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Zimbus Breezhaler (*indacaterol / glycopyrronium bromide / mometasone*)

An overview of Zimbus Breezhaler and why it is authorised in the EU

What is Zimbus Breezhaler and what is it used for?

Zimbus Breezhaler is an asthma medicine for inhalation. It is used for maintenance (regular) treatment in adults whose asthma is not controlled well enough with inhaled long-acting beta-2 agonist together with a high dose of an inhaled corticosteroid. It should be used for patients who have had at least one asthma attack (exacerbations) in the last year.

Zimbus Breezhaler contains the active substances indacaterol, glycopyrronium bromide and mometasone.

How is Zimbus Breezhaler used?

Zimbus Breezhaler is available as capsules for use in the inhaler supplied with the medicine. The medicine can only be obtained with a prescription.

The Zimbus Breezhaler capsule is placed in the inhaler and the patient breathes in the powder through the mouth. The patient should inhale the powder from one capsule once daily, at around the same time each day.

An electronic sensor is available for use with the medicine. When attached to the inhaler, it records the patient's use of the inhaler and it can send the information to the patient's smartphone or other mobile device. The sensor is optional and it is not needed for using the inhaler.

For more information about using Zimbus Breezhaler, see the package leaflet or contact your doctor or pharmacist.

How does Zimbus Breezhaler work?

The three active substances in Zimbus Breezhaler, indacaterol, glycopyrronium bromide and mometasone, have been in use in several inhaled medicines for treating patients with breathing disorders. They work in different ways to allow the patient to breathe more easily.

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Indacaterol is a long-acting beta-2 adrenergic receptor agonist. It relaxes the muscle around the airways into the lungs by activating targets called beta-2 receptors in the muscle cells. This helps to keep the airways open.

Glycopyrronium bromide is a muscarinic receptor antagonist. It blocks muscarinic receptors in muscle cells in the airways. Because these receptors help control the contraction of the airway muscles, blocking them causes the muscles to relax, helping to keep the airways open.

Mometasone is a corticosteroid that has anti-inflammatory effects. It works in a similar way to corticosteroid hormones in the body, reducing the activity of the immune system (the body's defences). Mometasone helps to keep the airways clear by blocking the release of substances, such as histamine, that are involved in inflammation and release of mucus in the airways.

What benefits of Zimbus Breezhaler have been shown in studies?

A main study involved 3,092 patients whose asthma was not well controlled on a combination of a long-acting beta-2 agonist and a corticosteroid used by inhalation. Patients had had at least one asthma exacerbation in the previous year. The study measured the change in patients' forced expiratory volume over 1 second (FEV_1, the maximum volume of air they could breathe out in 1 second) just before their next dose was due.

After 26 weeks of treatment, FEV_1 improved by 65 ml more in patients treated with Zimbus Breezhaler than in patients using an inhaler containing equivalent doses of indacaterol and mometasone, two of the three active substances in Zimbus Breezhaler.

What are the risks associated with Zimbus Breezhaler?

The most common side effects with Zimbus Breezhaler (which may affect more than 1 in 10 people) are worsening of asthma and nasopharyngitis (inflammation in the nose and throat). Other common side effects (which may affect up to 1 in 100 people) include upper respiratory tract infection (nose and throat infections) and headache.

For the full list of side effects and restrictions of Zimbus Breezhaler, see the package leaflet.

Why is Zimbus Breezhaler authorised in the EU?

In patients whose asthma is not controlled well enough on a combination of an inhaled long-acting beta-2 agonist and high-dose corticosteroid and who have had an exacerbation in the previous year, the improvement in FEV_1 with Zimbus Breezhaler was modest but considered to be clinically important. The side effects of Zimbus Breezhaler are similar to those of other inhaled medicines used for treating asthma.

The European Medicines Agency therefore decided that Zimbus Breezhaler's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Zimbus Breezhaler are continuously monitored. Side effects reported with Zimbus Breezhaler are carefully evaluated and any necessary action taken to protect patients.

Other information about Zimbus Breezhaler

Zimbus Breezhaler received a marketing authorisation valid throughout the EU on 03 July 2020.

Further information on Zimbus Breezhaler can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zimbus-breezhaler.

This overview was last updated in 07-2020.