

**PRODUK UBAT BARU YANG DIDAFTARKAN PADA 2015****Senarai produk yang didaftarkan pada 29 Januari 2015 (284)**

<b>BIL</b>	<b>NO. RUJUKAN/ NO. PENDAFTARAN</b>	<b>NAMA PRODUK</b>	<b>BAHAN AKTIF</b>	<b>PEMEGANG PENDAFTARAN</b>
1.	201310240001A/ MAL15015106AR	Betmiga prolonged- release tablets 25mg	Mirabegron 25mg	DKSH Malaysia Sdn Bhd
2.	201310242012A/ MAL15015107AR	Betmiga prolonged- release tablets 50mg	Mirabegron 50mg	DKSH Malaysia Sdn Bhd

**Senarai produk yang didaftarkan pada 27 Februari 2015 (285)**

<b>BIL</b>	<b>NO. RUJUKAN/ NO. PENDAFTARAN</b>	<b>NAMA PRODUK</b>	<b>BAHAN AKTIF</b>	<b>PEMEGANG PENDAFTARAN</b>
1.	201309192022A/ MAL15025044AC	Esmia 5mg Tablets	Ulipristal acetate 5mg	Hyphens Pharma Sdn. Bhd.
2.	201403072021A/ MAL15025045A	Ultibro Breezhaler 110/50mcg Inhalation Powder Hard Capsule	Indacaterol maleate 143mcg (Corresponds to 110mcg indacaterol and a target delivered dose of 85mcg) and Glycopyrronium bromide 63mcg (Corresponds to 50mcg glycopyrronium and a target delivered dose of 43mcg)	Novartis Corporation (Malaysia) Sdn. Bhd.

**Senarai produk yang didaftarkan pada 3 April 2015 (286)**

<b>BIL</b>	<b>NO. RUJUKAN/ NO. PENDAFTARAN</b>	<b>NAMA PRODUK</b>	<b>BAHAN AKTIF</b>	<b>PEMEGANG PENDAFTARAN</b>
1.	201302252016A/ MAL15045083A	NUCYNTA ER Tablets 50mg	Tapentadol hydrochloride 58.24 mg equivalent to tapentadol free base 50 mg	Johnson & Johnson Sdn Bhd
2.	201302252013A/ MAL15045080A	NUCYNTA ER Tablets 100mg	Tapentadol hydrochloride 116.48 mg equivalent to tapentadol free base 100 mg	Johnson & Johnson Sdn Bhd
3.	201302252012A/ MAL15045079A	NUCYNTA ER Tablets 150mg	Tapentadol hydrochloride 174.72 mg equivalent to tapentadol free base 150 mg	Johnson & Johnson Sdn Bhd
4.	201302252015A/ MAL15045082A	NUCYNTA ER Tablets 200mg	Tapentadol hydrochloride 232.96 mg equivalent to tapentadol free base 200 mg	Johnson & Johnson Sdn Bhd
5.	201302252014A/ MAL15045081A	NUCYNTA ER Tablets 250mg	Tapentadol hydrochloride 291.20 mg equivalent to tapentadol free base 250 mg	Johnson & Johnson Sdn Bhd
6.	201408130001A/ MAL15045075A	AUBAGIO 14mg Film-coated Tablets	Teriflunomide 14mg	Sanofi-Aventis (Malaysia) Sdn. Bhd
7.	201308292013A/ MAL15045078A	Lyxumia 10mcg Solution for Injection	Lixisenatide 0.05mg; 1ml(0.2ml per dose)	Sanofi-Aventis (Malaysia) Sdn. Bhd
8.	201308292012A/ MAL15045077A	Lyxumia 20mcg Solution for	Lixisenatide 0.1mg;1ml (0.2ml	Sanofi-Aventis (Malaysia) Sdn. Bhd

		Injection	per dose)	
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**Senarai produk yang didaftarkan pada 30 April 2015 (287)**

<b>BIL</b>	<b>NO. RUJUKAN/ NO. PENDAFTARAN</b>	<b>NAMA PRODUK</b>	<b>BAHAN AKTIF</b>	<b>PEMEGANG PENDAFTARAN</b>
1.	201306132012A/ MAL15045158A	Zymaxid (gatifloxacin ophthalmic solution) 0.5%	Gatifloxacin 0.5%w/v	Allergan Malaysia Sdn Bhd
2.	201405082016A/ MAL15045159AC R	Ribomustin 25mg/Vial Powder for Concentrate for Solution for Infusion	Bendamustine hydrochloride 25mg	Johnson & Johnson Sdn Bhd
3.	201405082015A/ MAL15045157AC R	Ribomustin 100mg/Vial Powder for Concentrate for Solution for Infusion	Bendamustine hydrochloride 100mg	Johnson & Johnson Sdn Bhd
4.	201405082012A/ MAL15045161A	Brintellix 5mg Film-coated Tablets	Vortioxetine hydrobromide 6.355mg (equivalent to 5mg vortioxetine)	LF Asia (Malaysia) Sdn Bhd
5.	201405080001A/ MAL15045160A	Brintellix 10mg Film-coated Tablets	Vortioxetine hydrobromide 12.710mg(equivalen t to 10mg vortioxetine)	LF Asia (Malaysia) Sdn Bhd
6.	201405082013A/ MAL15045162A	Brintellix 15mg Film-coated Tablets	Vortioxetine hydrobromide 19.065mg (equivalent to 15mg vortioxetine)	LF Asia (Malaysia) Sdn Bhd
7.	201405082014A/ MAL15045163A	Brintellix 20mg Film-coated	Vortioxetine hydrobromide 25.420mg	LF Asia (Malaysia) Sdn Bhd

		Tablets	(equivalent to 20mg vortioxetine)	
8.	201309182019A/ MAL15045173AR	Taflotan Ophthalmic Solution 0.0015%	Tafprost 0.0015mg/ml	LF Asia (Malaysia) Sdn Bhd

**Senarai produk yang didaftarkan pada 29 Jun 2015 (289)**

<b>BIL</b>	<b>NO. RUJUKAN/ NO. PENDAFTARAN</b>	<b>NAMA PRODUK</b>	<b>BAHAN AKTIF</b>	<b>PEMEGANG PENDAFTARAN</b>
1.	201501280001A/ MAL15065023AR	Exviera 250mg Film Coated Tablets	Dasabuvir sodium monohydrate 270.26mg (equivalent to dasabuvir 250mg)	Abbvie Sdn Bhd
2.	201501282012A/ MAL15065022AR	Viekirax 12.5 mg/75 mg/50 mg Film Coated Tablets	Ombitasvir 12.5mg, paritaprevir 75mg and ritonavir 50mg	Abbvie Sdn Bhd
3.	201405202014A/ MAL15065021A	Striverdi Respimat 2.5 mcg Solution for Inhalation	Olodaterol hydrochloride 2.7mcg (equivalent to olodaterol 2.5mcg per actuation)	Boehringer Ingelheim (Malaysia) Sdn. Bhd.
4.	201309192021A/ MAL15065020A	Cetraxal 2mg/ml Ear Drops Solution	1 ml solution contains 2 mg of ciprofloxacin as hydrochloride	Hyphens Pharma Sdn. Bhd.

**Senarai produk yang didaftarkan pada 3 Ogos 2015 (290)**

<b>BIL</b>	<b>NO. RUJUKAN/ NO. PENDAFTARAN</b>	<b>NAMA PRODUK</b>	<b>BAHAN AKTIF</b>	<b>PEMEGANG PENDAFTARAN</b>
1.	201305302015A/ MAL15085021AR	Edarbi 40mg Tablets	Azilsartan medoxomil 40mg	Takeda Malaysia Sdn Bhd
2.	201305302016A/ MAL15085022AR	Edarbi 80mg Tablets	Azilsartan medoxomil 80mg	Takeda Malaysia Sdn Bhd

3.	201306062012A/ MAL15085027AR	Edarbyclor 40mg/12.5mg Film-Coated Tablet	Azilsartan medoxomil 40mg Chlorthalidone 12.5mg	Takeda Malaysia Sdn Bhd
4.	201306062013A/ MAL15085028AR	Edarbyclor 40mg/25mg Film- Coated Tablet	Azilsartan medoxomil 40mg Chlorthalidone 25mg	Takeda Malaysia Sdn Bhd

**Senarai produk yang didaftarkan pada 20 Ogos 2015 (291)**

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201309192020A/ MAL15085079A	Cetraxal Plus Ear Drops Solution	Each ml of solution contains 3 mg of ciprofloxacin (as hydrochloride monohydrate 3.49mg/ml) and 0.25 mg of fluocinolone acetonide (Each bottle contains 10ml of solution	Hyphens Pharma Sdn. Bhd.
2.	201409020001A/ MAL15085076AC R	Tecfidera 120 mg gastro-resistant hard capsules	Dimethyl fumarate 120 mg	UCB Trading (Malaysia) Sdn Bhd
3.	201409022012A/ MAL15085078AC R	Tecfidera 240mg gastro-resistant hard capsules	Dimethyl fumarate 240 mg	UCB Trading (Malaysia) Sdn Bhd
4.	201309092013A/ MAL15085077A	Pliaglis 70 mg/g + 70 mg/g Cream	Lidocaine 70mg/g and tetracaine 70mg/g	Zuellig Pharma Sdn Bhd

**Senarai produk yang didaftarkan pada 28 September 2015 (292)**

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201502092013A/	Sovaldi 400mg	Sofosbuvir 400mg	Gilead Sciences

	MAL15095034AR	Film-Coated Tablets		Malaysia Sdn. Bhd.
2.	201407022014A/ MAL15095033A	Anoro Ellipta 62.5/25 Micrograms Inhalation Powder, Pre- Dispensed	Umeclidinium bromide 74.2mcg (equivalent to 62.5 umeclidinium) & Vilanterol trifenatate 40mcg (equivalent to vilanterol 25mcg)	Glaxosmithkline Pharmaceutical Sdn. Bhd.

**Senarai produk yang didaftarkan pada 22 Disember 2015 (294)**

<b>BIL</b>	<b>NO. RUJUKAN/ NO. PENDAFTARAN</b>	<b>NAMA PRODUK</b>	<b>BAHAN AKTIF</b>	<b>PEMEGANG PENDAFTARAN</b>
1.	201408280001A/ MAL15125055A	Jardiance 10mg Film-Coated Tablets	Empagliflozin 10mg	Boehringer Ingelheim (Malaysia) Sdn. Bhd.
2.	201408282012A/ MAL15125056A	Jardiance 25mg Film-Coated Tablets	Empagliflozin 25mg	Boehringer Ingelheim (Malaysia) Sdn. Bhd.
3.	201309092015A/ MAL15125050AC	Maxigesic 500mg/150mg Film Coated Tablets	Paracetamol 500mg  Ibuprofen 150mg	DKSH Malaysia Sdn Bhd
4.	201403262020A/ MAL15125051A	Afinitor 2mg Dispersible Tablet	Everolimus 2mg	Novartis Corporation (Malaysia) Sdn. Bhd.
5.	201404092015A/ MAL15125052A	Afinitor 3mg Dispersible Tablet	Everolimus 3mg	Novartis Corporation (Malaysia) Sdn. Bhd.
6.	201403262019A/ MAL15125054A	Afinitor 5mg Dispersible Tablet	Everolimus 5mg	Novartis Corporation (Malaysia) Sdn. Bhd.
7.	201506152017A/	Entresto 50mg Film-coated	Sacubitril/valsartan 56.551ng	Novartis Corporation

	MAL15125061AR	Tablets	[Corresponds to 50mg LCZ696 free anhydrous acid (sacubitril 24.3mg and valsartan 25.7mg). The API name for Entresto is LCZ696-ABA in all quality dossier].	(Malaysia) Sdn. Bhd.
8.	201506152016A/ MAL15125063AR	Entresto 200mg Film-coated Tablets	Sacubitril/valsartan 113.103mg [Corresponds to 100mg LCZ696 free anhydrous acid (sacubitril 48.6mg and valsartan 51.4mg). The API name for Entresto is LCZ696-ABA in all quality dossier].	Novartis Corporation (Malaysia) Sdn. Bhd.
9.	201506152015A/ MAL15125062AR	Entresto 100mg Film-coated Tablets	Sacubitril/valsartan 226.206mg [Corresponds to 200mg LCZ696 free anhydrous acid (sacubitril 97.2mg and valsartan 102.8mg). The API name for Entresto is LCZ696-ABA in all quality dossier].	Novartis Corporation (Malaysia) Sdn. Bhd.
10.	201405232014A/ MAL15125049A	NATRIXAM 1.5mg/10mg, modified-release tablets	Indapamide 1.5mg and amlodipine besilate 13.87mg (equivalent to 10mg amlodipine)	Servier Malaysia Sdn Bhd
11.	201405232013A/ MAL15125048A	NATRIXAM 1.5mg/5mg, modified release tablets	Indapamide 1.5mg and amlodipine besilate 6.935mg (equivalent to 5mg amlodipine)	Servier Malaysia Sdn Bhd
12.	201410212013A/ MAL15125060A	Triplixam 10 mg/ 2.5 mg/ 10 mg,	Perindopril arginine 10mg (equivalent to 6.790mg)	Servier Malaysia Sdn Bhd

		film-coated tablets	perindopril), indapamide 2.5mg and amlodipine besilate 13.870mg (equivalent to 10mg amlodipine)	
13.	201410210001A/ MAL15125059A	Triplixam 10 mg/ 2.5 mg/ 5 mg, film-coated tablets	Perindopril arginine 10mg (equivalent to 6.790mg perindopril), indapamide 2.5mg and amlodipine besilate 6.935mg (equivalent to 5mg amlodipine)	Servier Malaysia Sdn Bhd
14.	201410212012A/ MAL15125053A	Triplixam 2.5 mg/ 0.625 mg/ 5 mg, film-coated tablets	Perindopril arginine 2.5mg (equivalent to 1.6975mg perindopril), indapamide 0.625mg and amlodipine besilate 6.935mg (equivalent to 5mg amlodipine)	Servier Malaysia Sdn Bhd
15.	201410212014A/ MAL15125058A	Triplixam 5mg/ 1.25 mg/ 10 mg, film-coated tablets	Perindopril arginine 5mg (equivalent to 3.395mg perindopril) indapamide 1.25mg and amlodipine besilate 13.870mg (equivalent to 10mg amlodipine)	Servier Malaysia Sdn Bhd
16.	201410212015A/ MAL15125057A	Triplixam 5mg/1.25 mg/ 5 mg, film-coated tablets	Perindopril arginine 5mg (equivalent to 3.395mg perindopril) indapamide 1.25mg and amlodipine besilate 6.935mg (equivalent to 5mg amlodipine)	Servier Malaysia Sdn Bhd