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EPAR summary for the public

Onbrez Breezhaler

indacaterol

This is a summary of the European public assessment report (EPAR) for Onbrez Breezhaler. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Onbrez Breezhaler.

What is Onbrez Breezhaler?

Onbrez Breezhaler is a medicine that contains the active substance indacaterol. It is available as capsules containing a powder for inhalation (150 and 300 micrograms).

What is Onbrez Breezhaler used for?

Onbrez Breezhaler is used to keep the airways open in adults with chronic obstructive pulmonary disease (COPD). COPD is a long-term disease in which the airways and air sacs inside the lungs become damaged or blocked, leading to difficulty breathing air in and out of the lungs.

The medicine can only be obtained with a prescription.

How is Onbrez Breezhaler used?

Onbrez Breezhaler capsules are only used with a Onbrez Breezhaler inhaler and must not be swallowed. To take a dose, the patient places a capsule into the inhaler and breathes the powder in through the mouth.

The recommended dose is one 150 microgram capsule, once a day at the same time each day. A dose of one 300 microgram capsule may be used in cases of severe COPD, but this must only be done on the doctor's instructions.

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How does Onbrez Breezhaler work?

The active substance in Onbrez Breezhaler, indacaterol, is a beta 2 adrenergic receptor agonist. It works by attaching to beta 2 receptors that are found in the muscle cells of many organs and that cause the muscles to relax. When Onbrez Breezhaler is inhaled, indacaterol reaches the receptors in the airways and activates them. This causes the muscles of the airways to relax, helping to keep the airways open and allowing the patient to breathe more easily.

How has Onbrez Breezhaler been studied?

In three main studies involving over 4,000 patients with COPD, Onbrez Breezhaler at different doses has been compared with placebo (a dummy treatment), tiotropium or formoterol (other inhaled medicines used to treat COPD). The main measure of effectiveness was how Onbrez Breezhaler compared with placebo in improving patients' forced expiratory volumes (FEV_1) after 12 weeks. FEV_1 is the most air a person can breathe out in one second.

What benefit has Onbrez Breezhaler shown during the studies?

Onbrez Breezhaler was more effective than placebo at improving how well the lungs work in patients with COPD. On average, the improvement in FEV_1 in patients who received Onbrez Breezhaler was between 150 to 190 ml, while for patients who received placebo the change in FEV_1 ranged from a decrease of 10 ml to an increase of 20 ml. Overall, the effects of the 150 and 300 microgram doses of Onbrez Breezhaler were similar, but the results showed that the 300 microgram dose may provide better relief in patients with more severe disease.

What is the risk associated with Onbrez Breezhaler?

The most common side effects with Onbrez Breezhaler (seen in between 1 and 10 patients in 100) are nasopharyngitis (inflammation of the nose and throat), upper respiratory tract infection (colds), sinusitis (inflammation of the sinuses), dizziness, headache, chest pain, cough, oropharyngeal (mouth and throat) pain including throat irritation, rhinorrhoea (runny nose), , muscle spasm (cramps) and peripheral oedema (swelling, especially of the ankles and feet). For the full list of all side effects reported with Onbrez Breezhaler, see the package leaflet.

Onbrez Breezhaler must not be used in people who are hypersensitive (allergic) to indacaterol, lactose or any of the other ingredients.

Why has Onbrez Breezhaler been approved?

The CHMP decided that Onbrez Breezhaler's benefits are greater than its risks and recommended that Onbrez Breezhaler be given marketing authorisation.

What measures are being taken to ensure the safe use of Onbrez Breezhaler?

The company that makes Onbrez Breezhaler will ensure that doctors who are expected to prescribe the medicine and pharmacists in all Member States are provided with a card containing information on how the medicine is used.

Other information about Onbrez Breezhaler

European Commission granted a marketing authorisation valid throughout the European Union for Onbrez Breezhaler on 30 November 2009.

The full EPAR for Onbrez Breezhaler can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Onbrez Breezhaler, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2012.