18 October 2018
EMA/CHMP/70534/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Bevespi Aerosphere

glycopyrronium / formoterol fumarate dihydrate

On 18 October 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Bevespi Aerosphere, intended for the maintenance treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). The applicant for this medicinal product is AstraZeneca AB.

Bevespi Aerosphere is a fixed dose combination of a long-acting beta-2 receptor agonist (formoterol fumarate dihydrate) and a long-acting muscarinic antagonist (glycopyrronium). It will be available as a suspension for inhalation (7.2 micrograms / 5.0 micrograms). Formoterol and glycopyrronium relax bronchial smooth muscle helping to dilate the airways and make breathing easier (ATC code: R03AL07).

The benefit with Bevespi Aerosphere is its ability to relieve symptoms such as shortness of breath, wheezing and cough in patients with COPD. The most commonly reported adverse reactions are headache (1.9%), nausea (1.4%), muscle spasms (1.4%), and dizziness (1.3%).

The full indication is: "Bevespi Aerosphere is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD) (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.

[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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