23 June 2016
EMA/CHMP/431246/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Airexar Spiromax

salmeterol xinafoate/fluticasone propionate

On 23 June 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Airexar Spiromax, intended for the treatment of severe asthma and COPD in adult patients. The applicant for this medicinal product is Teva B.V.

Airexar Spiromax will be available in a single high strength 50µg/500µg inhalation powder. The active substances of Airexar Spiromax are salmeterol xinafoate, a selective long-acting inhaled β adrenoceptor agonist, and fluticasone propionate, an inhaled glucocorticoid with anti-inflammatory activity in the lungs (ATC code: R03AK06). Airexar Spiromax will not be available on the market at strengths lower than 50µg/500µg. When it is appropriate to titrate down to a lower strength, a change to an alternative fixed-dose combination of salmeterol and fluticasone propionate containing a lower dose of the inhaled corticosteroid is required. Airexar Spiromax should not be used for the initiation of treatment in patients with severe asthma unless the requirement for such a high dose of the corticosteroid together with a long-acting β2 agonist has been established previously.

The benefits with Airexar Spiromax are its ability to improve pulmonary function and symptoms and to reduce exacerbations. Patients should be provided with training by the prescribing healthcare professional to ensure that they understand how to use the inhaler correctly and that they understand the need to breathe in forcefully when inhaling to obtain the required dose. It is important that the patient inhales forcefully to ensure optimal dosing.

The most common side effects (frequency ≥1 in 10 patients) are headache and nasopharyngitis. Paradoxical bronchospasm may occur with an immediate increase in wheezing and shortness of breath after dosing. If this occurs Airexar Spiromax should be discontinued immediately and the patient should be treated with a rapid-acting bronchodilator straightaway. Due to the fluticasone propionate component, hoarseness and candidiasis (thrush) of the mouth and throat and, rarely, of the oesophagus, can occur in some patients.

Airexar Spiromax is a hybrid of Seretide Diskus, which has been authorised in the EU since 7 September 1998. Studies have demonstrated the satisfactory quality of Airexar Spiromax, and its bioequivalence to

[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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the reference product Seretide Diskus.

The full indication is:

“Airexar Spiromax is indicated for use in adults aged 18 years and older only.

Asthma

Airexar Spiromax is indicated for the regular treatment of patients with severe asthma where use of a combination product (inhaled corticosteroid and long-acting β_2 agonist) is appropriate:

- patients not adequately controlled on a lower strength corticosteroid combination product

or

- patients already controlled on a high dose inhaled corticosteroid and long-acting β_2 agonist.

Chronic Obstructive Pulmonary Disease (COPD)

Airexar Spiromax is indicated for the symptomatic treatment of patients with COPD, with a $FEV_1 < 60\%$ predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy”.

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.