

Product Update:

indacaterol maleate 143micrograms (equivalent to 110microgram indacaterol) with glycopyrronium bromide 63micrograms (equivalent to 50microgram glycopyrronium) inhalation powder hard capsules (Ultibro[®] Breezhaler[®] 85microgram/43microgram [delivered dose])

(No: 922/13)

Novartis Pharmaceuticals UK Limited

08 November 2013 (*Issued 07 November 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

indacaterol maleate plus glycopyrronium bromide inhalation powder hard capsules (Ultibro[®] Breezhaler[®]) is accepted for use within NHS Scotland.

Indication under review: maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

For patients in whom the combination of indacaterol maleate and glycopyrronium bromide is an appropriate choice of therapy, Ultibro[®] Breezhaler[®] provides the two ingredients in a single hard capsule at a lower cost than the individual components.

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 20 October 2014.

**Chairman,
Scottish Medicines Consortium**