25 September 2014
EMA/CHMP/436529/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vylaer Spiromax

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 Vylaer Spiromax 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 β_2 adrenoceptor agonist) is appropriate (in patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting β_2 adrenoceptor agonists, or in patients already adequately controlled on both inhaled corticosteroids and long-acting β_2 adrenoceptor agonists), and in the symptomatic treatment of adult patients with severe COPD (FEV_1 < 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.

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.

Vylaer Spiromax (ATC code: R03AK07) is a fixed-dose combination of the active substances budesonide, an inhaled glucocorticosteroid, and formoterol, a selective long-acting inhaled β_2 adrenoceptor agonist. Budesonide has anti-inflammatory activity in the lungs and formoterol has an effect on β_2 adrenergic receptors on bronchial smooth muscle to produce relaxation and bronchodilatation.

The benefits with Vylaer Spiromax 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 β_2 adrenoceptor agonist therapy, such as tremor and palpitations.

A Risk Management plan for Vylaer Spiromax will be implemented as part of the marketing authorisation.

[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

The approved indications are:

Vylaer Spiromax is indicated in adults 18 years of age and older only.

Asthma

Vylaer Spiromax is indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β_2 adrenoceptor agonist) is appropriate:

- in patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting β_2 adrenoceptor agonists.

or

- in patients already adequately controlled on both inhaled corticosteroids and long-acting β_2 adrenoceptor agonists.

COPD

Symptomatic treatment of patients with severe COPD (FEV_1 < 50% predicted normal) 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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Vylaer Spiromax and therefore recommends the granting of the marketing authorisation.