22 April 2021
EMA/CHMP/218046/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

BiResp Spiromax

budesonide / formoterol

On 22 April 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product BiResp Spiromax. The marketing authorisation holder for this medicinal product is Teva Pharma B.V..

The CHMP adopted an extension to the existing indication as follows:[2]

Asthma

BiResp Spiromax is indicated in adults **and adolescents (12 years and older)** for the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β2 adrenoceptor agonist) is appropriate:

-in patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting β2 adrenoceptor agonists.

or

-in patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists.

COPD

BiResp Spiromax is indicated in adults, aged 18 years and older for the 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 updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[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
[2] New text in bold

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