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EPAR summary for the public

Xoterna Breezhaler

Indacaterol / glycopyrronium

This is a summary of the European public assessment report (EPAR) for Xoterna 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 Xoterna Breezhaler.

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

What is Xoterna Breezhaler and what is it used for?

Xoterna Breezhaler is a medicine that contains two active substances, indacaterol (85 micrograms) and glycopyrronium (43 micrograms). It is used as maintenance (regular) treatment to relieve symptoms of chronic obstructive pulmonary disease (COPD) in adults. 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.

How is Xoterna Breezhaler used?

Xoterna Breezhaler is available as capsules containing a powder for inhalation can only be obtained with a prescription.

The recommended dose is one inhalation once a day of the powder content of a single capsule. It is taken at the same time each day using the Xoterno Breezhaler device. The contents of the capsules must not be inhaled using any other device.

In patients with severely reduced kidney function Xoterna Breezhaler should only be used after a careful benefit-risk assessment.

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How does Xoterna Breezhaler work?

The active substances in Xoterna Breezhaler, indacaterol and glycopyrronium, work in different ways to widen the airways and improve breathing in COPD.

Indacaterol is a long-acting beta-2 agonist. It works by attaching to beta-2-adrenergic receptors found in the muscles of many organs including the airways of the lungs. When inhaled, indacaterol reaches the receptors in the airways and activates them. This causes the muscles of the airways to relax.

Glycopyrronium is a muscarinic receptor antagonist. It works by blocking some receptors called muscarinic receptors, which control the contraction of muscles. When glycopyrronium is inhaled, it causes the muscles of the airways to relax.

The combined action of the two active substances helps to keep the airways open and allows the patient to breathe more easily. Muscarinic receptor antagonists and long-acting beta-2-adrenergic agonists are commonly combined in the management of COPD.

What benefits of Xoterna Breezhaler have been shown in studies?

Xoterna Breezhaler has been studied in two main studies involving a total of 2,667 patients with COPD. While one study compared the effects of Xoterna Breezhaler with those of placebo (a dummy treatment), or indacaterol or glycopyrronium alone, the other study compared Xoterna Breezhaler with fluticasone plus salmeterol, a standard treatment for COPD. In both studies, the main measure of effectiveness was how Xoterna Breezhaler improved patients' forced expiratory volumes (FEV_1, the maximum volume of air a person can breathe out in one second) after 26 weeks of treatment.

The first study showed that treatment with Xoterna Breezhaler was more effective than placebo and increased FEV_1 by an average of 200 ml more. Xoterna Breezhaler also increased FEV_1 by 70 ml more than indacaterol alone and 90 ml than glycopyrronium alone. In the second study the average increase in FEV_1 was 140 ml more with Xoterna Breezhaler than with treatment with fluticasone and salmeterol.

A third study studied the effects of Xoterna Breezhaler on the rate of exacerbations (flare-ups) patients experienced during 64 weeks of treatment when compared with treatment with glycopyrronium or tiotropium (other treatments for COPD). The reduction in the rate of exacerbations was 10 to 12% higher with Xoterna Breezhaler than with tiotropium and glycopyrronium.

What are the risks associated with Xoterna Breezhaler?

The most common side effects with Xoterna Breezhaler (which may affect more than 1 in 10 people) are upper respiratory tract infections (colds).

For the full list of all side effects reported with Xoterna Breezhaler, see the package leaflet.

Why is Xoterna Breezhaler approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Xoterna Breezhaler's benefits are greater than its risks and recommended that it be approved for use in the EU. The effects of Xoterna Breezhaler when used to relieve symptoms of COPD were clinically meaningful. However, the CHMP considered that its effects on reducing the rate of exacerbations were too small to recommend its use for reducing exacerbations. Regarding its safety, Xoterna Breezhaler is comparable to indacaterol and glycopyrronium used as separate medicines. Side effects seen in studies were generally benign and were considered manageable.

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

A risk management plan has been developed to ensure that Xoterna Breezhaler is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Xoterna Breezhaler, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Xoterna Breezhaler

The European Commission granted a marketing authorisation valid throughout the European Union for Xoterna Breezhaler on 19 September 2013.

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

This summary was last updated in 09-2013.