14 September 2017
EMA/CHMP/587955/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Elebrato Ellipta

fluticasone furoate / umeclidinium / vilanterol

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Elebrato Ellipta, intended for the maintenance treatment of adult patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD).

The applicant for this medicinal product is GlaxoSmithKline Trading Services.

Elebrato Ellipta will be available as 92 µg / 55 µg / 22 µg Inhalation powder, pre-dispensed. The active substances of Elebrato Ellipta are fluticasone furoate / umeclidinium / vilanterol, Drugs for obstructive airways disease (ATC code: R03AL08). Both umeclidinium (a long-acting muscarinic receptor antagonist) and vilanterol (a selective long-acting, beta$_2$-adrenergic receptor agonist) act locally to produce bronchodilatation by separate mechanisms . Umeclidinium exerts its bronchodilatory activity by competitively inhibiting the binding of acetylcholine with muscarinic receptors on airway smooth muscle.

Vilanterol stimulates the enzyme catalysing AMP into cyclic AMP leading to relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells.
Fluticasone furoate is a corticosteroid and reduces inflammation .

The benefits with Elebrato Ellipta are its ability to improve lung function (as defined by change from baseline trough FEV$_1$ at Week 24; co-primary endpoint) compared with budesonide/formoterol (BUD/FOR) 400 /12 micrograms administered twice-daily in moderate to severe patients not adequately controlled with corticosteroid and long acting B agonist.

The most common side effects are nasopharyngitis (7%), upper respiratory tract infection (2%) and headache (5%).

The full indication is:

Elebrato Ellipta is indicated as a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting β2-agonist (for effects on symptom control see section 5.1).

[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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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.