

PRODUK UBAT BARU YANG DIDAFTARKAN PADA 2016**Senarai produk yang didaftarkan pada 21 Januari 2016 (DCA 296)**

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201401232017A/ MAL16015077AR	Pomalyst Capsules 1mg	Pomalidomide 1mg	Celgene Sdn. Bhd.
2.	201401232012A/ MAL16015078AR	Pomalyst Capsules 2mg	Pomalidomide 2mg	Celgene Sdn. Bhd.
3.	201401232014A/ MAL16015079AR	Pomalyst Capsules 3mg	Pomalidomide 3mg	Celgene Sdn. Bhd.
4.	201401232016A/ MAL16015080AR	Pomalyst Capsules 4mg	Pomalidomide 4mg	Celgene Sdn. Bhd.
5.	201506290001A/ MAL16015076AR	Zykadia 150mg Hard Capsules	Ceritinib 150mg	Novartis Corporation (Malaysia) Sdn Bhd

Senarai produk yang didaftarkan pada 25 Februari 2016 (DCA 297)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201412292014A/ MAL16025029AC RZ	Imbruvica 140mg Capsules	Ibrutinib 140mg	Johnson & Johnson Sdn Bhd
2.	201405232012A/ MAL16025028AZ	Monavri XR 500mg Extended Release Tablet	Levetiracetam 500mg	UCB Trading (Malaysia) Sdn Bhd

Senarai produk yang didaftarkan pada 11 Mac 2016 (DCA298)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201405072013A/ MAL16035014A	Ranexa 375mg Prolonged- Release Tablets	Ranolazine 375mg	A. Menarini Singapore Pte. Ltd.

2.	201405072012A/ MAL16035012A	Ranexa 500mg Prolonged- Release Tablets	Ranolazine 500mg	A. Menarini Singapore Pte. Ltd.
3.	201405072014A/ MAL16035015A	Ranexa 750mg Prolonged- Release Tablets	Ranolazine 750mg	A. Menarini Singapore Pte. Ltd.
4.	201406030001A/ MAL16035016A	LUMIGAN 0.01% (bimatoprost ophthalmic solution)	Bimatoprost 0.01% w/v	Allergan Malaysia Sdn Bhd
5.	201504242014A/ MAL16035013A	HARVONI (Ledipasvir 90mg/Sofosbuvir 400mg) Film- coated Tablets	Ledipasvir 90mg & sofosbuvir 400mg	Gilead Sciences Malaysia Sdn. Bhd.
6.	201409042017A/ MAL16035018AR	Nesina 6.25mg Film-Coated Tablet	Alogliptin benzoate 8.5mg (As a free base, equivalent to 6.25mg aloglipin)	Takeda Malaysia Sdn Bhd
7.	201409042018A/ MAL16035019AR	Nesina 12.5mg Film-Coated Tablet	Alogliptin 17mg (As a free base, equivalent to 12.5mg aloglipin)	Takeda Malaysia Sdn Bhd
8.	201409042016A/ MAL16035017AR	Nesina 25mg Film-Coated Tablet	Alogliptin benzoate 34mg (As a free base, equivalent to 25mg aloglipin)	Takeda Malaysia Sdn Bhd

Senarai produk yang didaftarkan pada 28 April 2016 (DCA 299)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201503142014A/ MAL16045041ACZ	Lucrin 6 month depot 30mg injection	LEUPRORELIN ACETATE 30MG	Abbvie Sdn Bhd
2.	201501302015A/ MAL16045040AC RZ	Xigduo XR Tablet 10/1000 mg	Dapagliflozin Propanediol 10mg/ Metformin Hydrochloride 1000	Astrazeneca Sdn. Bhd.

			mg	
3.	201501302016A/ MAL16045043AC RZ	Xigduo XR Tablet 5/1000 mg	Dapagliflozin Propanediol 5mg/ Metformin Hydrochloride 1000 mg	Astrazeneca Sdn. Bhd.
4.	201501302017A/ MAL16045044AC RZ	Xigduo XR Tablet 10/500 mg	Dapagliflozin Propanediol 10mg/ Metformin Hydrochloride 500 mg	Astrazeneca Sdn. Bhd.
5.	201505182013A/ MAL16045046AC RZ	Daklinza 30 mg film-coated tablets	Daclatasvir dihydrochloride 33mg (equivalent to 30mg daclatasvir)	DKSH Malaysia Sdn Bhd
6.	201505182012A/ MAL16045037AC RZ	Daklinza 60 mg film-coated tablets	Daclatasvir dihydrochloride 66mg (equivalent to 60mg daclatasvir)	DKSH Malaysia Sdn Bhd
7.	201407072012A/ MAL16045039AC RZ	XTANDI 40mg Soft Capsules	ENZALUTAMIDE 40MG	DKSH Malaysia Sdn Bhd
8.	201412292013A/ MAL16045042AR Z	Invokana 100mg Film-Coated Tablets	Canagliflozin hemihydrates 102mg (equivalent to 100 mg canagliflozin)	Johnson & Johnson Sdn Bhd
9.	201412292012A/ MAL16045038AR Z	Invokana 300mg Film-Coated Tablets	Canagliflozin hemihydrates 306mg (equivalent to 300 mg canagliflozin)	Johnson & Johnson Sdn Bhd
10.	201502102013A/ MAL16045045AR Z	Noxafil 100mg Modified Release Tablet	POSACONAZOLE 100MG	Merck Sharp & Dohme (Malaysia) Sdn Bhd

Senarai produk yang didaftarkan pada 7 Jun 2016 (DCA 300)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201507022014A/ MAL16065014AC RZ	OFEV Soft Capsules 100 mg	Nintedanib esilate 120.40mg equivalent to 100 mg of nintedanib as	Boehringer Ingelheim (Malaysia) Sdn. Bhd.

			free base	
2.	201507022015A/ MAL16065015AC RZ	OFEV Soft Capsules 150 mg	Nintedanib esilate 180.60mg equivalent to 150 mg of nintedanib as free base	Boehringer Ingelheim (Malaysia) Sdn. Bhd.
3.	201410092012A/ MAL16065012AC RZ	Lodotra modified- release tablets 1mg	Prednisone 1mg	Mundipharma Pharmaceuticals Sdn. Bhd.
4.	201410092013A/ MAL16065011AC RZ	Lodotra modified- release tablets 2mg	Prednisone 2mg	Mundipharma Pharmaceuticals Sdn. Bhd.
5.	201410092014A/ MAL16065013AC RZ	Lodotra modified- release tablets 5mg	Prednisone 5mg	Mundipharma Pharmaceuticals Sdn. Bhd.
6.	201409032012A/ MAL16065029AC RZ	Opsumit 10mg film-coated tablets	MACITENTAN 10MG	Parexel International (Malaysia) Sdn Bhd
7.	201509102015A/ MAL16065002AR Z	Ibrance Capsules 75mg	Palbociclib 75mg	Pfizer (Malaysia) Sdn. Bhd.
8.	201509102016A/ MAL16065003AR Z	Ibrance Capsules 100mg	Palbociclib 100mg	Pfizer (Malaysia) Sdn. Bhd.
9.	201509102017A/ MAL16065004AR Z	Ibrance Capsules 125mg	Palbociclib 125mg	Pfizer (Malaysia) Sdn. Bhd.

Senarai produk yang didaftarkan pada 30 Jun 2016 (DCA 301)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201405072015A/ MAL16065042AZ	Ketesse 25mg granules for oral solution	Dexketoprofen trometamol 36.90mg (equivalent to 25mg dexketoprofen)	A. Menarini Singapore Pte. Ltd.
2.	201407090001A/ MAL16065043AZ	KETESSE 50mg/2ml solution for injection or concentrate for	Dexketoprofen trometamol 73.80mg (equivalent to 50mg of	A. Menarini Singapore Pte. Ltd.

		solution for infusion	dexketoprofen in 2ml)	
3.	201511022012A/ MAL16065041AC RZ	Lynparza 50mg hard capsules	OLAPARIB 50MG	Astrazeneca Sdn. Bhd.

Senarai produk yang didaftarkan pada 25 Julai 2016 (DCA 302)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201503180001A/ MAL16075032AZ	Femoston Conti 0.5mg/2.5mg Film Coated	0.517mg estradiol hemihydrate (equivalent to 0.5 mg estradiol) and 2.5 mg dydrogesterone	Abbott Laboratories (M) Sdn. Bhd.
2.	201506150001A/ MAL16075031AC RZ	Feburic 80 mg film-coated tablets	Febuxostat 80mg	DKSH Malaysia Sdn. Bhd.
3.	201507300001A/ MAL16075030AR Z	Jakavi 10 mg Tablets	Ruxolitinib phosphate 13.2 mg (corresponds to 10 mg of ruxolitinib free base)	Novartis Corporation (Malaysia) Sdn. Bhd.

Senarai produk yang didaftarkan pada 22 Ogos 2016 (DCA 303)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201503202012A/ MAL16085016AZ	SIMBRINZA 10mg/ml + 2mg/ml eye drops, suspension	Brinzolamide 10mg/ml and brimonidine 2mg/ml	Alcon Laboratories (Malaysia) Sdn. Bhd.
2.	201504062012A/ MAL16085032AC RZ	Sivextro Film- Coated Tablet 200mg	Tedizolid phosphate 200mg	Bayer Co. (Malaysia) Sdn. Bhd.
3.	201504060001A/ MAL16085033AC RZ	Sivextro Lyophilized Powder for Solution for Infusion 200mg per vial	Tedizolid phosphate 200mg	Bayer Co. (Malaysia) Sdn. Bhd.

Senarai produk yang didaftarkan pada 31 Oktober 2016 (DCA 305)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201506152012A/ MAL16105048AR Z	Signifor LAR 20mg powder and solvent for suspension for injection	Pasireotide pamoate 27.42 mg (equivalent to 20 mg pasireotide)	Novartis Corporation (Malaysia) Sdn. Bhd.
2.	201506152013A/ MAL16105049AR Z	Signifor LAR 40mg powder and solvent for suspension for injection	Pasireotide pamoate 54.84 mg (equivalent to 40 mg pasireotide)	Novartis Corporation (Malaysia) Sdn. Bhd.
3.	201506152014A/ MAL16105050AR Z	Signifor LAR 60mg powder and solvent for suspension for injection	Pasireotide pamoate 82.26 mg (equivalent to 60 mg pasireotide)	Novartis Corporation (Malaysia) Sdn. Bhd.
4.	201505222013A/ MAL16105047AZ	DUAVIVE 20 mg/0.45 mg modified - release tablets	Conjugated oestrogens (CE) 0.45 mg and bazedoxifene acetate 22.56 mg (equivalent to 20mg bazedoxifene)	Pfizer (Malaysia) Sdn. Bhd.

Senarai produk yang didaftarkan pada 25 November 2016 (DCA 306)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201512172015A/ MAL16115028AC RZ	Lenvima 4 mg Hard Capsules	Lenvatinib mesilate 4.90mg (equivalent to lenvatinib 4mg)	Eisai (Malaysia) Sdn Bhd
2.	201512172016A/ MAL16115029AC RZ	Lenvima 10 mg Hard Capsules	Lenvatinib mesilate 12.25mg (equivalent to lenvatinib 10mg)	Eisai (Malaysia) Sdn Bhd
3.	201501082012A/ MAL16115025AZ	Concor AM 5 mg/5 mg Tablets	Bisoprolol fumarate 5 mg and amlodipine besilate 6.95 mg (equivalent	Merck Sdn. Bhd.

			to 5 mg amlodipine)	
4.	201501082013A/ MAL16115026AZ	Concor AM 5 mg/10 mg Tablets	Bisoprolol fumarate 5 mg and amlodipine besilate 13.90 mg (equivalent to 10 mg amlodipine)	Merck Sdn. Bhd.
5.	201602242013A/ MAL16115027AC RZ	Esbriet Hard Capsules 267mg	PIRFENIDONE 267MG	Roche (Malaysia) Sdn. Bhd.

Senarai produk yang didaftarkan pada 22 Disember 2016 (DCA 307)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201605182012A/ MAL16125024AC RZ	Zerbaxa 1.5g powder for solution for injection	Ceftolozane sulphate 1147mg (equivalent to 1000mg ceftolozane) tazobactam sodium 537mg (equivalent to 500mg tazobactam)	Merck Sharp & Dohme (Malaysia) Sdn Bhd
2.	201408180001A/ MAL16125023AZ	FORSTAVIR-LE (Efavirenz 600 mg, Lamivudine 300mg and Tenofovir Disoproxil Fumarate 300 mg) Film-coated Tablets	Efavirenz 600mg, lamivudine 300mg and tenofovir disoproxil fumarate 300mg (equivalent to tenofovir disoproxil 245mg)	Unimed Sdn Bhd