

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

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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

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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

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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

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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 56.551ng [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

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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

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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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55.	MAL18046001ARZ	Kryxana 200mg Film-coated Tablets	Ribociclib succinate 254.4mg (equivalent to 200mg of ribociclib free base).	Novartis Singapore Pharmaceutical Manufacturing Ptd. Ltd.	USA	13-March-2017	13-March-2022	2-April-2018	5 years	13-March-2022
56.	MAL18086114ACRZ	Upravi 200 Microgram Film-Coated Tablets	Selexipag 200mcg	Excella Gmbh, Germany	USA	21 December 2015	21 December 2020	28 August 2018	5 years	21 December 2020
57.	MAL18086113ACRZ	Upravi 400 Microgram Film-Coated Tablets	Selexipag 400mcg	Excella Gmbh, Germany	USA	21 December 2015	21 December 2020	28 August 2018	5 years	21 December 2020
58.	MAL18086112ACRZ	Upravi 600 Microgram Film-Coated Tablets	Selexipag 600mcg	Excella Gmbh, Germany	USA	21 December 2015	21 December 2020	28 August 2018	5 years	21 December 2020
59.	MAL18086111ACRZ	Upravi 800 Microgram Film-Coated Tablets	Selexipag 800mcg	Excella Gmbh, Germany	USA	21 December 2015	21 December 2020	28 August 2018	5 years	21 December 2020
60.	MAL18086110ACRZ	Upravi 1000 Microgram Film-Coated Tablets	Selexipag 1000mcg	Excella Gmbh, Germany	USA	21 December 2015	21 December 2020	28 August 2018	5 years	21 December 2020
61.	MAL18086109ACRZ	Upravi 1200 Microgram Film-Coated Tablets	Selexipag 1200mcg	Excella Gmbh, Germany	USA	21 December 2015	21 December 2020	28 August 2018	5 years	21 December 2020
62.	MAL18086108ACRZ	Upravi 1400 Microgram Film-Coated Tablets	Selexipag 1400mcg	Excella Gmbh, Germany	USA	21 December 2015	21 December 2020	28 August 2018	5 years	21 December 2020
63.	MAL18086107ACRZ	Upravi 1600 Microgram Film-Coated Tablets	Selexipag 1600mcg	Excella Gmbh, Germany	USA	21 December 2015	21 December 2020	28 August 2018	5 years	21 December 2020

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64.	MAL18091001AZ	Lusefi 2.5mg film-coated tablet	Luseogliflozin hydrate 2.5mg	Taisho Pharmaceutical Co. Ltd., Japan	Japan	24 March 2014	23 March 2022	4 December 2018	5 years	24 March 2019
65.	MAL18091002AZ	Lusefi 5mg film-coated tablet	Luseogliflozin hydrate 5mg	Taisho Pharmaceutical Co. Ltd., Japan	Japan	24 March 2014	23 March 2022	4 December 2018	5 years	24 March 2019
66	MAL18046002AZ	Epclusa (sofosbuvir 400mg/velpatasvir 100mg) Film-Coated Tablets	*Velpatasvir 100mg [product contains sofosbuvir and velpatasvir] *DE for new active ingredient	Gilead Sciences Ireland UC, Ireland	USA	28 June 2016	28 June 2021	23 January 2019	5 years	28 June 2021
67	MAL19046009ACRZ	Rydapt 25mg Soft Capsules	Midostaurin 25mg	Catalent Germany Eberbach GmbH, Germany.	USA	28 April 2017	28 April 2024	4 April 2019	5 years	28 April 2022
68	MAL20046077ACRZ	Xofluza Film-Coated Tablet 20mg	Baloxavir marboxil 20mg	Shionogi & Co., Ltd. Settsu Plant, Japan	Japan	23 February 2018	23 February 2026	30 April 2020	5 years	23 February 2023
69	MAL20046078ACRZ	Xofluza Film-Coated Tablet 40mg	Baloxavir marboxil 40mg	Shionogi & Co., Ltd. Settsu Plant, Japan	Japan	23 February 2018	23 February 2026	30 April 2020	5 years	23 February 2023
70	MAL19096014ARZ	Prevmis 240mg Film-coated Tablet	Letemovir 240mg	MSD International GmbH T/A MSD Ireland (Ballydine), Ireland	Canada	1 November 2017	1 November 2025	13 July 2020	5 years	1 November 2022
71	MAL19096013ARZ	Prevmis 480mg Film-coated Tablet	Letemovir 480mg	MSD International GmbH T/A MSD Ireland (Ballydine), Ireland	Canada	1 November 2017	1 November 2025	13 July 2020	5 years	1 November 2022

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72	MAL19096021ARZ	Prevymis 240mg/12mL (20mg/mL) concentrate for solution for infusion	Letermovir 240mg/12mL	MSD International GmbH T/A MSD Ireland (Carlow), Ireland	Canada	1 November 2017	1 November 2025	13 July 2020	5 years	1 November 2022
73	MAL19096012ARZ	Prevymis 480mg/24mL (20mg/mL) concentrate for solution for infusion	Letermovir 480mg/24mL	MSD International GmbH T/A MSD Ireland (Carlow), Ireland	Canada	1 November 2017	1 November 2025	13 July 2020	5 years	1 November 2022
74	MAL20076010AZ	Vizimpro 15 mg Film-Coated Tablets	Dacomitinib 15mg	Pfizer Manufacturing Deutschland GmbH. Germany	USA	27 September 2018	27 September 2023	9 July 2020	5 years	27 September 2023
75	MAL20076011AZ	Vizimpro 30 mg Film-Coated Tablets	Dacomitinib 30mg	Pfizer Manufacturing Deutschland GmbH. Germany	USA	27 September 2018	27 September 2023	9 July 2020	5 years	27 September 2023
76	MAL20076012AZ	Vizimpro 45 mg Film-Coated Tablets	Dacomitinib 45mg	Pfizer Manufacturing Deutschland GmbH. Germany	USA	27 September 2018	27 September 2023	9 July 2020	5 years	27 September 2023
77	MAL20076006ARZ	Trezilent 50mg Film-Coated Tablets	Alpelisib 50mg	Novartis Pharma Stein AG, Switzerland.	USA	24 May 2019	24 May 2024	9 July 2020	5 years	24 May 2024
78	MAL20076007ARZ	Trezilent 150mg Film-Coated Tablets	Alpelisib 150mg	Novartis Pharma Stein AG, Switzerland.	USA	24 May 2019	24 May 2024	9 July 2020	5 years	24 May 2024
79	MAL20076008ARZ	Trezilent 200mg Film-Coated Tablets	Alpelisib 200mg	Novartis Pharma Stein AG, Switzerland.	USA	24 May 2019	24 May 2024	9 July 2020	5 years	24 May 2024
80	MAL19106005ACRZ	Steglatro 15mg Film-Coated Tablets	Ertugliflozin 15mg	Pfizer Manufacturing Deutschland GmbH., Germany	USA	19 December 2017	19 December 2022	13 August 2020	5 years	19 December 2022

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81	MAL19106006ACRZ	Steglatro 5mg Film-Coated Tablets	Ertugliflozin 5mg	Pfizer Manufacturing Deutschland GmbH., Germany	USA	19 December 2017	19 December 2022	13 August 2020	5 years	19 December 2022
82	MAL19106004AZ	Steglujan (Ertugliflozin 5mg/Sitagliptin 100mg) Film-Coated Tablets	*Ertugliflozin 5mg [product contains ertugliflozin and sitagliptin] *DE for new active ingredient	Schering-Plough Labo N.V., Belgium	USA	19 December 2017	19 December 2022	13 August 2020	5 years	19 December 2022
83	MAL19106003AZ	Steglujan (Ertugliflozin 15mg/Sitagliptin 100mg) Film-Coated Tablets	*Ertugliflozin 15mg [product contains ertugliflozin and sitagliptin] *DE for new active ingredient	Schering-Plough Labo N.V., Belgium	USA	19 December 2017	19 December 2022	13 August 2020	5 years	19 December 2022
84	MAL19126002ARZ	Maviret (Glecaprevir 100mg/ Pibrentasvir 40mg) Film Coated Tablets	Glecaprevir 100mg and Pibrentasvir 40mg	Fournier Laboratories Ireland Limited Anngrove, Ireland	EU	26 July 2017	26 July 2027	28 September 2020	5 years	26 July 2022
85	MAL20106001ARZ	RINVOQ 15mg Extended Release Film Coated Tablets	Upadacitinib	Abbvie Ireland NL B.V (IRELAND)	USA	16 August 2019	16 August 2024	2 October 2020	5 years	16 August 2024
86	MAL20126003AZ	Lorviqua 25 mg Film-Coated Tablets	Lorlatinib 25 mg	Pfizer Manufacturing Deutschland GmbH, Germany	Japan	21 September 2018	21 September 2026	3 December 2020	5 years	21 September 2023

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87	MAL20126004AZ	Lorviqua 100 mg Film-Coated Tablets	Lorlatinib 100 mg	Pfizer Manufacturing Deutschland GmbH, Germany	Japan	21 September 2018	21 September 2026	3 December 2020	5 years	21 September 2023
88	MAL21036003ACZ	SPRAVATO 28mg Nasal Spray	Esketamine Hydrochloride	Renaissance Lakewood LLC (UNITED STATES)	USA	5 March 2019	5 March 2024	2 March 2021	5 years	5 March 2024
89	MAL21086002ARZ	Evrysdi Powder for oral solution 0.75 mg/mL	Risdiplam	F.Hoffmann-La Roche Ltd, Switzerland	USA	7 August 2020	7 August 2027	5 August 2021	5 years	7 August 2025
90	MAL21106005AZ	Calquence Hard Capsules 100mg	Acalabrutinib	AstraZeneca AB, Sweden	USA	21 November 2019	21 November 2026	08 October 2021	5 years	21 November 2024
91	MAL21116005ARZ	Kiendra 0.25 mg Film-coated Tablet	Siponimod fumaric acid 0.25 mg	Novartis Pharma Stein AG, Switzerland	USA	26 March 2019	26 March 2024	17 November 2021	5 years	26 March 2024
92	MAL21116006ARZ	Kiendra 2 mg Film-coated Tablet	Siponimod fumaric acid 2 mg	Novartis Pharma Stein AG, Switzerland	USA	26 March 2019	26 March 2024	17 November 2021	5 years	26 March 2024
93	MAL22046007ACRZ	Sybrava 284mg/1.5ml Solution for Injection in Pre-filled Syringe	Inclisiran	Corden Pharma S.P.A., Italy.	EU	10 December 2020	10 December 2028	7 April 2022	5 years	10 December 2025

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94	MAL22046004ARZ	Rahika 150mg Film-coated Tablet	Capmatinib dihydrochloride monohydrate	Novartis Pharma Produktions GmbH, Germany	USA	6 May 2020	6 May 2025	7 April 2022	5 years	6 May 2025
95	MAL22046005ARZ	Rahika 200mg Film-coated Tablet	Capmatinib dihydrochloride monohydrate	Novartis Pharma Produktions GmbH, Germany	USA	6 May 2020	6 May 2025	7 April 2022	5 years	6 May 2025
96	MAL22126004AZ	Verquvo Film Coated Tablet 2.5mg	Vericiguat micronized	Bayer AG, Germany	USA	19 January 2021	19 January 2026	13 December 2022	5 years	19 January 2026
97	MAL22126005AZ	Verquvo Film Coated Tablet 5mg	Vericiguat micronized	Bayer AG, Germany	USA	19 January 2021	19 January 2026	13 December 2022	5 years	19 January 2026
98	MAL22126006AZ	Verquvo Film Coated Tablet 10mg	Vericiguat micronized	Bayer AG, Germany	USA	19 January 2021	19 January 2026	13 December 2022	5 years	19 January 2026
99	MAL23056001ARZ	Scemblix 20mg film-coated tablet	Asciminib hydrochloride	Novartis Pharma Stein AG, Switzerland	USA	29 October 2021	29 October 2026	11 May 2023	5 years	29 October 2026
100	MAL23056002ARZ	Scemblix 40mg film-coated tablet	Asciminib hydrochloride	Novartis Pharma Stein AG, Switzerland	USA	29 October 2021	29 October 2026	11 May 2023	5 years	29 October 2026

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
101	MAL24046010AZ	Firialta Film Coated Tablet 10mg	Finerenone	BAYER AG, Leverkusen, Germany.	USA	09 July 2021	09 July 2026	04 April 2024	5 years	09 July 2026
102	MAL24046011AZ	Firialta Film Coated Tablet 20mg	Finerenone	BAYER AG, Leverkusen, Germany.	USA	09 July 2021	09 July 2026	04 April 2024	5 years	09 July 2026
103	MAL24086002ACRZ	SOTYKTU 6 mg film coated tablets	Deucravacitinib	PATHEON INC., Canada	USA	09 September 2022	09 September 2027	01 August 2024	5 years	09 September 2027
104	MAL24106010ARZ	Litfulo 50 mg Hard Capsules	Ritlecitinib	Pfizer Manufacturing Deutschland GmbH, Germany	USA	23 June 2023	23 June 2028	3 October 2024	5 years	23 June 2028
105	MAL24126001ACRZ	KOPOZGO 2.5mg capsules	Mavacamten	PATHEON INC. Canada	USA	28 April 2022	28 April 2027	2 December 2024	5 years	28 April 2027
106	MAL24126002ACRZ	KOPOZGO 5mg capsules	Mavacamten	PATHEON INC. Canada	USA	28 April 2022	28 April 2027	2 December 2024	5 years	28 April 2027
107	MAL24126003ACRZ	KOPOZGO 10mg capsules	Mavacamten	PATHEON INC. Canada	USA	28 April 2022	28 April 2027	2 December 2024	5 years	28 April 2027

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
108	MAL24126004ACRZ	KOPOZGO 15mg capsules	Mavacamten	PATHEON INC. Canada	USA	28 April 2022	28 April 2027	2 December 2024	5 years	28 April 2027
109	MAL25056001ARZ	TRUQAP 160MG Film-Coated Tablets	Capivasertib	ASTRAZENECA AB Sodertalje, Sweden.	USA	16 November 2023	16 November 2028	22 May 2025	5 years	16 November 2028
110	MAL25056002ARZ	TRUQAP 200MG Film-Coated Tablets	Capivasertib	ASTRAZENECA AB Sodertalje, Sweden.	USA	16 November 2023	16 November 2028	22 May 2025	5 years	16 November 2028
111	MAL23096003ACRZ	LUMAKRAS FILM-COATED TABLET 120MG	Sotorasib	PATHEON INC. Canada	USA	28 May 2021	28 May 2028	22 May 2025	5 years	28 May 2026
112	MAL25036129ARZ	Fabhalta 200mg Hard Capsules	Iptacopan hydrochloride monohydrate	Novartis Pharma Produktions GmbH, Germany	USA	5 December 2023	5 December 2028	25 March 2025	5 years	5 December 2028
113	MAL26036114ACZ	IQIRVO® 80mg Film-coated Tablet	Elafibranor	Delpharm Milano s.r.l., Italy	USA	10 June 2024	10 June 2029	05 March 2026	5 years	10 June 2029
114	MAL26046002ARZ	Itovebi 3mg Film-Coated Tablets	Inavolisib	F. Hoffmann-La Roche Ag, Basel, Switzerland	USA	10 October 2024	10 October 2029	02 April 2026	5 years	10 October 2029

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
115	MAL26046003ARZ	Itovebi 9mg Film-Coated Tablets	Inavolisib	F. Hoffmann-La Roche Ag, Basel, Switzerland	USA	10 October 2024	10 October 2029	02 April 2026	5 years	10 October 2029

DCA: Drug Control Authority; DE: Data Exclusivity