13 December 2018
EMA/598794/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Trimbow

beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium

On 13 December 2018, 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 an extension to the existing indication as follows:[2]

> "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 beta$_2$-agonist **or a combination of a long-acting beta$_2$-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 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.

[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

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