28 January 2021
EMA/52882/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Seffalair Spiromax

salmeterol / fluticasone

On 28 January 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Seffalair Spiromax, intended for the treatment of asthma in adults and adolescents aged 12 years and older. The applicant for this medicinal product is Teva B.V.

Seffalair Spiromax will be available as a powder for inhalation. Each delivered dose contains 12.75 micrograms of salmeterol (as salmeterol xinafoate) and 100 or 202 micrograms of fluticasone propionate. Salmeterol is a selective long-acting inhaled beta-2 adrenoceptor agonist, and fluticasone, an inhaled glucocorticoid with anti-inflammatory activity in the lungs (ATC code: R03AK06).

The benefits with Seffalair Spiromax are its ability to improve pulmonary function and asthma symptoms. 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 are nasopharyngitis and headache. Paradoxical bronchospasm may occur with an immediate increase in wheezing and shortness of breath after dosing. If this occurs Seffalair Spiromax should be discontinued immediately and the patient should be treated with a rapid-acting bronchodilator straightaway. Due to the fluticasone component, hoarseness and candidiasis (thrush) of the mouth and throat and, rarely, of the oesophagus, can occur in some patients.

The full indication is:

> Seffalair Spiromax is indicated in the regular treatment of asthma in adults and adolescents aged 12 years and older not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β_2 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

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.