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Year 2013
Products Approved For Additional Indication (DCA 266 – 25 Julai 2013)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **OZURDEX 700 MICROGRAMS INTRAVITREAL IMPLANT IN APPLICATOR** [Dexamethasone 700 micrograms]	➢ Indication: *Ozurdex is indicated for the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis.* ➢ Posology: *There is only very limited information on repeat dosing intervals less than 6 months. There is currently no experience of repeat administrations in posterior segment non-infectious uveitis or beyond 2 implants in Retinal Vein Occlusion.* *Paediatric population* *There is no relevant use of Ozurdex in the paediatric population in macular oedema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO). The safety and efficacy of Ozurdex in uveitis in the paediatric population have not been established. No data are available.*	**ALLERGAN MALAYSIA SDN. BHD.** Level 5-02, Block A, PJ8, No. 23 Jalan Barat, Seksyen 8, 46050 Petaling Jaya, Selangor.
2.	2.1 **SIMPONI 50MG (0.5ML) SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE** [Golimumab 50mg/0.5 mL]	➢ Indication: *This application is for the extension of the indication for Simponi in combination with methotrexate for inhibiting the progression of structural damage in Rheumatoid Arthritis (RA) and Psoriatic arthritis (PsA) patients.*	**JOHNSON & JOHNSON SDN BHD** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor.

3.	3.1 **REBIF 22mcg** [Recombinant Human Interferon Beta 22mcg/5ml] 3.2 **REBIF 44mcg** [Recombinant Human Interferon Beta 44mcg/5ml]	➢ Indication: *Patients with single demyelinating event, with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis.* ➢ Posology: *<u>Posology</u>:* *When first starting treatment with Rebif, in order to allow tachyphylaxis to develop thus reducing adverse reactions it is recommended that 8.8 mcg (0.1ml of the 44mcg strength or 0.2 ml of the 22mcg strength) be administered three times per week during the initial 2 weeks of therapy, 22mcg (0.25ml of the 44mcg strength or the total of 22mcg strength) be administered by subcutaneous injection three times per week in weeks 3 and 4, and the total of 44 mcg strength be administered three times per week from the fifth week onwards.* *<u>First demyelinating event</u>* *The recommended posology for patients who have experienced a first demyelinating event is 44mcg of Rebif given three times per week by subcutaneous injection.*	**MERCK SDN. BHD.** Level 3, Menara Sunway Annexe, Jalan Lagoon Timur, Bandar Sunway, 46150 Petaling Jaya, Selangor Darul Ehsan..
4.	4.1 **IMOJEV Japanese Encephalitis Vaccine (Live, Attenuated)** [Each 0.5 ml dose contains: Live, attenuated, recombinant Japanese encephalitis virus 4.0 - 5.8 log PFU* * Plaque Forming Unit] 4.2 **IMOJEV Japanese Encephalitis Vaccine (live, attenuated) MD** [Each 0.5 ml dose contains: Live, attenuated, recombinant Japanese encephalitis virus 4.0 - 5.8 log PFU*	➢ Indication: *Imojev is indicated for prophylaxis of Japanese encephalitis caused by the Japanese encephalitis virus, in persons from 9 months of age and over.* ➢ Posology: *Persons 9 months of age and over: a single dose of reconstituted Imojev 0.5 mL injection should be administered for primary immunization.* *In children, if a long term protection* is required, a*	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** 8th Floor, PNB Damansara, No. 19, Lorong Dungun, Damansara Heights, 50490 Kuala Lumpur

	* Plaque Forming Unit]	*booster dose of Imojev should be given after the first vaccination. The booster dose should be given preferably 1 year after the first vaccination and can be given up to 2 years after the first vaccination. Imojev can also be given as a booster vaccination in children who were previously given an inactivated Japanese encephalitis vaccine for primary vaccination, in accordance with the recommended timing for the booster of the inactivated Japanese encephalitis vaccine.* ** Immunity is maintained at a high level at least 3 years after the booster dose* *In adults, there is no need for a booster dose up to 5 years after the administration of a single dose of Imojev.* *Once the freeze-dried vaccine has been completely reconstituted using the diluent provided (see section "Instructions for use"), it is administered via the subcutaneous route.* *In persons 2 years of age and over, the recommended injection site is the deltoid region of the upper arm.* *In persons between 9 and 24 months of age, the recommended injection site is the anterolateral aspect of the thigh or the deltoid region.* *Do not administer by intravascular injection.* *Imojev must not be mixed with any other injectable vaccine(s) or medicinal product(s).* *Contact with disinfectants is to be avoided since they may inactivate the vaccine virus.*	