



12 November 2020
EMA/599401/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Trimbow

beclometasone / formoterol / glycopyrronium bromide

On 12 November 2020, 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 Trimbow. The marketing authorisation holder for this medicinal product is Chiesi Farmaceutici S.p.A.

The CHMP adopted a new pharmaceutical strength (172 micrograms/5 micrograms/9 micrograms) with a new indication as follows:

Asthma

Maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and high dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.

The CHMP also adopted this indication for the already authorised strength (87 micrograms/5 micrograms/9 micrograms) as follows:²

COPD

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 a 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).

Asthma

Maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous

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

² New text in **bold**



year.

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