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Seebri Breezhaler *(glycopyrronium bromide)*

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

What is Seebri Breezhaler and what is it used for?

Seebri Breezhaler is a medicine that is used to relieve the 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. Seebri Breezhaler is used for maintenance (regular) treatment.

Seebri Breezhaler contains the active substance glycopyrronium bromide.

How is Seebri Breezhaler used?

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

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.

Seebri Breezhaler can only be obtained with a prescription.

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

How does Seebri Breezhaler work?

The active substance in Seebri Breezhaler, glycopyrronium bromide, is a muscarinic receptor antagonist. This means that it widens the airways by blocking muscarinic receptors (targets) in muscle cells in the lungs. Muscarinic receptors control the contraction of muscles and when glycopyrronium bromide is inhaled, it relaxes the muscles of the airways. This helps to keep the airways open and allows the patient to breathe more easily.

What benefits of Seebri Breezhaler have been shown in studies?

Seebri Breezhaler was found to be more effective than placebo (a dummy treatment) at relieving symptoms of COPD in two main studies involving a total of 1,888 patients with COPD. In both studies,

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the main measure of effectiveness was improvement in patients' forced expiratory volumes (FEV_1, the maximum volume of air a person can breathe out in one second).

After 12 weeks of treatment, Seebri Breezhaler increased FEV_1 by 97 ml more than with placebo in the first study, and by 108 ml more in the second study.

What are the risks associated with Seebri Breezhaler?

The most common side effects with Seebri Breezhaler (seen in more than 1 patient in 100) are dry mouth, nasopharyngitis (inflammation of the nose and throat), insomnia (difficulty sleeping), muscle and bone pain and gastroenteritis (diarrhoea and vomiting). For the full list of all side effects and restrictions with Seebri Breezhaler, see the package leaflet.

Why is Seebri Breezhaler authorised in the EU?

The European Medicines Agency noted that Seebri Breezhaler had a modest but relevant benefit for patients in terms of improving lung function, and also improved the symptoms of COPD. The Agency also noted that the fact that the medicine is used once a day may help patients to adhere to their treatment. In addition, there were no major safety concerns with Seebri Breezhaler, with side effects similar to other muscarinic receptor antagonist medicines. Therefore, the Agency decided that Seebri 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 use of Seebri Breezhaler?

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

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

Other information about Seebri Breezhaler

Seebri Breezhaler received a marketing authorisation valid throughout the EU for Seebri Breezhaler on 28 September 2012.

Further information on Seebri 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 Seebri Breezhaler, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This overview was last updated in 06-2018.