18 May 2017
EMA/CHMP/290028/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Trimbow

beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium

On 18 May 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trimbow, intended for the maintenance treatment of moderate to severe chronic obstructive pulmonary disease (COPD). The applicant for this medicinal product is Chiesi Farmaceutici S.p.A., Italy.

Trimbow is a triple combination of an inhaled glucocorticoid (beclometasone dipropionate), a long-acting beta2 receptor agonist (formoterol fumarate dihydrate) and a long-acting muscarinic antagonist (glycopyrronium bromide). It will be available as a pressurised metered dose inhaler delivering a solution with a nominal dose per actuation of 87 micrograms / 5 micrograms / 9 micrograms of the active substances respectively. Beclometasone reduces inflammation in the lungs, whereas formoterol and glycopyrronium produce relaxation of bronchial smooth muscle helping to dilate the airways and make breathing easier (ATC code: R03AL09).

The benefits with Trimbow are its ability to relieve and prevent symptoms such as shortness of breath, wheezing and cough and to reduce exacerbations of COPD symptoms. The most common side effects of Trimbow are oral candidiasis, muscle spasm and dry mouth.

The full indication is:

“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 (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.

[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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