Maklumat tambahan indikasi
Year 2019
Products Approved For Additional Indication (DCA 339 – 3 Oktober 2019)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Actemra 162mg/0.9mL Solution for Injection in Pre-Filled Syringe** [Tocilizumab 162mg/0.9mL]	➢ Indication: *Systemic Juvenile Idiopathic Arthritis (sJIA)* *Tocilizumab is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. Tocilizumab can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.* ➢ Posology: *Systemic Juvenile Idiopathic Arthritis (sJIA)* *The recommended dose of SC tocilizumab for patients with sJIA is:* • *162 mg once every two weeks for patients below 30 kg,* • *162 mg once every week for patients ≥ 30 kg* *A change in dose should only be based on a consistent change in the patient's body weight over time. Tocilizumab can be used alone or in combination with MTX.* *Patients must have a minimum body weight of 10kg when receiving Actemra subcutaneously.*	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle Persiaran Lagoon Bandar Sunway 47500 Subang Jaya, Selangor
2.	2.1 **Spiriva Respimat 2.5 microgram, solution for inhalation** [Tiotropium 2.5 mcg/puff]	➢ Indication: *Asthma* *Spiriva Respimat is indicated as add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year.*	**BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.** Suite 15-5 Level 15, Wisma UOA Damansara II, No 6, Jalan Changkat

		➢ Posology: *Paediatric population:* *<u>Asthma</u>* *The recommended dosage of tiotropium using the SPIRIVA RESPIMAT in patients 6 to 17 years of age is 5 micrograms. This is administered as two puffs once daily from the RESPIMAT inhaler, at the same time each day (see RESPIMAT inhaler Instructions for Use). Tiotropium has not been studied in children less than 1 year.*	Sematan, Damansara Heights, 50490 Kuala LumpurSelangor
3.	3.1 **Kryxana 200mg Film-coated Tablets** [Ribociclib succinate 254.40mg (equivalent to 200mg of ribociclib free base)]	➢ Indication: *KRYXANA is indicated in combination with:* o *an aromatase inhibitor for the treatment of <u>pre/perimenopausal</u> or postmenopausal women, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer as initial endocrine-based therapy.* o *fulvestrant for the treatment of postmenopausal women with HR-positive; HER2-negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy.* ➢ Posology: *Dosing and Administration* *The recommended dose of KRYXANA is 600 mg (three 200 mg film-coated tablets) taken orally, once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days. KRYXANA can be taken with or without food.* *When given with KRYXANA, refer to the Full Prescribing Information for the recommended dose of the aromatase inhibitor being used.* *When given with KRYXANA, the recommended dose of*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

		fulvestrant is 500 mg administered on Days 1, 15, 29, and once monthly thereafter. Please refer to the Full Prescribing Information of fulvestrant. *Pre/perimenopausal women treated with the combination KRYXANA plus an aromatase inhibitor should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards. Patients should take their dose of KRYXANA at approximately the same time each day, preferably in the morning.*	