Maklumat tambahan indikasi untuk upload pada laman web
Year 2015
Products Approved For Additional Indication (DCA 293 – 26 Oktober 2015)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **HUMIRA SOLUTION FOR INJECTION** [Adalimumab 40MG/0.8 ML]	➢ Indication: *Polyarticular Juvenile Idiopathic Arthritis* *Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 2 years old who had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance of methotrexate or when continued treatment with methotrexate is inappropriate.* ➢ Posology: *Polyarticular Juvenile Idiopathic Arthritis from 13 years of age* *The recommended dose of Humira for patients with polyarticular juvenile idiopathic arthritis, aged 13 years and above is 40 mg adalimumab administered every other week as a single dose via subcutaneous injections. Available data suggest that clinical response is usually achieved within 12 weeks of treatment. Continued therapy should be carefully reconsidered in patient not responding within this time period.* Polyarticular Juvenile Idiopathic Arthritis from 2 to 12 years of age *The recommended dose of Humira for patients with polyarticular juvenile idiopathic, aged 2-12 years, is 24mg/m2 body surface area up to a maximum single dose of 20mg adalimumab (for patients aged 2-<4) and up to a maximum single dose of 40mg adalimumab (for patients aged 4-12) administered every other week via subcutaneous injection. The volume for injection is selected based on the patient's height and weight (Table 1). A 40mg paediatric vial is available for patients who need to administer less than the full 40 mg dose.*	**ABBVIE SDN BHD** No. 24, Jalan Pemaju U1/15, Seksyen U1,Hicom-Glenmarie Industrial Park, 40150 Shah Alam, Selangor

2	2.1 **ENBREL 25MG SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE** [Etanercept 50mg/ml] 2.2 **ENBREL 50MG SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE** [Etanercept 50mg/ml] 2.3 **ENBREL INJECTION 25MG/VIAL** [Etanercept 25mg/vial]	➢ Indication: *Non-radiographic Axial Spondyloarthritis* *Treatment of adults with active* non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) change who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDS).* **Active disease is defined as a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of ≥ 4.* ➢ Posology: *The proposed posology for this additional indication is the same with the approved posology for psoriatic arthritis and ankylosing spondylitis which is as below:* *The recommended dose is 25 mg Enbrel administered twice weekly, or 50 mg administered once weekly*	**PFIZER (MALAYSIA) SDN. BHD** Level 9-2, 10 & 11, Wisma Averis, (Tower 2) Avenue 5, Bangsar South, No. 8 Jalan Kerinchi 59200 Kuala Lumpur
3	3.1 **Aloxi Solution for Injection 50mcg/ml** [Palonosetron hydrochloride]	➢ Indication: *Aloxi® is indicated in paediatric patients 1 month of age and older for:* *Chemotherapy-Induced Nausea and Vomiting* • *The prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.* ➢ Posology: *Paediatric population* *Chemotherapy-Induced Nausea and Vomiting* *Children and Adolescents (aged 1 month to 17 years):* *20 micrograms/kg (the maximum total dose should not exceed 1500mcg) palonosetron administration as a single 15 minute intravenous infusion beginning approximately 30 minutes before the start of chemotherapy.* *The safety and efficacy of Aloxi® in children aged less than 1 month have not been established. No data are available*	**MUNDIPHARMA PHARMACEUTICALS SDN. BHD** A-5-01 Level 5, Block A, , PJ8, No. 23 Jalan Barat, Seksyen 8,, 46050 Petaling Jaya

4	4.1 **Lipanthyl Penta 145, film-coated tablet** [Fenofibrate 145mg]	➢ Indication: LIPANTHYL® PENTA 145 is indicated for the reduction in the progression of diabetic retinopathy in patients with type 2 diabetes and existing diabetic retinopathy. Lipanthyl does not replace the appropriate control of blood pressure, blood glucose and blood lipids in reducing the progression of diabetic retinopathy. ➢ Posology: Dietary measures initiated before therapy should be continued. Adults: The recommended dose is one tablet containing 145mg fenofibrate taken once daily. Patients currently taking one 200mg capsule or one 160mg tablet can be changed to one 145mg fenofibrate tablet without further dose adjustment. If a patient needs fenofibrate for both indications, only one tablet of fenofibrate 145mg per day should be taken.	**ABBOTT LABORATORIES (M) SDN BHD** 22, Jalan Pemaju U1/15, Seksyen U1, Hicom-Glenmarie Industrial Park, 40150 Shah Alam, Selangor.