15 October 2020
EMA/CHMP/64785/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Trixeo Aerosphere

Formoterol / glycopyrronium bromide/ budesonide

On 15 October 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trixeo Aerosphere, intended for maintenance treatment of chronic obstructive pulmonary disease (COPD) in adults whose disease is not adequately controlled. The applicant for this medicinal product is AstraZeneca AB.

Trixeo Aerosphere will be available as a pressurised inhalation suspension; each actuation will contain 5 micrograms of formoterol fumarate dihydrate, glycopyrronium bromide 9 micrograms, equivalent to 7.2 micrograms of glycopyrronium, and budesonide 160 micrograms. Formoterol is a long-acting $beta_2$ receptor agonist (LABA), glycopyrronium bromide is a long-acting muscarinic receptor antagonist (LAMA) and budesonide is an inhaled glucocorticoid. Formoterol and glycopyrronium bromide produce relaxation of bronchial smooth muscle helping to dilate the airways and make breathing easier, whereas budesonide reduces inflammation in the lungs (ATC code: R03AL11).

The benefits of Trixeo Aerosphere are its ability to reduce the rate of moderate or severe COPD exacerbations as defined by rate of moderate or severe COPD exacerbations over 52 weeks and improve lung function measured as change from baseline in morning pre-dose trough FEV_1 over 24 weeks.

The most common side effects are pneumonia (4.6%), headache (2.7%) and urinary tract infection (2.7%).

The full indication is:

> Trixeo Aerosphere is indicated as a 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 (for effects on symptoms control and prevention of exacerbations see section 5.1).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.