[1]02 April 2020
EMA/CHMP/74496/2020 Rev.
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[2] (initial authorisation)

Atectura Breezhaler

indacaterol / mometasone furoate

On 02 April 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Atectura Breezhaler, intended for the treatment of asthma.

The applicant for this medicinal product is Novartis Europharm Limited.

Atectura Breezhaler will be available as 125 µg/260 µg, 125 µg/127.5 µg and 125 µg/62.5 µg hard capsules containing a powder for inhalation. The active substances of Atectura Breezhaler are indacaterol and mometasone furoate, medicines for obstructive airway diseases (ATC code: R03AK14). Indacaterol is a long acting beta-2 adrenergic agonist and acts locally in the lung as a bronchodilator. Mometasone furoate is an inhaled corticosteroid with high affinity for glucocorticoid receptors and anti-inflammatory properties.

The benefits with Atectura Breezhaler are its ability to improve pulmonary function and to provide overall asthma control. The most common side effects are asthma (exacerbation), nasopharyngitis, upper respiratory tract infection and headache.

The full indication is:

> Atectura Breezhaler is indicated as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short acting beta2-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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Adopted via written procedure on 02 April 2020
[2] 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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