23 July 2026
EMADOC-1700519818-3346632
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Riltrava Aerosphere

formoterol/glycopyrronium bromide/budesonide

On 23 July 2026 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Riltrava Aerosphere. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a new strength of the pressurised inhalation suspension (5 micrograms of formoterol fumarate dihydrate, glycopyrronium bromide 18 micrograms, equivalent to 14.4 micrograms of glycopyrronium, and budesonide 160 micrograms) associated with a new indication as follows:

> Riltrava Aerosphere is indicated as a maintenance treatment of asthma in patients 12 years of age and older who are not adequately controlled by a combination of a medium dose inhaled corticosteroid and a long-acting beta2-agonist.

For information, the full indications for Riltrava Aerosphere will be as follows:[2]

> Riltrava 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).
>
> **Riltrava Aerosphere is indicated as a maintenance treatment of asthma in patients 12 years of age and older who are not adequately controlled by a combination of a medium dose inhaled corticosteroid and a long-acting beta2-agonist.**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.
[2] New text in bold.

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