

Register of Data Exclusivity Granted in Malaysia

As described and stipulated in “Direktif Penguatkuasaan Keperluan Melaksanakan Data Eksklusiviti di Malaysia” Bil. (11) BPFK/PPP/01/03 Jilid 1, dated 28 February 2011 and effective from 01 March 2011, Data Exclusivity has been granted by the Drug Control Authority, Ministry of Health Malaysia, for the New Drug Products containing New Chemical Entities as listed below.

The period of Data Exclusivity is calculated from the date the product is first registered or granted marketing authorisation AND granted Data Exclusivity in the country of origin or in any country recognised and deemed appropriate by the Director of Pharmaceutical Services.

No.	Registration (MAL) No.	Product Name	Active Ingredient	Manufacturer	DCA Reference Country for DE			DE Granted by DCA		
					Country	Registration Date	Exclusivity Expiration	Registration Date	Protection Period	Exclusivity Expiration
1	MAL12015017A	Gilenya 0.5mg Hard Capsule	Fingolimod Hydrochloride	Novartis Pharma Stein AG, Switzerland	USA	21-Sep-10	21-Sep-15	19-Jan-12	5 years	21-Sep-15
2	MAL12035083AR	Victrelis 200mg Hard Capsules	Boceprevir	Schering-Plough (Singapore) Pte. Ltd., Singapore	USA	13-May-11	13-May-16	29-Mar-12	5 years	13-May-16
3	MAL12095101A	Halaven 0.44mg/ml Solution for Injection	Eribulin mesylate	Nerviano Medical Sciences S.r.l., Italy	USA	15-Nov-10	15-Nov-15	27-Sept-12	5 years	15-Nov-15
4	MAL12095102A	Xalkori 200mg Hard Capsules	Crizotinib	Pfizer Manufacturing Deutschland GmbH Germany	USA	26-Aug-11	26-Aug-16	27-Sept-12	5 years	26-Aug-16
5	MAL12095103A	Xalkori 250mg Hard Capsules	Crizotinib	Pfizer Manufacturing Deutschland GmbH Germany	USA	26-Aug-11	26-Aug-16	27-Sept-12	5 years	26-Aug-16
6	MAL12115076AC	Zinforo 600mg powder for concentrate for solution for infusion	Ceftaroline fosamil	ACS Dobfar S.p.A., Italy	USA	29-Oct-10	29-Oct-15	29-Nov-12	5 years	29-Oct-15

7	MAL13025059A	Jakavi 5mg Tablet	Ruxolitinib phosphate 6.60mg (corresponds to 5mg ruxolitinib free base)	Novartis Pharma Stein AG, Switzerland	USA	16-Nov-11	16-Nov-16	28-Feb-13	5 years	16-Nov-16
8	MAL13025060A	Jakavi 15mg Tablet	Ruxolitinib phosphate 19.80mg (corresponds to 15mg ruxolitinib free base)	Novartis Pharma Stein AG, Switzerland	USA	16-Nov-11	16-Nov-16	28-Feb-13	5 years	16-Nov-16
9	MAL13025061A	Jakavi 20mg Tablet	Ruxolitinib phosphate 26.40mg (corresponds to 20mg ruxolitinib free base)	Novartis Pharma Stein AG, Switzerland	USA	16-Nov-11	16-Nov-16	28-Feb-13	5 years	16-Nov-16
10	MAL13065048A	Stivarga 40mg Film-coated Tablets	Regorafenib monohydrate 41.49mg (equivalent to 40mg regorafenib)	Bayer Pharma AG, Germany	USA	27-Sept-12	27-Sept-17	27-June-13	5 years	27-Sept-17
11	MAL13115126A	Inlyta Film-coated Tablets 1mg	Axitinib 1mg	Pfizer Manufacturing Deutschland GmbH, Germany	USA	27-Jan-12	27-Jan-17	6-Nov-13	5 years	27-Jan-17
12	MAL13115127A	Inlyta Film-coated Tablets 5mg	Axitinib 5mg	Pfizer Manufacturing Deutschland GmbH, Germany	USA	27-Jan-12	27-Jan-17	6-Nov-13	5 years	27-Jan-17
13	MAL14015013A	Forxiga 5mg Film- Coated Tablet	Dapagliflozin Propanediol 6.150mg (equivalent to dapagliflozin 5mg)	Bristol-Myers Squibb Company, US	EU	12-Nov-2012	12-Nov-2017	23-Jan-2014	5 years	12-Nov-2017
14	MAL14015014A	Forxiga 10mg Film- Coated Tablet	Dapagliflozin Propanediol 12.30mg (equivalent to dapagliflozin 10mg)	Bristol-Myers Squibb Company, US	EU	12-Nov-2012	12-Nov-2017	23-Jan-2014	5 years	12-Nov-2017

15	MAL14035002A	Fycompa 2mg film-coated tablets	Perampanel 2.1mg (Anhydrous basis 2mg)	Eisai Manufacturing Limited, UK	EU	23-July-2012	23-July-2017	27-March-2014	5 years	23-July-2017
16	MAL14035005A	Fycompa 4mg film-coated tablets	Perampanel 4.2mg (Anhydrous basis 4mg)	Eisai Manufacturing Limited, UK	EU	23-July-2012	23-July-2017	27-March-2014	5 years	23-July-2017
17	MAL14035003A	Fycompa 6mg film-coated tablets	Perampanel 6.2mg (Anhydrous basis 6mg)	Eisai Manufacturing Limited, UK	EU	23-July-2012	23-July-2017	27-March-2014	5 years	23-July-2017
18	MAL14035001A	Fycompa 8mg film-coated tablets	Perampanel 8.3mg (Anhydrous basis 8mg)	Eisai Manufacturing Limited, UK	EU	23-July-2012	23-July-2017	27-March-2014	5 years	23-July-2017
19	MAL14035004A	Fycompa 10mg film-coated tablets	Perampanel 10.4mg (Anhydrous basis 10mg)	Eisai Manufacturing Limited, UK	EU	23-July-2012	23-July-2017	27-March-2014	5 years	23-July-2017
20	MAL14035006A	Fycompa 12mg film-coated tablets	Perampanel 12.5mg (Anhydrous basis 12mg)	Eisai Manufacturing Limited, UK	EU	23-July-2012	23-July-2017	27-March-2014	5 years	23-July-2017
21	MAL14055146AC	Xofigo (Radium-223 Dichloride) 1000 kBq/mL Solution for Injection	Radium-223 Dichloride 6000kBq/6mL	Institute for Energy Technology, Kjeller, Norway.	USA	15-May-2013	15-May-2018	9-May-2014	5 years	15-May-2018
22	MAL14075067A	Xeljanz Film-Coated Tablets 5mg	Tofacitinib citrate 8.078mg, equivalent to 5mg tofacitinib	Pfizer Manufacturing Deutschland GmbH, Germany	USA	6-November-2012	6-November-2017	24-July -2014	5 years	6-November-2017
23	MAL14115019AR	Adempas 0.5 mg Film Coated Tablet	Riociguat 0.5mg	Bayer Pharma AG, Germany	USA	8-October-2013	8-October-2018	24-November - 2014	5 years	8-October-2018
24	MAL14115022AR	Adempas 1.0mg Film Coated Tablet	Riociguat 1.0mg	Bayer Pharma AG, Germany	USA	8-October-2013	8-October-2018	24-November - 2014	5 years	8-October-2018

25	MAL14115020AR	Adempas 1.5 mg Film Coated Tablet	Riociguat 1.5mg	Bayer Pharma AG, Germany	USA	8-October-2013	8-October-2018	24-November - 2014	5 years	8-October-2018
26	MAL14115023AR	Adempas 2.0 mg Film Coated Tablet	Riociguat 2.0mg	Bayer Pharma AG, Germany	USA	8-October-2013	8-October-2018	24-November - 2014	5 years	8-October-2018
27	MAL14115021AR	Adempas 2.5 mg Film Coated Tablet	Riociguat 2.5mg	Bayer Pharma AG, Germany	USA	8-October-2013	8-October-2018	24-November - 2014	5 years	8-October-2018
28	MAL15045161A	Brintellix 5mg Film- coated Tablets	Vortioxetine hydrobromide 6.355mg (equivalent to 5mg vortioxetine)	H.Lundbeck A/S, Denmark	USA	30-September- 2013	30-September- 2018	30-April-2015	5 years	30-September- 2018
29	MAL15045160A	Brintellix 10mg Film-coated Tablets	Vortioxetine hydrobromide 12.710mg (equivalent to 10mg vortioxetine)	H.Lundbeck A/S, Denmark	USA	30-September- 2013	30-September- 2018	30-April-2015	5 years	30-September- 2018
30	MAL15045162A	Brintellix 15mg Film-coated Tablets	Vortioxetine hydrobromide 19.065mg (equivalent to 15mg vortioxetine)	H.Lundbeck A/S, Denmark	USA	30-September- 2013	30-September- 2018	30-April-2015	5 years	30-September- 2018
31	MAL15045163A	Brintellix 20mg Film-coated Tablets	Vortioxetine hydrobromide 25.420mg (equivalent to 20mg vortioxetine)	H.Lundbeck A/S, Denmark	USA	30-September- 2013	30-September- 2018	30-April-2015	5 years	30-September- 2018
32	MAL15085076ACR	Tecfidera 120 mg gastro-resistant hard capsules	Dimethyl fumarate 120 mg	Vifor SA, Switzerland	USA	27-March-2013	27-March-2018	20-August-2015	5 years	27-March-2018

33	MAL15085078ACR	Tecfidera 240 mg gastro-resistant hard capsules	Dimethyl fumarate 240 mg	Vifor SA, Switzerland	USA	27-March-2013	27-March-2018	20-August-2015	5 years	27-March-2018
34	MAL15095034A	Sovaldi 400mg Film-Coated Tablets	Sofosbuvir 400mg	Gilead Sciences Ireland UC, Ireland	USA	6-December-2013	6-December-2018	28-September-2015	5 years	6-December-2018
35	MAL15125055A	Jardiance 10mg Film-Coated Tablets	Empagliflozin 10mg	Boehringer Ingelheim Pharma GmbH & Co. KG, Germany	Australia	30-April-2014	30-April-2019	22-December-2015	5 years	30-April-2019
36	MAL15125056A	Jardiance 25mg Film-Coated Tablets	Empagliflozin 25mg	Boehringer Ingelheim Pharma GmbH & Co. KG, Germany	Australia	30-April-2014	30-April-2019	22-December-2015	5 years	30-April-2019
37	MAL15125061AR	Entresto 50mg Film-coated Tablets	Sacubitril/valsartan 56.551mg [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].	Novartis Pharma Stein AG, Switzerland	USA	7-July-2015	7-July-2020	22-December-2015	5 years	7-July-2020
38	MAL15125062AR	Entresto 100mg 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 Pharma Stein AG, Switzerland	USA	7-July-2015	7-July-2020	22-December-2015	5 years	7-July-2020

39	MAL15125063AR	Entresto 200mg 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 Pharma Stein AG, Switzerland	USA	7-July-2015	7-July-2020	22-December- 2015	5 years	7-July-2020
40	MAL16015076AR	Zykadia 150mg Hard Capsules	Ceritinib 150mg	Novartis Pharma Stein AG, Switzerland	USA	29-April-2014	29-April-2019	21-January-2016	5 years	29-April-2019
41	MAL16065014ACRZ	OFEV Soft Capsules 100 mg	Nintedanib esilate 120.40mg equivalent to 100 mg of nintedanib as free base	Catalent Germany Eberbach GmbH, Germany	USA	15-October-2014	15-October-2019	7-June-2016	5 years	15-October-2019
42	MAL16065015ACRZ	OFEV Soft Capsules 150 mg	Nintedanib esilate 180.60mg equivalent to 150 mg of nintedanib as free base	Catalent Germany Eberbach GmbH, Germany	USA	15-October-2014	15-October-2019	7-June-2016	5 years	15-October-2019
43	MAL16065029ACRZ	Opsumit 10mg Film-Coated Tablets	Macitentan 10mg	Patheon Italia S.P.A., Italy	USA	18-October-2013	18-October-2018	7-June-2016	5 years	18-October-2018
44	MAL16065002ARZ	Ibrance Capsules 75mg	Palbociclib 75mg	Pfizer Manufacturing Deutschland GmbH, Germany	USA	3-February-2015	3-February-2020	7-June-2016	5 years	3-February-2020
45	MAL16065003ARZ	Ibrance Capsules 100mg	Palbociclib 100mg	Pfizer Manufacturing Deutschland GmbH, Germany	USA	3-February-2015	3-February-2020	7-June-2016	5 years	3-February-2020
46	MAL16065004ARZ	Ibrance Capsules 125mg	Palbociclib 125mg	Pfizer Manufacturing Deutschland GmbH, Germany	USA	3-February-2015	3-February-2020	7-June-2016	5 years	3-February-2020

47	MAL16065041ACRZ	Lynparza 50mg Hard Capsules	Olaparib 50mg	Patheon Pharmaceuticals Inc., United States	EU	16-December-2014	16-December-2019	30-June-2016	5 years	16-December-2019
48	MAL16125024ACRZ	Zerbaxa 1.5g powder for solution for injection	*Ceftolozane sulphate [product contains ceftolozane sulphate and tazobactam sodium] *DE for new active ingredient	Steri-Pharm, LLC, United States	USA	19-December-2014	19-December-2019	22-December-2016	5 years	19-December-2019
49.	MAL20172807AZ	Tagrisso Film-Coated Tablet 40mg	Osimertinib mesylate 47.7mg (equivalent to 40mg osimertinib)	AstraZeneca AB, Sweden	USA	13-November-2015	13-November-2020	28-April-2017	5 years	13-November-2020
50.	MAL20172808AZ	Tagrisso Film-Coated Tablet 80mg	Osimertinib mesylate 95.4mg (equivalent to 80mg osimertinib)	AstraZeneca AB, Sweden	USA	13-November-2015	13-November-2020	28-April-2017	5 years	13-November-2020
51.	MAL17025019ARZ	Farydak 10mg Hard Capsules	Panobinostat lactate anhydrous 12.576mg (Corresponding to 10.000 mg of panobinostat)	Novartis Farmaceutica S.A., Spain.	USA	23-February-2015	24-February-2020	24-February-2017	5 years	24-February-2020
52.	MAL17025020ARZ	Farydak 15mg Hard Capsules	Panobinostat lactate anhydrous 18.864mg (Corresponding to 15.000 mg of panobinostat)	Novartis Farmaceutica S.A., Spain.	USA	23-February-2015	24-February-2020	24-February-2017	5 years	24-February-2020
53.	MAL17025021ARZ	Farydak 20mg Hard Capsules	Panobinostat lactate anhydrous 25.152mg (Corresponding to 20.000 mg of panobinostat)	Novartis Farmaceutica S.A., Spain.	USA	23-February-2015	24-February-2020	24-February-2017	5 years	24-February-2020

54.	MAL17107002ACZ	Duaklir Genuair 340/12 mcg Inhalation Powder	Acclidinium bromide 400 mcg (the delivered dose is 396 mcg of acclidinium bromide equivalent to 340 mcg of acclidinium) and formoterol fumarate dihydrate 12 mcg (the delivered dose is 11.8 mcg formoterol fumarate dihydrate)	Industrias Farmaceuticas Almirall, Spain.	EU	19-November-2014	19-November-2022	3-October-2017	5 years	19-November-2019
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