Maklumat tambahan indikasi untuk upload pada laman web
Year 2013
Products Approved For Additional Indication (DCA 264 – 30 Mei 2013)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **TRAJENTA 5MG FILM-COATED TABLETS** [Linagliptin 5 mg]	➢ Indication: *Linagliptin is indicated in adult patients with type 2 diabetes mellitus (T2DM) to improve glycaemic control in conjunction with diet and exercise, as monotherapy or as add on to metformin, sulphonylureas, insulin (with or without metformin) or metformin plus sulphonylureas.* ➢ Posology: *The dose of linagliptin is 5 mg once daily. When linagliptin is added to metformin, the dose of metformin should be maintained, and linagliptin administered concomitantly.* *When linagliptin is used in combination with a sulphonylurea or with insulin, a lower dose of the sulphonylurea or insulin, may be considered to reduce the risk of hypoglycaemia.*	**BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.** Suite 15-5 Level 15, Wisma UOA Damansara II, No 6, Jalan Changkat Semantan, Damansara Heights, 50490 Kuala Lumpur.
2.	2.1 **AVASTIN INJECTION 25 MG/ML** [Bevacizumab 25mg/ml]	➢ Indication: • *Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer* *Avastin, in combination with carboplatin and gemcitabine is indicated for the treatment of patients with recurrent, platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer who have not received prior bevacizumab or other VEGF*-targeted angiogenesis inhibitors.*	**ROCHE (M) SDN BHD** Level 56- 58, Vista Tower, The Intermark, 182, Jalan Tun Razak, 50400 Kuala Lumpur.

		**VEGF: Vascular Endothelial Growth Factor* ➢ Posology: • *Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer* *Treatment of recurrent disease:* *Avastin is administered in combination to carboplatin and gemcitabine for 6 cycles and up to 10 cycles followed by continued use of Avastin as single agent until disease progression.* *The recommended dose of Avastin is 15 mg/kg of body weight given once every 3 weeks as an intravenous infusion.*	
3.	3.1 **Enbrel 25mg Solution For Injection In A Pre-Filled Syringe** [Etanercept 25mg] 3.2 **Enbrel 50mg Solution For Injection In A Pre-Filled Syringe** [Etanercept 50mg] 3.3 **Enbrel Injection 25mg/Vial** [Etanercept 25mg/ vial]	➢ Indication: • *Pediatric plaque psoriasis:* *Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.* • *Polyarticular juvenile idiopathic arthritis:* *Treatment of active polyarticular JIA in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Enbrel has not been studied in children aged less than 2 years.* ➢ Posology: • *Pediatric plaque psoriasis (age 6 years and above):* *The recommended dose is 0.8 mg/kg (up to a maximum of 50 mg per dose) once weekly for up to 24weeks. Treatment should be discontinued in*	**PFIZER (MALAYSIA) SDN. BHD.** Level 9-2, 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur.

		patients who show no response after 12 weeks. *If re-treatment with Enbrel is indicated, the above guidance on treatment duration should be followed.The dose should be 0.8 mg/kg (up to a maximum of 50 mg per dose) once weekly.* *There is generally no applicable use of Enbrel in children aged below 6 years in the indication plaque psoriasis.* • *Polyarticular juvenile idiopathic arthritis:* *The recommended dose is 0.4 mg/kg (up to a maximum of 25 mg per dose) after reconstitution of Enbrel in 1 ml of solvent, given twice weekly as a subcutaneous injection with an interval of 3-4 days between doses. Discontinuation of treatment should be considered in patients who show no response after 4 months.* *No formal clinical trials have been conducted in children aged 2 to 3 years. However, limited safety data from a patient registry suggest that the safety profile in children from 2 to 3 years of age is similar to that seen in adults and children aged 4 years and older, when dosed every week with 0.8 mg/kg subcutaneously.* *There is generally no applicable use of Enbrel in children aged below 2 years in the indication polyarticular juvenile idiopathic arthritis.*	