11 November 2021
EMA/CHMP/627233/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Riltrava Aerosphere

formoterol/ glycopyrronium bromide/ budesonide

On 11 November 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Riltrava 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.

Riltrava 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 Riltrava 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 application for Riltrava Aerosphere was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Riltrava Aerosphere is Trixeo Aerosphere.

The full indication is:

Riltrava Aerosphere is indicated as a maintenance treatment in adult patients with moderate to

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