

PRODUK UBAT BARU YANG DIDAFTARKAN PADA 2020

Senarai produk yang didaftarkan pada 9 Januari 2020 (DCA 342)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201903071892A/ MAL20016181AR Z	Segluromet (Ertugliflozin/ Metformin) 2.5/500 mg Film- Coated Tablets	Ertugliflozin(as ertugliflozin L- pyroglutamic acid) 2.5mg and metforminhydrochlorid e 500 mg	MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.
2.	201903071893A/ MAL20016180AR Z	Segluromet (Ertugliflozin/ Metformin) 2.5/1000 mg Film-Coated Tablets	Ertugliflozin(as ertugliflozin L- pyroglutamic acid) 2.5mg and metformin hydrochloride 1000 mg	MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.
3.	201903071894A/ MAL20016179AR Z	Segluromet (Ertugliflozin/ Metformin) 7.5/500 mg Film- Coated Tablets	Ertugliflozin(as ertugliflozin L- pyroglutamic acid) 7.5mg and metformin hydrochloride 500 mg	MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.
4.	201903071895A/ MAL20016178AR Z	Segluromet (Ertugliflozin/ Metformin) 7.5/1000 mg Film-Coated Tablets	Ertugliflozin(as ertugliflozin L- pyroglutamic acid) 7.5mg and metformin hydrochloride 1000 mg	MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.

Senarai produk yang didaftarkan pada 13 Februari 2020 (DCA 343)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201901081674A/ MAL20026050AZ	Symbicort Rapihaler 80/4.5 micrograms/actua tion, pressurised inhalation, suspension	Budesonide 80 mcg and formoterol fumarate dihydrate 4.5 mcg	ASTRAZENECA SDN. BHD.
2.	201901081675A/ MAL20026051AZ	Symbicort Rapihaler 160/4.5 micrograms/actua tion, pressurised inhalation, suspension	Budesonide 160 mcg and formoterol fumarate dihydrate 4.5 mcg	ASTRAZENECA SDN. BHD.
3.	201812031490A/ MAL20026049AZ	Enstilar® 50 micrograms/g + 0.5 mg/g Cutaneous Foam	Calcipotriol (as monohydrate) 50mcg & betamethasone dipropionate 0.5mg	DKSH MALAYSIA SDN. BHD.
4.	201901101695A/ MAL20026041ARZ	Erleada 60 mg Film-Coated Tablets	Apalutamide 60 mg	JOHNSON & JOHNSON SDN. BHD.
5.	201807130705A/ MAL20026042ARZ	Rexulti 0.25mg film-coated tablets	Brexpiprazole 0.25mg	LUNDBECK MALAYSIA SDN. BHD.
6.	201807130706A/ MAL20026043ARZ	Rexulti 0.5mg film-coated tablets	Brexpiprazole 0.5mg	LUNDBECK MALAYSIA SDN. BHD.
7.	201807130707A/ MAL20026044ARZ	Rexulti 1mg film- coated tablets	Brexpiprazole 1mg	LUNDBECK MALAYSIA SDN. BHD.
8.	201807130708A/ MAL20026045ARZ	Rexulti 2mg film- coated tablets	Brexpiprazole 2mg	LUNDBECK MALAYSIA SDN. BHD.
9.	201807130709A/ MAL20026046ARZ	Rexulti 3mg film- coated tablets	Brexpiprazole 3mg	LUNDBECK MALAYSIA SDN. BHD.
10.	201807130710A/ MAL20026047ARZ	Rexulti 4mg film- coated tablets	Brexpiprazole 4mg	LUNDBECK MALAYSIA SDN. BHD.

11.	201801180011A/ MAL20026052AZ	LAMIHOPE-T (Lamivudine 300 mg and Tenofovir Disoproxil Fumarate 300 mg Film-coated Tablets)	Lamivudine 300 mg and Tenofovir Disoproxil Fumarate 300 mg (equivalent to tenofovir disoproxil 245mg)	SYNERRV SDN BHD
12.	201810101165A/ MAL20026039AZ	Lonsurf Film-coated Tablet 15 mg/6.14 mg	15.00mg Trifluridine and 7.065 mg of Tipiracil Hydrochloride is equivalent to 6.14 mg of Tipiracil	ZUELLIG PHARMA SDN BHD
13.	201810101166A/ MAL20026040AZ	Lonsurf Film-coated Tablet 20 mg/8.19 mg	20.00mg Trifluridine and 9.420 mg of Tipiracil Hydrochloride is equivalent to 8.19 mg of Tipiracil	ZUELLIG PHARMA SDN BHD
14.	201809141046A/ MAL20026048AZ	Airtal 100mg Film-Coated Tablet	Aceclofenac 100mg	ZUELLIG PHARMA SDN BHD

Senarai produk yang didaftarkan pada 30 April 2020 (DCA344)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201901071656A/ MAL20046076AZ	Xarelto 2.5mg Film-Coated Tablets	Rivaroxaban micronized 2.5 mg	BAYER CO. (MALAYSIA) SDN. BHD.
2.	201809030963A/ MAL20046082AZ	Livalo Film-coated Tablets 2mg	Pitavastatin Calcium (as Hydrate) 2.2mg equivalent to Pitavastatin Calcium 2mg	DKSH MALAYSIA SDN. BHD.
3.	201809030964A/ MAL20046083AZ	Livalo Film-coated Tablets 4mg	Pitavastatin Calcium (as Hydrate) 4.4mg equivalent to Pitavastatin Calcium 4mg	DKSH MALAYSIA SDN. BHD.

4.	201909132677A/ MAL20046071AZ	Lenangio 5 (Lenalidomide Hard Capsules 5mg)	Lenalidomide (Povidone) 10mg (equivalent to lenalidomide 5mg)	DR. REDDY'S LABORATORIE S MALAYSIA SDN. BHD.
5.	201909132678A/ MAL20046072AZ	Lenangio 10 (Lenalidomide Hard Capsules 10mg)	Lenalidomide (Povidone) 20mg (equivalent to lenalidomide 10mg)	DR. REDDY'S LABORATORIE S MALAYSIA SDN. BHD.
6.	201909132679A/ MAL20046073AZ	Lenangio 15 (Lenalidomide Hard Capsules 15mg)	Lenalidomide (Povidone) 30mg (equivalent to lenalidomide 15mg)	DR. REDDY'S LABORATORIE S MALAYSIA SDN. BHD.
7.	201909132680A/ MAL20046074AZ	Lenangio 25 (Lenalidomide Hard Capsules 25mg)	Lenalidomide (Povidone) 50mg (equivalent to lenalidomide 25mg)	DR. REDDY'S LABORATORIE S MALAYSIA SDN. BHD.
8.	201902271851A/ MAL20046079AR Z	Verzenio 50mg film-coated tablets	Abemaciclib 50mg	ELI LILLY (MALAYSIA) SDN. BHD.
9.	201902271852A/ MAL20046080AR Z	Verzenio 100mg film-coated tablets	Abemaciclib 100mg	ELI LILLY (MALAYSIA) SDN. BHD.
10.	201902271854A/ MAL20046081AR Z	Verzenio 150mg film-coated tablets	Abemaciclib 150mg	ELI LILLY (MALAYSIA) SDN. BHD.
11.	201809040974A/ MAL20046064AZ	Baclofen Intrathecal Sintetica 0.05mg/ml Solution Injectable	Baclofen 0.05mg/ml	IMEKS PHARMA SDN. BHD.
12.	201901101699A/ MAL20046065AZ	Baclofen Intrathecal Sintetica 0.5mg/ml Solution Injectable	Baclofen 0.5mg/ml	IMEKS PHARMA SDN. BHD.

13.	201901101698A/ MAL20046066AZ	Baclofen Intrathecal Sintetica 2mg/ml Solution Injectable	Baclofen 2mg/ml	IMEKS PHARMA SDN. BHD.
14.	201811301481A/ MAL20046067AZ	INVEGA TRINZA 175mg/0.875mL Prolonged- Release Suspension for Intramuscular Injection	Paliperidone 175mg/0.875mL (as paliperidone palmitate 273mg/0.875mL)	JOHNSON & JOHNSON SDN BHD
15.	202001063227A/ MAL20046068AZ	INVEGA TRINZA 263mg/1.315mL Prolonged- Release Suspension for Intramuscular Injection	Paliperidone 263mg/1.315mL (as paliperidone palmitate 410mg/1.315mL)	JOHNSON & JOHNSON SDN BHD
16.	202001063228A/ MAL20046069AZ	INVEGA TRINZA 350mg/1.750mL Prolonged- Release Suspension for Intramuscular Injection	Paliperidone 350mg/1.750mL (as paliperidone palmitate 546mg/1.750mL)	JOHNSON & JOHNSON SDN BHD
17.	202001063229A/ MAL20046070AZ	INVEGA TRINZA 525mg/2.625mL Prolonged- Release Suspension for Intramuscular Injection	Paliperidone 525mg/2.625mL (as paliperidone palmitate 819mg/2.625mL)	JOHNSON & JOHNSON SDN BHD
18.	201810161186A/ MAL20046075AR Z	Gilenya 0.25mg Hard Capsules	Fingolimod hydrochloride 0.25mg	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
19.	201907222406A/ MAL20046077AC RZ	Xofluza Film- Coated Tablet 20mg	Baloxavir marboxil 20mg	ROCHE (MALAYSIA) SDN. BHD.

20.	201907222407A/ MAL20046078AC RZ	Xofluza Film- Coated Tablet 40mg	Baloxavir marboxil 40mg	ROCHE (MALAYSIA) SDN. BHD.
21.	201808210906A/ MAL20046063AR Z	LOXOTOP PAP 100mg Patch	Loxoprofen sodium hydrate 113.4 mg (equivalent to 100 mg of loxoprofen sodium anhydrous)	ZUELLIG PHARMA SDN BHD

Senarai produk yang didaftarkan pada 12 Jun 2020 (DCA 345)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201812051506A/ MAL20066001AZ	Vokanamet (Canagliflozin 150mg/ Metformin 500mg) Film- Coated Tablet	150 mg of canagliflozin and 500 mg of metformin hydrochloride	JOHNSON & JOHNSON SDN BHD
2.	201812051507A/ MAL20066002AZ	Vokanamet (Canagliflozin 150mg/ Metformin 850mg) Film- Coated Tablet	150 mg of canagliflozin and 850 mg of metformin hydrochloride	JOHNSON & JOHNSON SDN BHD
3.	201812051508A/ MAL20066003AZ	Vokanamet (Canagliflozin 150mg/ Metformin 1000mg) Film- Coated Tablet	150 mg of canagliflozin and 1000 mg of metformin hydrochloride	JOHNSON & JOHNSON SDN BHD
4.	201903211940A/ MAL20066004AZ	ZIRIN Softgel Capsules 10mg	Cetirizine dihydrochloride 10mg	MEGA LIFESCIENCES SDN. BHD.

Senarai produk yang didaftarkan pada 9 Julai 2020 (DCA 346)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201909052648A/ MAL20076006AR Z	Trezilent 50mg Film-Coated Tablets	Alpelisib 50mg	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD
2.	201909052649A/ MAL20076007AR Z	Trezilent 150mg Film-Coated Tablets	Alpelisib 150mg	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD
3.	201909052650A/ MAL20076008AR Z	Trezilent 200mg Film-Coated Tablets	Alpelisib 200mg	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD
4.	201901241749A/ MAL20076070AC Z	Sirturo 100mg Tablets	Bedaquiline Fumarate 120.89 mg (equivalent to 100 mg bedaquiline free base)	JOHNSON & JOHNSON SDN. BHD.
5.	201903011868A/ MAL20076009AC RZ	NERLYNX (Neratinib) Film- Coated Tablets 40 mg	Neratinib maleate 48.31 mg (equivalent to 40 mg of neratinib free base)	PHARMA TO MARKET SDN. BHD.
6.	201912203186A/ MAL20076010AZ	Vizimpro 15 mg Film-Coated Tablets	Dacomitinib Monohydrate 15mg	PFIZER (MALAYSIA) SDN. BHD.
7.	201912203187A/ MAL20076011AZ	Vizimpro 30 mg Film-Coated Tablets	Dacomitinib Monohydrate 30mg	PFIZER (MALAYSIA) SDN. BHD.
8.	201912203188A/ MAL20076012AZ	Vizimpro 45 mg Film-Coated Tablets	Dacomitinib Monohydrate 45mg	PFIZER (MALAYSIA) SDN. BHD.
9.	201906202286A/ MAL20076013AC Z	Glanatec ophthalmic solution 0.4%	Ripasudil 0.4%w/v	DKSH MALAYSIA SDN BHD

10.	201812131574A/ MAL20076014AR Z	ERDOMED® 300mg Hard Capsules	Erdosteine 300mg	HYPHENS PHARMA SDN. BHD.
11.	201812131575A/ MAL20076015AR Z	ERDOMED® 300mg Dispersible Tablets	Erdosteine 300mg	HYPHENS PHARMA SDN. BHD.
12.	201808170897A/ MAL20076016AC RZ	Amitiza 8mcg Soft Capsule	Lubiprostone 8mcg	TAKEDA MALAYSIA SDN. BHD.
13.	201808170896A/ MAL20076017AC RZ	Amitiza 24mcg Soft Capsule	Lubiprostone 24mcg	TAKEDA MALAYSIA SDN. BHD.

Senarai produk yang didaftarkan pada 6 Ogos 2020 (DCA 347)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201909052647A/ MAL20086001AZ	Symvenu 1.5mg Hard Capsules	Cariprazine hydrochloride 1.645mg (equivalent to 1.5mg free base)	ZUELLIG PHARMA SDN. BHD.
2.	201909052646A/ MAL20086002AZ	Symvenu 3mg Hard Capsules	Cariprazine hydrochloride 3.270mg (equivalent to 3mg free base)	ZUELLIG PHARMA SDN. BHD.
3.	201909052645A/ MAL20086003AZ	Symvenu 4.5mg Hard Capsules	Cariprazine hydrochloride 4.905mg (equivalent to 4.5mg free base)	ZUELLIG PHARMA SDN. BHD.
4.	201908092491A/ MAL20086004AZ	Symvenu 6mg Hard Capsules	Cariprazine hydrochloride 6.540mg (equivalent to 6mg free base)	Zuellig Pharma Sdn. Bhd.

Senarai produk yang didaftarkan pada 3 September 2020 (DCA 348)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201902181819A MAL20096002AZ	ALPHAGAN P Ophthalmic Solution 0.1%	Brimonidine tartrate 0.1%	ALLERGAN MALAYSIA SDN. BHD.
2.	201908212547A MAL20096001AR Z	Mavenclad® 10mg Tablets	Cladribine 10mg	MERCK SDN BHD

Senarai produk yang didaftarkan pada 1 Oktober 2020 (DCA 349)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	202003273591A / MAL20106001AR Z	RINVOQ® 15mg Extended Release Film Coated Tablets	Upadacitinib Hemihydrate 15.4mg (corresponds to 15 mg of upadacitinib on an anhydrous basis)	ABBVIE SDN BHD

Senarai produk yang didaftarkan pada 2 November 2020 (DCA 350)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201908212550A / MAL20116001AZ	Locoa 40mg Transdermal Patch	Esflurbiprofen 40mg	HOE PHARMACEUTI CALS SDN. BHD.
2.	201910112816A / MAL20116002AC RZ	Nocdurna® Oral Lyophilisate for Sublingual 25 mcg	Desmopressin 25 mcg	FERRING SDN. BHD.
3.	201910112817A / MAL20116003AC RZ	Nocdurna® Oral Lyophilisate for Sublingual 50 mcg	Desmopressin 50 mcg	FERRING SDN. BHD.

Senarai produk yang didaftarkan pada 3 Disember 2020 (DCA 351)

BIL	NO. RUJUKAN/ NO. PENDAFTARAN	NAMA PRODUK	BAHAN AKTIF	PEMEGANG PENDAFTARAN
1.	201811281461A/ MAL20126002AZ	Skudexa (Tramadol hydrochloride 75mg / Dexketoprofen 25mg) Film- Coated Tablets	Tramadol hydrochloride 75mg + Dexketoprofen 25mg	A. MENARINI SINGAPORE PTE. LTD
2.	201908212544A/ MAL20126003AZ	Lorviqua 25 mg Film-Coated Tablets	Lorlatinib 25 mg	PFIZER (MALAYSIA) SDN. BHD.
3.	201908212545A/ MAL20126004AZ	Lorviqua 100 mg Film-Coated Tablets	Lorlatinib 100 mg	PFIZER (MALAYSIA) SDN. BHD.
4.	201812181602A/ MAL20126001ACZ	Zavicefta (Ceftazidime 2g/Avibactam 0.5g) Powder for Concentrate for Solution for Infusion.	Ceftazidime Pentahydrate 2g / Avibactam Sodium 0.5g	PFIZER (MALAYSIA) SDN. BHD.