

Abbreviated Submission

fluticasone propionate/ formoterol fumarate 50microgram/5microgram,
125microgram/5microgram pressurised inhalation, suspension

(Flutiform k-haler[®])

SMC2016

Napp Pharmaceuticals Ltd

4 May 2018

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 propionate/ formoterol fumarate (Flutiform k-haler[®]) is accepted for use within NHS Scotland.

Indication under review: for 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 with ICS as 'as required' inhaled short-acting β_2 -agonist or
- For patients already adequately controlled on both ICS and a LABA

Flutiform k-haler is a breath-actuated inhaler that is bioequivalent to Flutiform metered-dose inhaler (pMDI) and costs the same.

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 15 March 2018.

Chairman
Scottish Medicines Consortium

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