EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 April 2020
EMA/CHMP/233503/2020
Media and Public Relations

Press release

First triple combination therapy for asthma with optional electronic sensor

EMA's human medicines committee (CHMP) has recommended granting a marketing authorisation in the European Union for Enerzair breezhaler, a new asthma treatment which includes an optional digital sensor.

This is the first asthma triple combination therapy; it consists of a fixed dose combination of three active substances (indacaterol, glycopyrronium and mometasone furoate) in capsules, to be administered using an inhaler. An optional electronic sensor may also be co-packed with the product. The sensor will be attached to the base of the inhaler to collect data on the use of the inhaler by the patient. The sensor will send the data to an app on a smart phone or other suitable device.

Asthma is a chronic lung disease caused by the interaction of genetic and environmental factors. It causes airways to narrow and swell and produce mucus. The main symptoms are coughing, wheezing and shortness of breath. Severe asthma attacks can lead to hospitalisation. Currently, there is no cure for asthma and treatments available are used to control the symptoms or to reduce the frequency and severity of the attacks.

Enerzair breezhaler is indicated for adult patients whose symptoms are not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a high dose of an inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year. It is a long-term treatment aimed at symptom control by preventing exacerbations and preserving lung function.

Indacaterol is a long-acting beta agonist that acts locally by widening the airways in the lungs. It has a rapid onset of action and a long duration of action. Glycopyrronium is an inhaled long-acting muscarinic receptor antagonist (anticholinergic) which dilates the airways by blocking the action of the neurotransmitter acetylcholine on smooth muscle cells. Mometasone furoate is a synthetic corticosteroid with high affinity for glucocorticoid receptors and anti-inflammatory properties.

The safety and efficacy of Enerzair Breezhaler in adult patients with persistent asthma was evaluated in a phase III randomised, double blind study which showed clinically meaningful improvements in lung function and reduction of exacerbations. The main side effects observed in the study are asthma exacerbation, nasopharyngitis (common cold), upper respiratory tract infection and headache.

The CHMP also adopted a positive opinion for Zimbus Breezhaler (indacaterol, glycopyrronium and mometasone furoate), which is a duplicate of Enerzair Breezhaler for the treatment of asthma.

The opinion adopted by the CHMP is an intermediary step on Enerzair Breezhaler's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. The applicant for Enerzair Breezhaler is Novartis Europharm Limited.
2. The safety and efficacy of Enerzair Breezhaler in paediatric patients below 18 years of age have not been established. No data are available.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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