20 February 2014
EMA/65875/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ulunar Breezhaler

indacaterol / glycopyrronium bromide

On 20 February 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 Ulunar Breezhaler, 85 mcg/43 mcg, inhalation powder, hard capsule intended for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). The applicant for this medicinal product is Novartis Europharm Ltd. 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.

Ulunar Breezhaler (R03AL04) is a fixed-dose combination of the active substances indacaterol, a beta-2-adrenergic agonist, and glycopyrronium bromide, an anticholinergic. Indacaterol activates the relaxation of the muscles of the airways, and glycopyrronium blocks the bronchoconstrictor action of acetylcholine on airway smooth muscle cells, thereby dilating the airways.

The benefits with Ulunar Breezhaler are its ability to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). The most common side effects are the beta-adrenergic and anticholinergic symptoms related to the individual components of the combination.

A pharmacovigilance plan for Ulunar Breezhaler will be implemented as part of the marketing authorisation.

The approved indication is: "Ulunar Breezhaler is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)."

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.

[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 CHMP, on the basis of quality, safety and efficacy data submitted for the reference product Ultibro Breezhaler, considers there to be a favourable benefit-to-risk balance for Ulunar Breezhaler and therefore recommends the granting of the marketing authorisation.