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Year 2014
Products Approved For Additional Indication (DCA 274 – 27 Mac 2014)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Foster 100/6 mcg/dose pressurised inhalation solution** [Beclometasone dipropionate 100mcg and formoterol fumarate dihydrate 6mcg]	➢ Indication: *Foster is indicated in the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate:* • *patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled rapid-acting beta2-agonist or* • *patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists.* ➢ Posology: ***A. Maintenance therapy:*** *Foster is taken as regular maintenance treatment with a separate as needed rapid-acting bronchodilator.* ***B. Maintenance and reliever therapy:*** *Foster is taken as regular maintenance treatment and as needed in response to asthma symptoms.* ***A. Maintenance therapy*** *Patients should be advised to have their separate rapid-acting bronchodilator available for rescue use at all times.* ***Dose recommendations for adults 18 years and above:*** *One or two inhalations twice daily.* *The maximum daily dose is 4 inhalations.* ***B. Maintenance and reliever therapy*** *Patients take their daily maintenance dose of Foster and in addition take Foster as needed in response to asthma symptoms. Patients should be advised to always have Foster available for rescue use.*	**ORIENT EUROPHARMA (M) SDN. BHD.** 33, Jalan U1/30, Seksyen U1 40150 Shah Alam, Selangor

Foster maintenance and reliever therapy should especially be considered for patients with:

- *not fully controlled asthma and in need of reliever medication*
- *asthma exacerbations in the past requiring medical intervention*

Close monitoring for dose-related adverse effects is needed in patients who frequently take high numbers of Foster as-needed inhalations.

Dose recommendations for adults 18 years and above:
The recommended maintenance dose is 1 inhalation twice daily (one inhalation in the morning and one inhalation in the evening).

Patients should take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken.

The maximum daily dose is 8 inhalations.

Patients requiring frequent use of rescue inhalations daily, should be strongly recommended to seek medical advice. Their asthma should be reassessed and their maintenance therapy should be reconsidered.

Dose recommendations for children and adolescents under 18 years:
The safety and efficacy of Foster in children and adolescents under 18 years of age have not been established yet. No data are available with Foster in children under 12 years of age. Only limited data are available in adolescents between 12 and 17 years of age. Therefore Foster is not recommended for children and adolescents under 18 years until further data become available.

Instructions for use
To ensure proper administration of the drug, the patient should be shown how to use the inhaler

		correctly by a physician or other health professional. Correct use of the pressurised metered dose inhaler is essential in order that treatment is successful. The patient should be advised to read the Patient Information Leaflet carefully and follow the instructions for use as given in the leaflet. *Cleaning* *Patients should be advised to read the Patient Information Leaflet carefully for cleaning instructions. For the regular cleaning of the inhaler, patients should remove the cap from the mouthpiece and wipe the outside and inside of the mouthpiece with a dry cloth. They should not use water or other liquids to clean the mouthpiece.* *There are no clinical data available on the use of Foster with a spacer, therefore the recommended posology refers to the inhalation of the medicinal product without a spacer (with a standard actuator). Foster must not be used with any spacing device; if a spacing device is required the patients should have their treatment changed to either an alternative pressurised metered dose inhaler with a named spacing device or an inhalation powder.*	
2.	2.1 **Isentress 400mg Tablet** [Raltegravir Potassium 434.4mg (equivalent to 400mg raltegravir [free phenol])	➢ Indication: *Isentress in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection in adults, adolescents and children from the age of 6 years.* *This indication is based on analyses of plasma HIV-1 RNA levels up through 96 weeks in three double blind controlled studies of Isentress. Two of these studies were conducted in clinically advanced, 3-class antiretroviral (NNRTI, NRTI, PI) treatment-experienced adults and one was conducted in treatment-naïve adults.* *Isentress is available for patients 6 years of age and older (see V. DOSAGE AND ADMINISTRATION).*	**MERCK SHARP & DOHME (MALAYSIA) SDN BHD** T2-9, Jaya 33, No.3 (Lot 33) Jalan Semangat, Seksyen 13 46100 Petaling Jaya, Selangor

		The safety and efficacy have not been established in paediatric patients under 2 years of age (see IIId. Clnical Trials). ➢ Posology: *Isentress can be administered with or without food. It is not recommended to chew, crush or split the tablet.* *Isentress is to be given in a combination regimen with other antiretroviral agents. For the treatment of patients with HIV-1 infection, the dosage of Isentress is as follows:* *Adults:* *One 400mg tablet twice daily, orally.* *Children and adolescents:* • *12 years of age and older: One 400mg tablet twice daily, orally.* • *6 to less than 12 years of age: One 400mg tablet twice daily, orally (if at least 25kg in weight, and able to swallow a tablet).* *Isentress 400mg tablets are not recommended for patients under 6 years of age.*	
3.	3.1 **Xyntha 250 IU Powder and Solvent for Solution for Injection** [Moroctocog Alfa 250IU/vial] 3.2 **Xyntha 500 IU Powder and Solvent for Solution for Injection** [Moroctocog Alfa 500IU/vial] 3.3 **Xyntha 1000 IU Powder and Solvent for Solution for Injection** [Moroctocog Alfa 1000IU/vial] 3.4 **Xyntha 2000 IU Powder and Solvent for Solution for Injection** [Moroctocog Alfa 2000IU/vial]	➢ Indication: *Xyntha is appropriate for use in children of all ages, including newborns.*	**PFIZER (MALAYSIA) SDN. BHD.** Level 9-2, 10 & 11, Wisma Averis, Tower 2 Avenue 5, Bangsar South, No.8, Jalan Kerinchi 59200 Kuala Lumpur