

Product Update:

beclometasone dipropionate and formoterol fumarate dihydrate metered dose inhaler 100microgram / 6microgram (Fostair®) (No: 976/14)

Chiesi Ltd

06 June 2014

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

beclometasone dipropionate and formoterol fumarate dihydrate metered dose inhaler 100microgram / 6microgram (Fostair®) is accepted for use within NHS Scotland.

Indication under review: Symptomatic treatment of patients with severe COPD (FEV₁ <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.

Fostair® should be used in patients for whom beclometasone and formoterol are appropriate choices of corticosteroid and long-acting beta₂-agonist respectively, and for whom a metered dose inhaler is an appropriate delivery device.

The introduction of Fostair® is likely to be cost neutral. The 100mcg dose of beclometasone in Fostair® is not bioequivalent to a 100mcg dose of beclometasone in several other inhaler formulations.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 16 May 2014.

**Co-Vice Chairman
Scottish Medicines Consortium**

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