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Atectura Breezhaler *(indacaterol / mometasone)*

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

What is Atectura Breezhaler and what is it used for?

Atectura Breezhaler is a medicine that is used to keep the airways open in adults and children aged 12 years and older whose asthma is not adequately controlled with inhaled corticosteroids and inhaled short acting beta-2 agonists. Atectura Breezhaler is used for maintenance (regular) treatment.

The medicine contains the active substances indacaterol and mometasone.

How is Atectura Breezhaler used?

Atectura Breezhaler capsules, which contain a powder for inhalation, are to be used only with the inhaler provided with each prescription and must not be swallowed. To receive a dose, the patient places a capsule into the inhaler and breathes in the powder through the mouth.

The recommended dose is one capsule, once a day at the same time each day. Patients should not use more than one capsule in a day. The capsules are available in three strengths (125 micrograms / 62.5 micrograms, 125 micrograms / 127.5 micrograms, 125 micrograms / 260 micrograms) and the doctor will decide which strength the patient should use based on the patient's need.

The medicine can only be obtained with a prescription.

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

How does Atectura Breezhaler work?

The two active substances in Atectura Breezhaler are well known and are present in several medicines used to treat respiratory obstructive diseases, either alone or in combination with other medicines.

Indacaterol is a long acting beta-2 adrenergic receptor agonist. It works by attaching to targets called beta-2 receptors in the muscle cells that surround the airways into the lungs. When Atectura Breezhaler is inhaled, indacaterol reaches the receptors 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. Mometasone belongs to a group of anti-inflammatory medicines known as corticosteroids. It works in a similar way to naturally occurring corticosteroid hormones, reducing the activity of the immune system. By attaching to receptors in various immune cells, it blocks the release of substances involved

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in the inflammation process, such as histamine, thereby helping to keep the airways clear and allowing the patient to breathe more easily.

What benefits of Atectura Breezhaler have been shown in studies?

In two main studies involving over 3,000 patients with asthma, Atectura Breezhaler was compared with mometasone alone or a combination of salmeterol and fluticasone (other inhaled medicines used to treat asthma). The main measure of effectiveness was based on changes in patients' forced expiratory volume (FEV_1, the maximum volume of air a person can breathe out in one second). FEV_1 was measured just before the next dose was due when it was likely to be at its lowest.

In the first study, Atectura Breezhaler was more effective than mometasone alone at improving how well the airways work in patients with asthma. The average FEV_1 in patients who received Atectura Breezhaler (125 micrograms/62.5 micrograms) was about 180 ml more than with an equivalent dose of mometasone after 12 weeks of treatment.

In the second study, medium and high strength Atectura Breezhaler led after 26 weeks to average FEV_1 of about 130 ml to 210 ml more than patients who received equivalent doses of mometasone. The treatment difference between high strength Atectura Breezhaler (125 micrograms/260 micrograms and the combination of salmeterol and fluticasone was about 40 ml in favour of Atectura Breezhaler.

The studies also showed an improvement in symptoms such as breathlessness and wheezing.

What are the risks associated with Atectura Breezhaler?

The most common side effects with Atectura 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 all side effects and restrictions with Atectura Breezhaler, see the package leaflet.

Why is Atectura Breezhaler authorised in the EU?

The European Medicines Agency concluded that Atectura Breezhaler was effective at improving lung function and symptoms in asthma. The Agency also noted that there were no major safety concerns with Atectura Breezhaler, with side effects being manageable and similar to other inhaled medicines of the same class. Therefore, the Agency decided that Atectura 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 Atectura Breezhaler?

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

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

Other information about Atectura Breezhaler

Atectura Breezhaler received a marketing authorisation valid throughout the EU on 30 May 2020.

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

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