



formoterol fumarate dihydrate / glycopyrronium / budesonide 5mcg/7.2mcg/160mcg pressurised inhalation, suspension (Trixeo® Aerosphere)

AstraZeneca

15 January 2021

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

formoterol fumarate dihydrate / glycopyrronium / budesonide (Trixeo® Aerosphere) is accepted for restricted use within NHSScotland.

Indication under review: maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist.

SMC restriction: in patients with severe COPD (forced expiratory volume in one second [FEV₁] less than 50% predicted normal).

Formoterol fumarate dihydrate / glycopyrronium / budesonide (Trixeo® Aerosphere) offers an additional treatment choice of long-acting beta2-agonist (LABA), long-acting muscarinic antagonist (LAMA) and inhaled corticosteroid (ICS) in a single inhaler.

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 01 December 2020.

Chairman
Scottish Medicines Consortium