

Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 367 – 13 Disember 2021)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	BOOSTRIX VACCINE [1 dose (0.5 ml) contains Diphtheria Toxoid (NLT 2IU), Tetanus Toxoid (NLT 20IU), and <i>Bordetella Pertussis</i> Antigens [pertussis toxoid (8µg), filamentous haemagglutinin (8 µg), pertactin (2.5 µg)]]	<p>INDICATION :</p> <p>Boostrix is also indicated for passive protection against pertussis in early infancy following maternal immunisation during pregnancy.</p> <p>The use of Boostrix should be in accordance with official recommendations.</p> <p>POSODOLOGY:</p> <p>A single 0.5 ml dose of the vaccine is recommended.</p> <p>Boostrix can be administered to pregnant women during the second or the third trimester to provide passive protection of infants against pertussis.</p>	<p>GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.</p> <p>Level 6, Quill 9, 112, Jalan Prof. Khoo Khay Kim, 46300 Petaling Jaya, Selangor.</p>

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2.	Foster Nexthaler 100 micrograms/ 6 micrograms per dose inhalation powder [Beclomethasone dipropionate 0.1mg, Formoterol fumarate 0.006mg]	<p>INDICATION :</p> <p>Removal of the following statement from the current approved indication: “Note: there are no relevant clinical data on the use of Foster NEXThaler for the treatment of acute asthma attacks.”</p> <p>POSOLOGY :</p> <p>There are two treatment approaches: A. Maintenance therapy: Foster NEXThaler is taken as regular maintenance treatment with a separate as needed rapid-acting bronchodilator. B. Maintenance and reliever therapy: Foster NEXThaler is taken as regular maintenance treatment and as needed in response to asthma symptoms.</p> <p><u>A. Maintenance therapy</u> Patients should be advised to have their separate rapid-acting bronchodilator available for rescue use at all times.</p> <p><u>B. Maintenance and reliever therapy</u> Patients take their daily maintenance dose of Foster NEXThaler and in addition take Foster NEXThaler as needed in response to asthma symptoms. Patients should be advised to always have Foster NEXThaler available for rescue use.</p> <p>Foster NEXThaler maintenance and reliever therapy should especially be considered for patients with:</p> <ul style="list-style-type: none"> • not fully controlled asthma and in need of reliever medication • asthma exacerbations in the past requiring medical intervention <p>Close monitoring for dose-related adverse effects is needed in patients who frequently take high numbers of Foster NEXThaler as-needed inhalations.</p>	<p>ORIENT EUROPHARMA (M) SDN. BHD. E-08, Garden Shoppe, One City, Jalan USJ 25/1C, 47650 Subang Jaya, Selangor.</p>

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		<p>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.</p> <p>The maximum daily dose is 8 inhalations.</p> <p>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.</p>	