apremilast 30mg	Celgene Sdn. Bhd.
5.	201708080656A/ MAL18116089AC Z	Descovy® (emtricitabine 200 mg/ tenofovir alafenamide 10 mg) film-coated tablets	Emtricitabine 200mg and Tenofovir alafenamide fumarate (TAF) 11.2mg equivalent to 10 mg of tenofovir alafenamide.	Gilead Sciences Malaysia Sdn. Bhd.
6.	201708210688A/ MAL18116088AC Z	Descovy® (emtricitabine 200 mg/ tenofovir alafenamide 25 mg) film-coated tablets	Emtricitabine 200mg and Tenofovir alafenamide fumarate (TAF) 28mg equivalent to 25mg of tenofovir alafenamide	Gilead Sciences Malaysia Sdn. Bhd.
7.	201710120888A/ MAL18116091AC Z	Odefsey® (200mg Emtricitabine/ 25mg Rilpivirine/25mg Tenofovir alafenamide) Film Coated Tablets	Emtricitabine 200mg, Rilpivirine hydrochloride 27.50 mg (corresponds to 25 mg of rilpivirine) and Tenofovir alafenamide fumarate 28.04 mg (corresponds to 25 mg of tenofovir alafenamide).	Gilead Sciences Malaysia Sdn. Bhd.
8.	201605302027A/ MAL18116082AR	Pamorelin 11.25mg Powder	Triptorelin Embonate 15.5mg	Orient Europharma (M) Sdn Bhd.

	Z	for Suspension for Injection	(equivalent to 11.25mg triptorelin)	
9.	201605302028A/ MAL18116083AR Z	Pamorelin 22.5mg Powder for Suspension for Injection	Triptorelin Embonate 31mg (equivalent to 22.5mg triptorelin)	Orient Europharma (M) Sdn Bhd.
10.	201708250714A/ MAL18116090AZ	Lenzetto 1.53 mg/spray transdermal spray, solution	Estradiol Hemihydrate 1.58mg equivalent to Estradiol 1.53mg	Pahang Pharmacy Sdn. Bhd.
11.	201705160303A/ MAL18116087AZ	Strepsils Max Pro Direct 8.75mg Spray	1.62% w/v; 1 dose = 0.540ml, which contains 8.748 mg of flurbiprofen	Reckitt Benckiser (Malaysia) Sdn. Bhd.