Maklumat tambahan indikasi untuk upload pada laman web
Year 2013
Products Approved For Additional Indication (DCA 260 – 23 Januari 2013)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **MABTHERA 100MG /10ML VIALS** [Rituximab 100mg/10 ml vials] 1.2 **MABTHERA 500MG /50ML VIALS** [Rituximab 500mg/ 50ml vials] 1.3 **MABTHERA 100MG /10ML VIALS** [Rituximab 100mg/10ml vials] 1.4 **MABTHERA 500MG /50ML VIALS** [Rituximab 500mg/ 50ml vials] 1.5 **MABTHERA VIALS 10MG /ML CONCENTRATE FOR SOLUTION FOR INFUSION** [Rituximab 10mg/vial]	➢ Granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) and Microscopic polyangiitis (MPA) MabThera /Rituxan in combination with glucocorticoids is indicated for the treatment of adult patients with severe, active Granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) and Microscopic polyangiitis (MPA)	**ROCHE (M) SDN BHD** Level 56- 58, Vista Tower, The Intermark, 348, Jalan Tun Razak 50400 Kuala Lumpur.
2.	2.1 **Prevenar 13 Suspension For Injection** [1 dose (0.5ml) contains Pneumococcal polysaccharide serotype 11 2.2µg Pneumococcal polysaccharide serotype 31 2.2µg Pneumococcal polysaccharide serotype 41 2.2µg Pneumococcal polysaccharide serotype 6A1 2.2µg Pneumococcal polysaccharide serotype 6B1 4.4µg Pneumococcal polysaccharide serotype 7F1 2.2µg Pneumococcal polysaccharide serotype 9V1 2.2µg Pneumococcal polysaccharide serotype 141 2.2µg Pneumococcal polysaccharide serotype 18C1 2.2µg Pneumococcal polysaccharide serotype 19A1 2.2µg Pneumococcal polysaccharide serotype 19F1 2.2µg Pneumococcal polysaccharide serotype 23F1 2.2µg 1Conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate (0.125mg aluminium)]	➢ Active immunisation for the prevention of pneumococcal disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F (including invasive disease, pneumonia and acute otitis media) in infant and children from 2 months to 5 years of age.	**PFIZER (M) 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 **TORISEL CONCENTRATE FOR INJECTION, 25MG/ML** [Temsirolimus 25 mg/ml]	➢ Indication: *Torisel is indicated for the treatment of patients with relapsed and/or refractory mantle cell lymphoma.* ➢ Posology: *Dilution* *For mantle cell lymphoma, multiple vials will be required for each dose over 25 mg. Each vial of Torisel should be diluted with diluents according to the instruction below. The required diluted contents from each vial should be combined in one syringe for injection into 250 mL of 0.9 % sodium chloride injection.* *Mantle cell lymphoma* *The recommended dosing regimen of Temsirolimus Concentrate for Injection for the treatment of mantle cell lymphoma is 175 mg IV, infused over a 30 - 60 minute period once weekly for 3 weeks followed by weekly doses of 75 mg IV, infused over a 30-60 minute period.* *Management of suspected drug reactions may require temporary interruption and/or dose reduction of temsirolimus therapy. If a suspected reaction is not manageable with dose delays, then Torisel should be reduced as follows: if the reaction occurs during 175 mg dosing, the 175 mg weekly dose should be reduced to 75 mg weekly. Thereafter, dose may be reduced by 25 mg/week decrements, to a minimum of 25 mg weekly.*	**PFIZER (M) SDN BHD** Level 9-2, 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur..