

PRODUK UBAT BARU YANG DIDAFTARKAN PADA 2019

Senarai produk yang didaftarkan pada 3 Januari 2019 (DCA 330)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201708240707A/ MAL19016047AZ	Ajalorin 2.5mg Orodispersible Tablet	Desloratadine 2.5mg	AJ RESEARCH & PHARMA SDN. BHD.
2.	201708250706A/ MAL19016044AZ	Ajalorin 5mg Orodispersible Tablet	Desloratadine 5mg	AJ RESEARCH & PHARMA SDN. BHD.
3.	201710250953A/ MAL19016045AZ	Viacoram 3.5mg/2.5mg tablets	Perindopril arginine 3.5mg (corresponding in perindopril base 2.378mg) and amlodipine besilate 3.4675mg (corresponding in amlodipine base 2.5mg).	SERVIER MALAYSIA SDN BHD.
4.	201710250954A/ MAL19016046AZ	Viacoram 7mg/5mg tablets	Perindopril arginine 7mg (corresponding in perindopril base 4.756mg) and amlodipine besilate 6.935mg (corresponding in amlodipine base 5mg).	SERVIER MALAYSIA SDN BHD.
5.	201709050738A/ MAL19016040AZ	Cosyrel 5mg/5mg film coated tablets	Bisoprolol fumarate 5mg/Perindopril arginine 5mg	SERVIER MALAYSIA SDN BHD.
6.	201709050735A/ MAL19016043AZ	Cosyrel 5mg/10mg film coated tablets	Bisoprolol fumarate 5mg/Perindopril arginine 10mg	SERVIER MALAYSIA SDN BHD.
7.	201709050736A/ MAL19016042AZ	Cosyrel 10mg/5mg film coated tablets	Bisoprolol fumarate 10mg/Perindopril arginine 5mg	SERVIER MALAYSIA SDN BHD.
8.	201709050737A/ MAL19016041AZ	Cosyrel 10mg/10mg film coated tablets	Bisoprolol fumarate 10mg/Perindopril arginine 10mg	SERVIER MALAYSIA SDN BHD.

Senarai produk yang didaftarkan pada 30 Januari 2019 (DCA 331)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201711241103A/ MAL19016095AR Z	QTERN 5 MG/10 MG FILM- COATED TABLETS	SAXAGLIPTIN 5MG + DAPAGLIFLOZIN 10MG	ASTRAZENECA SDN. BHD.

Senarai produk yang didaftarkan pada 4 April 2019 (DCA333)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201712191240A/ MAL19046008AZ	Akynzeo (netupitant/ palonosetron) 300mg/0.5mg Hard Capsules	Netupitant 300mg / Palonosetron 0.5mg	MUNDIPHARMA PHARMACEUTICALS SDN. BHD.
2.	201801081293A/ MAL19046009AC RZ	RYDAPT 25MG SOFT CAPSULES	MIDOSTAURIN 25MG	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.

Senarai produk yang didaftarkan pada 2 Mei 2019 (DCA 334)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201711171072A/ MAL19056002AR Z	Vocinti 10mg film- coated tablet	Vonoprazan fumarate 13.36mg equivalent to vonoprazan free base 10mg	TAKEDA MALAYSIA SDN BHD
2.	201711171071A/ MAL19056003AR Z	Vocinti 20mg film- coated tablet	Vonoprazan fumarate 26.72mg equivalent to vonoprazan free base 20mg	TAKEDA MALAYSIA SDN BHD

Senarai produk yang didaftarkan pada 30 Mei 2019 (DCA 335)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201804130334A/ MAL19056104AZ	BEVESPI AEROSPHERE 7.2 / 5.0 micrograms pressurised inhalation, suspension	Glycopyrronium bromide 9.0 micrograms, equivalent to 7.2 micrograms of Glycopyrronium, Formoterol Fumarate Dihydrate 5.0 micrograms equivalent to 4.8 micrograms of Formoterol Fumarate	ASTRAZENECA SDN. BHD.
2.	201802050053A/ MAL19056102AC RZ	Iclusig Film- Coated Tablet 15 mg	Ponatinib Hydrochloride 15 mg	SMART MEDICINE SDN BHD.
3.	201802050052A/ MAL19056103AC RZ	Iclusig Film- Coated Tablet 45 mg	Ponatinib Hydrochloride 45 mg	SMART MEDICINE SDN BHD.

Senarai produk yang didaftarkan pada 5 September 2019 (DCA 338)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201812121567A/ MAL19096014AR Z	Prevymis 240mg Film-coated Tablet	Letemovir 240mg	MERCK SHARP &DOHME (MALAYSIA) SDN. BHD.
2.	201812121569A/ MAL19096013AR Z	Prevymis 480mg Film-coated Tablet	Letemovir 480mg	MERCK SHARP &DOHME (MALAYSIA) SDN. BHD.
3.	201812121568A/ MAL19096021AR Z	Prevymis 240mg/12mL (20mg/mL) concentrate for solution for infusion	Letemovir 240mg/12mL	MERCK SHARP &DOHME (MALAYSIA) SDN. BHD.
4.	201812121570A/ MAL19096012AR	Prevymis 480mg/24mL	Letemovir	MERCK SHARP &DOHME

	Z	(20mg/mL) concentrate for solution for infusion	480mg/24mL	(MALAYSIA) SDN. BHD.
5.	201806110563A/ MAL19096029AZ	Kestine 10mg film-coated tablets	Ebastine 10mg	ZUELLIG PHARMA SDN BHD
6.	201806110564A/ MAL19096026AZ	Kestine 20mg film-coated tablets	Ebastine 20mg	ZUELLIG PHARMA SDN BHD

Senarai produk yang didaftarkan pada 3 Oktober 2019 (DCA 339)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201809281113A/ MAL19106011AC RZ	Lynparza 100 mg Film-Coated Tablets	Olaparib 100 mg	ASTRAZENECA SDN. BHD.
2.	201809281112A/ MAL19106013AC RZ	Lynparza 150 mg Film-Coated Tablets	Olaparib 150 mg	ASTRAZENECA SDN. BHD.
3.	201903071888A/ MAL19106006AC RZ	Steglatro 5mg Film-Coated Tablets	Ertugliflozin 5mg (as ertugliflozin L- pyroglutamic acid)	MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.
4.	201903071889A/ MAL19106005AC RZ	Steglatro 15mg Film-Coated Tablets	Ertugliflozin 15mg (as ertugliflozin L- pyroglutamic acid)	MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.
5.	201903071890A/ MAL19106004AZ	Steglujan (Ertugliflozin 5mg/Sitagliptin 100mg) Film- Coated Tablets	Ertugliflozin 5mg/ Sitagliptin 100mg	MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.
6.	201903071891A/ MAL19106003AZ	Steglujan (Ertugliflozin 15mg/Sitagliptin 100mg) Film- Coated Tablets	Ertugliflozin 15mg/ Sitagliptin 100mg	MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.
7.	201805030401A/ MAL19106017AR Z	Ilevro (Nepafenac Ophthalmic Suspension 0.3%)	Nepafenac 0.3% w/v	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.

8.	201808070831A/ MAL19106015AR Z	Tasigna 50mg Capsules	Nilotinib hydrochloride monohydrate 55.15mg equivalent to 50mg nilotinib anhydrous	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
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Senarai produk yang didaftarkan pada 13 November 2019 (DCA 340)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201808060826A/ MAL19116038AC RZ	Parsabiv 2.5mg solution for injection	Etelcalcetide hydrochloride 3.1mg (equivalent to 2.5mg free base) in 0.5 mL	ZUELLIG PHARMA SDN. BHD.
2.	201808060825A/ MAL19116039AC RZ	Parsabiv 5mg solution for injection	Etelcalcetide hydrochloride 6.2mg (equivalent to 5mg free base) in 1 mL	ZUELLIG PHARMA SDN. BHD.
3.	201808060824A/ MAL19116040AC RZ	Parsabiv 10mg solution for injection	Etelcalcetide hydrochloride 12.3mg (equivalent to 10mg free base) in 2 mL	ZUELLIG PHARMA SDN. BHD.

Senarai produk yang didaftarkan pada 5 Disember 2019 (DCA 341)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201809060997A/ MAL19126002AR Z	Maviret (Glecaprevir 100mg/ Pibrentasvir 40mg) Film	Glecaprevir 100mg/Pibrentasvir 40mg	ABBVIE SDN. BHD.
2.	201812031484A/ MAL19126006AZ	VASTAREL XR 80mg, prolonged- release hard capsule	Trimetazidine Dihydrochloride 80mg	SERVIER MALAYSIA SDN BHD
3.	201808130868A/	Ninlaro Hard	Ixazomib 2.3mg	TAKEDA MALAYSIA SDN. BHD.

	MAL19126003AC RZ	Capsule 2.3mg	(equivalent to 3.3 mg of ixazomib citrate)	
4.	201808130867A/ MAL19126004ACR Z	Ninlaro Hard Capsule 3mg	Ixazomib 3mg (equivalent to 4.3 mg of ixazomib citrate)	TAKEDA MALAYSIA SDN. BHD.
5.	201808130866A/ MAL19126005ACR Z	Ninlaro Hard Capsule 4mg	Ixazomib 4mg (equivalent to 5.7 mg of ixazomib citrate)	TAKEDA MALAYSIA SDN. BHD.