oate30 April 2020
EMA/CHMP/138288/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zimbus Breezhaler

indacaterol / glycopyrronium / mometasone furoate

On 30 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 Zimbus Breezhaler, for maintenance treatment of asthma in adults whose disease is not adequately controlled. The applicant for this medicinal product is Novartis Europharm Limited.

Zimbus Breezhaler will be available as a 114 µg / 46 µg / 136 µg inhalation powder in hard capsules. The active substances of Zimbus Breezhaler are indacaterol, glycopyrronium and mometasone furoate. Indacaterol is a long-acting beta$_2$-adrenergic agonist (LABA), which relaxes bronchial smooth muscle; glycopyrronium is a long-acting muscarinic receptor antagonist (LAMA), which dilates the airways by blocking cholinergic bronchoconstrictor action; and mometasone furoate is a synthetic corticosteroid with anti-inflammatory activity.

The benefits with Zimbus Breezhaler are its ability to improve lung function as measured by FEV_1 and to reduce exacerbations of asthma.

The most common side effects are asthma (exacerbation), nasopharyngitis, upper respiratory tract infection and headache.

The full indication is:

> Zimbus Breezhaler is indicated as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union