

Register of AI Data Exclusivity Granted in Malaysia

For a Second indication of a registered drug product

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 Second indication of a registered product as listed below.

The period of Data Exclusivity is calculated from the date the Second indication is first approved 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	Additional Indication approval date	Exclusivity Expiration	Additional Indication approval date	Protection Period	Exclusivity Expiration
1	MAL20102019AR	Onglyza Tablet 2.5mg	Saxagliptin hydrochloride	Bristol-Myers Squibb Company, USA	USA	16-Dec-11	16-Dec-14	28-Jun-12	3 years	16-Dec-14
2	MAL20102020AR	Onglyza Tablet 5mg	Saxagliptin hydrochloride	Bristol-Myers Squibb Company, USA	USA	16-Dec-11	16-Dec-14	28-Jun-12	3 years	16-Dec-14
3	MAL11115002A	Xarelto 15mg film-coated tablet	Rivaroxaban 15mg	Bayer Pharma AG, Germany	USA	2-Nov-12	2-Nov-15	28-Mar-13	3 years	2-Nov-15
4	MAL11115001A	Xarelto 20mg film-coated tablet	Rivaroxaban 20mg	Bayer Pharma AG, Germany	USA	2-Nov-12	2-Nov-15	28-Mar-13	3 years	2-Nov-15
5	MAL13065048A	Stivarga 40mg Film-coated Tablets	Regorafenib monohydrate 41.49mg (equivalent to 40mg regorafenib)	Bayer Pharma AG, Germany	USA	25-Feb-13	25-Feb-16	23-Jan-14	3 years	25-Feb-16
6	MAL15125055AZ	Jardiance 10mg film coated tablets	Empagliflozin 10 mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	2-Dec-16	2-Dec-19	27-Nov-17	3 years	2-Dec-19

7	MAL15125056AZ	Jardiance 25mg film coated tablets	Empagliflozin 25 mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	2-Dec-16	2-Dec-19	27-Nov-17	3 years	2-Dec-19
8	MAL14075068AZ	Giotrif 20mg film-coated tablets	Afatinib Dimaleate 20mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	15-Apr-16	15-Apr-23	28-Feb-18	3 years	15-Apr-19
9	MAL14075070AZ	Giotrif 30mg film-coated tablets	Afatinib Dimaleate 30mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	15-Apr-16	15-Apr-23	28-Feb-18	3 years	15-Apr-19
10	MAL14075069AZ	Giotrif 40mg film-coated tablets	Afatinib Dimaleate 40mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	15-Apr-16	15-Apr-23	28-Feb-18	3 years	15-Apr-19
11	MAL14075071AZ	Giotrif 50mg film-coated tablets	Afatinib Dimaleate 50mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	15-Apr-16	15-Apr-23	28-Feb-18	3 years	15-Apr-19
12	MAL12095102AZ	Xalkori 200mg Hard Capsules	Crizotinib 200 mg	Pfizer Manufacturing Deutschland GmbH Germany.	USA	11-Mar-16	11-Mar-23	31-May-18	3 years	11-Mar-19
13	MAL12095103AZ	Xalkori 250mg Hard Capsules	Crizotinib 250 mg	Pfizer Manufacturing Deutschland GmbH Germany.	USA	11-Mar-16	11-Mar-23	31-May-18	3 years	11-Mar-19

DCA: Drug Control Authority; DE: Data Exclusivity