Providing advice about the status of all newly licensed medicines



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Product Update

fluticasone proprionate and formoterol fumarate metered dose inhaler, 50microgram/5microgram, 125microgram/5 microgram 250microgram/10 microgram (flutiform®) (No:736/11)

Napp Pharmaceuticals Ltd

07 October 2011 (Issued 7 September, 2012)

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

fluticasone proprionate and formoterol fumarate metered dose inhaler (flutiform®) is accepted for use in NHS Scotland.

Indication under review: in the regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting β_2 agonist (LABA)] is appropriate:

- for patients not adequately controlled on ICS and 'as required' inhaled short-acting β₂ agonist or
- for patients already adequately controlled on both an ICS and a LABA.

Flutiform® should be used in patients for whom fluticasone and formoterol are appropriate choices of corticosteroid and long-acting beta-agonist, respectively, and for whom a metered dose inhaler is an appropriate delivery device. It has demonstrated clinical non-inferiority to another combination product containing a corticosteroid and long-acting beta₂-agonist and may offer cost savings.

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 23 August 2012.

Chairman, Scottish Medicines Consortium