30 January 2020
EMA/CHMP/44189/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Budesonide/Formoterol Teva Pharma B.V.

budesonide / formoterol fumarate dihydrate

On 30 January 2020, 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., intended for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

The applicant for this medicinal product is Teva Pharma B.V.

Budesonide/Formoterol Teva Pharma B.V. will be available as an inhalation powder in two strengths (160 micrograms budesonide with 4.5 micrograms formoterol fumarate dihydrate and 320 micrograms budesonide with 9 micrograms formoterol fumarate dihydrate). The active substance budesonide is an inhaled glucocorticosteroid and the active substance formoterol fumarate dihydrate is a selective long-acting inhaled beta-2 adrenoceptor agonist (ATC code: R03AK07). Budesonide has anti-inflammatory activity in the airways and formoterol acts mainly 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 improve pulmonary function and reduce exacerbations in COPD and provide overall asthma control. The most common side effects are predictable adverse reactions of beta-2 adrenoceptor agonist therapy, such as tremor and palpitations.

Budesonide/Formoterol Teva Pharma B.V. is a duplicate of DuoResp Spiromax which was approved via the centralised procedure on 28 April 2014.

The full indication is:

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

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:

[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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- 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.

COPD

Symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV_1) < 70% predicted normal (post bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators."

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.