

PRODUK UBAT BARU YANG DIDAFETAR PADA 2014

Senarai produk yang didaftarkan pada 23.1.2014 (DCA 272)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201304182034A / MAL14015013A	Forxiga 5mg Film-Coated Tablet	Dapagliflozin Propanediol 6.150mg (equivalent to dapagliflozin 5mg)	ASTRAZENC A SDN. BHD.
2	201304182035A / MAL14015014A	Forxiga 10mg Film-Coated Tablet	Dapagliflozin Propanediol 12.30mg (equivalent to dapagliflozin 10mg)	ASTRAZENC A SDN. BHD.
3	201301102016A / MAL14015011A	Seebri Breezhaler 50mcg Inhalation Powder Hard Capsule	Glycopyrronium bromide 63mcg [Corresponds to 50mcg glycopyrronium (salt free) and a target delivered dose of 44mcg]	NOVARTIS CORPORATI ON (MALAYSIA) SDN. BHD.
4	201208030001A / MAL14015009A R	Bydureon 2mg Powder And Solvent For Prolonged-Release Suspension For Injection	Exenatide 2mg	ASTRAZENC A SDN. BHD.
5	201212212012A / MAL14015012A	Dexilant Delayed-Release Capsules 30mg	Dexlansoprazole 30mg	TAKEDA MALAYSIA SDN BHD
6	201212210001A / MAL14015010A	Dexilant Delayed-Release Capsules 60mg	Dexlansoprazole 60mg	TAKEDA MALAYSIA SDN BHD

Senarai produk yang didaftarkan pada 27.2.2014 (DCA 273)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201202082016A/ MAL14025003A C	Abstral 100 Microgram Sublingual Tablets	Fentanyl citrate, micronized, 0.1571mg (equivalent to 100mcg fentanyl)	A. MENARINI SINGAPORE PTE. LTD.
2	201202082017A/ MAL14025004A C	Abstral 200 Microgram Sublingual Tablets	Fentanyl citrate, micronized, 0.3142mg (equivalent to 200mcg fentanyl)	A. MENARINI SINGAPORE PTE. LTD.
3	201202082016A/ MAL14025005A C	Abstral 400 Microgram Sublingual Tablets	Fentanyl citrate, micronized, 0.6284mg (equivalent to 400mcg fentanyl)	A. MENARINI SINGAPORE PTE. LTD.

Senarai produk yang didaftarkan pada 27.3.2014 (DCA 274)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201306062016A/ MAL14035002A	Fycompa 2mg Film-Coated Tablets	Perampanel 2.1mg (Anhydrous basis 2mg)	EISAI (MALAYSIA) SDN BHD
2	201306062017A/ MAL14035005A	Fycompa 4mg Film-Coated Tablets	Perampanel 4.2mg (Anhydrous basis 4mg)	EISAI (MALAYSIA) SDN BHD
3	201306062019A/ MAL14035003A	Fycompa 6mg Film-Coated Tablets	Perampanel 6.2mg (Anhydrous basis 6mg)	EISAI (MALAYSIA) SDN BHD
4	201306062015A/ MAL14035001A	Fycompa 8mg Film-Coated Tablets	Perampanel 8.3mg (Anhydrous basis 8mg)	EISAI (MALAYSIA) SDN BHD
5	201306062020A/ MAL14035004A	Fycompa 10mg Film-Coated Tablets	Perampanel 10.4mg (Anhydrous basis 10mg)	EISAI (MALAYSIA) SDN BHD
6	201306062018A/ MAL14035006A	Fycompa 12mg Film-Coated Tablets	Perampanel 12.5mg (Anhydrous basis 12mg)	EISAI (MALAYSIA) SDN BHD

Senarai produk yang didaftarkan pada 9.5.2014 (DCA 275)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201311150001A/ MAL14055146A C	Xofigo (Radium-223 Dichloride) 1000 kBq/ml Solution for Injection	Radium-223 Dichloride 6000kBq/6mL	BAYER CO. (MALAYSIA) SDN. BHD.
2	201310162017A/ MAL14055050A	Tivicay 50mg Film-Coated Tablets	50mg dolutegravir (as 52.6mg dolutegravir sodium)	GLAXOSMIT HKLINE PHARMACEUTICAL SDN BHD
3	201210302012A/ MAL14055045A	Eligard 7.5mg Powder & Solvent for Solution for Injection	7.5 mg leuprorelin acetate, equivalent to 6.96 mg leuprorelin	DKSH MALAYSIA SDN BHD
4	201210302013A/ MAL14055046A	Eligard 22.5mg Powder & Solvent for Solution for Injection	22.5 mg leuprorelin acetate, equivalent to 20.87 mg leuprorelin	DKSH MALAYSIA SDN BHD
5	201210302014A/ MAL14055047A	Eligard 45mg Powder & Solvent for Solution for Injection	45 mg leuprorelin acetate, equivalent to 41.7 mg leuprorelin.	DKSH MALAYSIA SDN BHD
6	201304172014A/ MAL14055048A C	Norvasc ODT Orodispersible Tablet 5mg	Amlodipine besilate 6.93mg (equivalent to amlodipine 5mg)	PFIZER (MALAYSIA) SDN. BHD.
7	201304172013A/ MAL14055049A C	Norvasc ODT Orodispersible Tablet 10mg	Amlodipine besilate 13.86mg (equivalent to amlodipine 10mg)	PFIZER (MALAYSIA) SDN. BHD.

Senarai produk yang didaftarkan pada 26.5.2014 (DCA 276)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201212212013A/ MAL14055147A	Pravafen 40mg/160mg Hard Capsule	40mg pravastatin sodium & 160mg fenofibrate	HYPHENS PHARMA SDN. BHD.

Senarai produk yang didaftarkan pada 7.7.2014 (DCA 277)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201305312013A/ MAL14075041A	Signifor 0.3mg/1ml Solution for Injection	Pasireotide diaspartate 0.3762mg (equivalent to 0.3mg pasireotide)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
2	201305312014A/ MAL14075042A	Signifor 0.6mg/1ml Solution for Injection	Pasireotide diaspartate 0.7524mg (equivalent to 0.6mg pasireotide)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
3	201305312015A/ MAL14075043A	Signifor 0.9mg/1ml Solution for Injection	Pasireotide diaspartate 1.1286mg (equivalent to 0.9mg pasireotide)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
4	201304302015A/ MAL14075044A C	Exelon Patch 15	Rivastigmine base (Each patch of 15 cm ² contains 27 mg rivastigmine base, in vivo release rate of 13.3 mg/24 hours)	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.

Senarai produk yang didaftarkan pada 24.7.2014 (DCA 278)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201211080001A/ MAL14075062A	Otrivin Complete Nasal Spray Solution	1 ml contains 0.5 mg xylometazoline hydrochloride and 0.6 mg ipratropium bromide	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
2	20130919023A/ MAL14075068A	GIOTRIF 20mg Film-Coated Tablets	Afatinibdimaleate 29.56mg equivalent to afatinib 20mg	BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.
3	20130919026A/ MAL14075070A	GIOTRIF 30mg Film-Coated Tablets	Afatinibdimaleate 44.34mgequivalent to afatinib 30mg	BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.
4	20130919025A/ MAL14075069A	GIOTRIF 40mg Film-Coated Tablets	Afatinibdimaleate 59.12mgequivalent to afatinib 40mg	BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.
5	20130919027A/ MAL14075071A	GIOTRIF 50mg Film-Coated Tablets	Afatinibdimaleate 73.90mgequivalent to afatinib 50mg	BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.
6	201307162012A/ MAL14075067A	Xeljanz Film-Coated Tablets 5mg	Tofacitinib citrate 8.078mg, equivalent to 5mg tofacitinib	PFIZER (MALAYSIA) SDN BHD

Senarai produk yang didaftarkan pada 28.8.2014 (DCA 279)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201306032012A/ MAL14085008A	Bilaxten 20mg Tablets	Bilastine 20mg	A. MENARINI SINGAPORE PTE. LTD.

Senarai produk yang didaftarkan pada 18.9.2014 (DCA 280)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTAR AN PRODUK
1	201309062014A/ MAL14095053A C	Sativex Oromucosal Spray	Cannabidiol 2.5mg;0.1ml + Delta(9)- tetrahydrocannab inol 2.7mg;0.1ml	NOVARTIS CORPORATI ON (MALAYSIA) SDN. BHD.
2	201303112046A/ MAL14095052A	Flixotide Nebules 0.5mg/2ml	Fluticasone propionate 0.5mg/2ml	GLAXOSMIT HKLINE PHARMACEU TICAL SDN. BHD.

Senarai Produk yang didaftarkan pada 24.11.2014 (DCA 281)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201403072012A/ MAL14115019A R	ADEMPAS 0.5 MG FILM-COATED TABLET	Riociguat 0.5mg	BAYER CO. (MALAYSIA) SDN. BHD.
2	201403072017A/ MAL14115022A R	ADEMPAS 1.0 MG FILM-COATED TABLET	Riociguat 1.0mg	BAYER CO. (MALAYSIA) SDN. BHD.
3	201403072013A/ MAL14115020A R	ADEMPAS 1.5 MG FILM-COATED TABLET	Riociguat 1.5mg	BAYER CO. (MALAYSIA) SDN. BHD.
4	201403072022A/ MAL14115023A R	ADEMPAS 2.0 MG FILM-COATED TABLET	Riociguat 2.0mg	BAYER CO. (MALAYSIA) SDN. BHD.
5	201403072015A/ MAL14115021A R	ADEMPAS 2.5 MG FILM-COATED TABLET	Riociguat 2.5mg	BAYER CO. (MALAYSIA) SDN. BHD.
6	201304232013A/ MAL14115015A	MENOPUR MULTIDOSE 600IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	Highly purified menotrophin (human menopausal gonadotrophin, HMG) corresponding to follicle stimulating hormone activity FSH 600 IU and luteinising hormone activity LH 600 IU	FERRING SDN. BHD.
7	201304232014A/ MAL14115016A	MENOPUR MULTIDOSE 1200 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	Highly purified menotrophin (human menopausal gonadotrophin, HMG) corresponding to follicle stimulating hormone activity FSH 1200 IU and luteinising hormone activity LH 1200 IU	FERRING SDN. BHD.
8	201309132012A/ MAL14115017A	Relvar Ellipta 100/25 micrograms Inhalation Powder, pre-dispensed	Fluticasone furoate 100mcg & Vilanterol trifenate 40mcg (equivalent to vilanterol 25mcg)	GLAXOSMIT HKLINE PHARMACEUTICAL SDN. BHD.

9	201309132013A/ MAL14115018A	Relvar Ellipta 200/25 micrograms Inhalation Powder, pre-dispensed	Fluticasone furoate 200mcg & Vilanterol trifenate 40mcg (equivalent to vilanterol 25mcg)	GLAXOSMIT HKLINE PHARMACEUTICAL SDN. BHD.
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Senarai Produk yang didaftarkan pada 4.12.2014 (DCA 282)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201312042016A/ MAL14125081A R	Janumet XR 100mg/1000mg (Sitagliptin phosphate/Metformin HCl extended-release) film-coated tablets	Sitagliptin phosphate 128.5mg equivalent to sitagliptin 100mg; metformin hydrochloride 1000mg	MERCK SHARP & DOHME (MALAYSIA) SDN BHD
2	201312042017A/ MAL14125082A R	Janumet XR 50mg/500mg (Sitagliptin phosphate/Metformin HCl extended-release) film-coated tablets	Sitagliptin phosphate 64.25mg equivalent to sitagliptin 50mg; metformin hydrochloride 500mg	MERCK SHARP & DOHME (MALAYSIA) SDN BHD
3	201312042018A/ MAL14125083A R	Janumet XR 50mg/1000mg (Sitagliptin phosphate/Metformin HCl extended-release) film-coated tablets	Sitagliptin phosphate 64.25mg equivalent to sitagliptin 50mg; metformin hydrochloride 1000mg	MERCK SHARP & DOHME (MALAYSIA) SDN BHD
4	201306180001A/ MAL14125061A R	Abraxane for Injectable Suspension 100 mg	Paclitaxel 100mg/vial	CELGENE SDN. BHD.
5	201311200001A/ MAL14125085A C	Flutiform 50 microgram/5 microgram per actuation pressurized inhalation, suspension	Fluticasone propionate 0.174% w/w and Formoterol fumarate dehydrate) 0.00714% w/w	MUNDIPHAR MA PHARMACEU TICALS SDN. BHD.
6	201311202012A/ MAL14125107A C	Flutiform 125 microgram/5 microgram per actuation pressurized inhalation, suspension	Fluticasone propionate 0.179% w/w and Formoterol fumarate dehydrate 0.00714% w/w	MUNDIPHAR MA PHARMACEU TICALS SDN. BHD.
7	201311202013A/ MAL14125108A C	Flutiform 250 microgram/10 microgram per actuation pressurized inhalation, suspension	Fluticasone propionate 0.357% w/w and Formoterol fumarate dehydrate 0.00143% w/w	MUNDIPHAR MA PHARMACEU TICALS SDN. BHD.

Senarai produk yang didaftarkan pada 23.12.2014 (DCA 283)

NO.	NO. RUJUKAN / NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN PRODUK
1	201312052016A/ MAL14125150A R	OxyContin Controlled-Release Tablets 10mg	Oxycodone hydrochloride 10 mg	MUNDIPHAR MA PHARMACEUTICALS SDN. BHD.
2	201312052015A/ MAL14125148A R	OxyContin Controlled-Release Tablets 20mg	Oxycodone hydrochloride 20 mg	MUNDIPHAR MA PHARMACEUTICALS SDN. BHD.
3	201312052014A/ MAL14125147A R	OxyContin Controlled-Release Tablets 40mg	Oxycodone hydrochloride 40 mg	MUNDIPHAR MA PHARMACEUTICALS SDN. BHD.
4	201312052017A/ MAL14125152A R	OxyContin Controlled-Release Tablets 80mg	Oxycodone hydrochloride 80 mg	MUNDIPHAR MA PHARMACEUTICALS SDN. BHD.
5	201309252014A/ MAL14125151A	Cialis 2.5mg Film-Coated Tablets	Tadalafil 2.5mg	ELI LILLY (MALAYSIA) SDN. BHD.
6	201309252013A/ MAL14125149A	Cialis 5mg Film-Coated Tablets	Tadalafil 5mg	ELI LILLY (MALAYSIA) SDN. BHD.