Maklumat tambahan indikasi
Year 2019
Products Approved For Additional Indication (DCA 338 – 5 September 2019)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Revolade Film-coated Tablet 25mg** [Eltrombopag Olamine 25MG] 1.2 **Revolade Film-coated Tablet 50mg** [Eltrombopag Olamine 50MG]	➢ Indication: *Revolade is indicated for the treatment of patients aged 6 years and above with primary immune thrombocytopenia (ITP) lasting 6 months or longer from diagnosis and who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).* ➢ Posology: *<u>Immune (primary) thrombocytopenia</u>* *Adults and paediatric population aged 6 to 17 years* *The recommended starting dose of Revolade is 50 mg once daily. For patients of East Asian ancestry (such as Chinese, Japanese, Taiwanese, Korean or Thai), Revolade should be initiated at a reduced dose of 25 mg once daily.* *<u>Special populations</u>* *Paediatric population* *The safety and efficacy of Revolade have not been established in paediatric ITP patients younger than one year. In paediatric clinical trials, subjects between 1 to 5 years of age were administered Revolade as a powder for oral suspension formulation. Revolade is only available as tablets and cannot be used in patients who are unable to swallow Revolade tablets whole. The safety and efficacy of Revolade in paediatric patients with chronic HCV related thrombocytopenia or SAA have not been established.*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

2.	2.1 **Duphaston Tablet 10mg** [Dydrogesterone 10mg]	➢ Indication: *Luteal support as part of an Assisted Reproductive Technology (ART) treatment.* ➢ Posology: *Luteal support as part of an Assisted Reproductive Technology (ART) treatment.* *Take one tablet three times daily (30mg daily) starting at the day of oocyte retrieval and continuing for 10 weeks if pregnancy is confirmed.*	**ABBOTT LABORATORIES (M) SDN. BHD.** No.22, Jalan Pemaju U1/15, Seksyen U1 Hicom-Glenmarie Industrial Park 40150 Shah Alam, Selangor
3.	3.1 **Prolia Solution for Injection 60mg Pre-filled Syringe** [Denosumab 60mg/ml]	➢ Indication: *<u>Glucocorticoid-induced osteoporosis</u>* *Treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months.* ➢ Posology: *Administration* *Administration should be performed by an individual who has been adequately trained in injection techniques.* *Dosage* *The recommended dose of Prolia is a single subcutaneous injection of 60 mg administered once every 6 months.* *Patients should receive calcium and vitamin D supplements whilst undergoing treatment.* *Populations* *<u>Children</u>* *Prolia is not recommended in paediatric patients as the safety and effectiveness of Prolia have not been established in the paediatric age group. In animal studies, inhibition of*	**ZUELLIG PHARMA SDN BHD** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong 40150 Shah Alam, Selangor

		RANK/RANK ligand (RANKL) with a construct of osteoprotegerin bound to Fc (OPG-Fc) has been coupled to inhibition of bone growth and lack of tooth eruption (see section 5.3). Therefore, treatment with denosumab may impair bone growth in children with open growth plates and may inhibit eruption of dentition. *<u>Elderly</u>* *Based on the available safety and efficacy data in the elderly, no dosage adjustment is required.* *<u>Renal impairment</u>* *Based on the available safety and efficacy data in the elderly, no dosage adjustment is required in patients with renal impairment (see section 4.4 for recommendations relating to monitoring of calcium).* *No data is available in patients with long-term systemic glucocorticoid therapy and severe renal impairment (GFR < 30 mL/min).* *<u>Hepatic impairment</u>* *The safety and efficacy of Prolia have not been studied in patients with hepatic impairment (see section 5.2).*	