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EPAR summary for the public

Oslif Breezhaler

indacaterol

This is a summary of the European public assessment report (EPAR) for Oslif Breezhaler. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Oslif Breezhaler.

For practical information about using Oslif Breezhaler, patients should read the package leaflet or contact their doctor or pharmacist.

What is Oslif Breezhaler and what is it used for?

Oslif Breezhaler is a medicine that 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. Oslif Breezhaler is used for maintenance (regular) treatment.

The medicine contains the active substance indacaterol.

How is Oslif Breezhaler used?

Oslif Breezhaler capsules, which contain a powder for inhalation, are only used with a Oslif Breezhaler inhaler and must not be swallowed. To receive 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. The doctor may increase the dose to one 300 microgram capsule once a day in cases of severe COPD.

The medicine can only be obtained with a prescription.

How does Oslif Breezhaler work?

The active substance in Oslif 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

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muscles to relax. When Oslif 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.

What benefits of Oslif Breezhaler have been shown in studies?

In three main studies involving over 4,000 patients with COPD, Oslif Breezhaler was compared with placebo (a dummy treatment), tiotropium or formoterol (other inhaled medicines used to treat COPD). The main measure of effectiveness was based on changes in the patients' forced expiratory volumes (FEV_1, the maximum volume of air a person can breathe out in one second) after 12 weeks.

Oslif Breezhaler was more effective than placebo at improving how well the lungs work in patients with COPD. On average, the increase in FEV_1 in patients who received Oslif 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 Oslif Breezhaler were similar, but the results showed that the 300 microgram dose may provide better relief in patients with more severe disease. The increase in FEV_1 was 130 ml with tiotropium, and 80 ml with formoterol.

What are the risks associated with Oslif Breezhaler?

The most common side effects with Oslif Breezhaler (which may affect more than 1 in 10 people) are nasopharyngitis (inflammation of the nose and throat) and upper respiratory tract infection (infection of the nose and throat). Other common side effects include chest pain, cough and muscle cramps.

For the full list of all side effects and restrictions with Oslif Breezhaler, see the package leaflet.

Why is Oslif Breezhaler approved?

The European Medicines Agency concluded that Oslif Breezhaler was shown to be effective at improving the lung function in COPD. The Agency also noted that there were no major safety concerns with Oslif Breezhaler, with side effects being manageable and similar to other beta-2 adrenergic receptor agonist medicines. Therefore, the Agency decided that Oslif Breezhaler's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Oslif Breezhaler?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Oslif Breezhaler have been included in the summary of product characteristics and the package leaflet.

Other information about Oslif Breezhaler

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

The full EPAR for Oslif 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 Oslif Breezhaler, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2017.