



25 September 2014  
EMA/CHMP/443986/2014  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Budesonide/Formoterol Teva Pharma B.V.

budesonide / formoterol

On 25 September 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Budesonide/Formoterol Teva Pharma B.V. 160/4.5 and 320/9 micrograms inhalation powder intended for intended for the regular treatment of asthma in adults, where use of a combination (inhaled corticosteroid and long-acting  $\beta_2$  adrenoceptor agonist) is appropriate (in patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting  $\beta_2$  adrenoceptor agonists, or in patients already adequately controlled on both inhaled corticosteroids and long-acting  $\beta_2$  adrenoceptor agonists).

The applicant for this medicinal product is Teva Pharma B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

Budesonide/Formoterol Teva Pharma B.V. (ATC code: R03AK07) is a fixed-dose combination of the active substances budesonide, an inhaled glucocorticosteroid, and formoterol, a selective long-acting inhaled  $\beta_2$  adrenoceptor agonist. Budesonide has anti-inflammatory activity in the lungs and formoterol has an effect on  $\beta_2$  adrenergic receptors on bronchial smooth muscle to produce relaxation and bronchodilatation.

The benefits with Budesonide/Formoterol Teva Pharma B.V. are its ability to provide overall asthma control. The most common side effects are predictable adverse reactions of  $\beta_2$  adrenoceptor agonist therapy, such as tremor and palpitations.

A Risk Management plan for Budesonide/Formoterol Teva Pharma B.V. will be implemented as part of the marketing authorisation.

The approved indications are:

Budesonide/Formoterol Teva Pharma B.V. is indicated in adults 18 years of age and older only.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



## Asthma

Budesonide/Formoterol Teva Pharma B.V. is indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting  $\beta_2$  adrenoceptor agonist) is appropriate:

- in patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting  $\beta_2$  adrenoceptor agonists.

or

- in patients already adequately controlled on both inhaled corticosteroids and long-acting  $\beta_2$  adrenoceptor agonists.

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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Budesonide/Formoterol Teva Pharma B.V. and therefore recommends the granting of the marketing authorisation.

Medicinal product no longer authorised