



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2014
EMA/CHMP/137719/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Revinty Ellipta Fluticasone furoate/vilanterol

On 20 March 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 Revinty Ellipta, fluticasone furoate 184 µg/vilanterol 22 µg and fluticasone furoate 92 µg/vilanterol 22 µg, inhalation powder, pre-dispensed, intended for the regular treatment of asthma and Revinty Ellipta, fluticasone furoate 92 µg/vilanterol 22 µg, inhalation powder, pre-dispensed, for the symptomatic treatment of chronic obstructive pulmonary disease (COPD). The applicant for this medicinal product is Glaxo Group Limited. 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.

Revinty Ellipta (ATC code: R03AK10, Drugs for obstructive airways diseases, Adrenergics and other drugs for obstructive airway disease) is a fixed-dose combination of the active substance fluticasone furoate, a synthetic corticosteroid with potent anti-inflammatory activity, and the active substance vilanterol, a selective long-acting beta₂-receptor agonist. Beta₂-receptor agonists stimulate intracellular adenylate cyclase which converts ATP into cyclic AMP. Increased cyclic AMP levels cause relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.

The benefits with Revinty Ellipta in the symptomatic treatment of COPD are its ability to improve the weighted mean FEV₁ 0-4 hours at day in 6 months studies versus placebo and to improve the annual rate of moderate and severe exacerbations in one year clinical studies versus vilanterol 25 µg.

The benefits with Revinty Ellipta in the regular treatment of asthma are its ability to improve trough FEV₁ in a 24 weeks study comparing the 184/22 µg strength versus placebo, fluticasone furoate 200 µg and fluticasone propionate 1000 µg and to reduce the number of severe exacerbations in a 24 weeks study comparing the 92/22 µg strength versus fluticasone furoate 100 µg.

The most common side effects are headache and nasopharyngitis and upper respiratory tract infections. Cases of pneumonia have been reported in patients taking Revinty Ellipta in both

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.



indications. Pneumonia has been included as an important identified risk in the Risk Management Plan and the applicant will conduct two post-authorisation safety studies to further investigate this risk.

A Pharmacovigilance plan for Revinty Ellipta will be implemented as part of the marketing authorisation.

The approved indications are:

“Asthma

Revinty Ellipta is indicated for the regular treatment of asthma in adults and adolescents aged 12 years old and older where use of a combination medicinal product (long-acting beta₂-agonist and inhaled corticosteroid) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and “as needed” inhaled short acting beta₂-agonists.

COPD (Chronic Obstructive Pulmonary Disease)

Revinty Ellipta is indicated for the symptomatic treatment of adults with COPD with a FEV₁ < 70% predicted normal (post-bronchodilator) with an exacerbation history 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.

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