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EPAR summary for the public

Seebri Breezhaler

glycopyrronium bromide

This is a summary of the European public assessment report (EPAR) for Seebri Breezhaler. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Seebri Breezhaler.

What is Seebri Breezhaler?

Seebri Breezhaler is a medicine that contains the active substance glycopyrronium bromide. It is available as capsules containing a powder for inhalation.

What is Seebri Breezhaler used for?

Seebri Breezhaler 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.

The medicine can only be obtained with a prescription.

How is Seebri Breezhaler used?

Seebri Breezhaler capsules 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 contained in the capsule. For detailed information on how to use the inhaler correctly, see the instructions in the package leaflet.

The recommended dose is one capsule once a day at the same time each day. Patients should not take more than one capsule in a day.

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How does Seebri Breezhaler work?

Seebri Breezhaler is an anticholinergic bronchodilator. This means that it widens the airways by blocking some receptors in muscle cells in the lungs called muscarinic receptors, which control the contraction of muscles. When the active substance in Seebri Breezhaler, glycopyrronium bromide, is inhaled, it causes the muscles of the airways to relax, helping to keep the airways open and allowing the patient to breathe more easily.

How has Seebri Breezhaler been studied?

The effects of Seebri Breezhaler were first tested in experimental models before being studied in humans.

Seebri Breezhaler has been studied in two main studies involving a total of 1,888 patients with COPD, where Seebri Breezhaler was compared with placebo (a dummy treatment). In both studies, the main measure of effectiveness was how Seebri Breezhaler improved patients' forced expiratory volumes (FEV_1, the maximum volume of air a person can breathe out in one second) after 12 weeks of treatment.

What benefit has Seebri Breezhaler shown during the studies?

Seebri Breezhaler was more effective than placebo at improving how well the lungs work in patients with COPD: after 12 weeks of treatment, the increase in FEV_1 with Seebri Breezhaler was 97 ml more than with placebo in the first study and 108 ml more in the second study.

What is the risk associated with Seebri Breezhaler?

The most common side effects with Seebri Breezhaler (seen in between 1 and 10 patients in 100) are dry mouth, nasopharyngitis (inflammation of the nose and throat), insomnia (difficulty sleeping) and gastroenteritis (diarrhoea and vomiting). For the full list of all side effects reported with Seebri Breezhaler, see the package leaflet.

Seebri Breezhaler must not be used in people who are hypersensitive (allergic) to glycopyrronium bromide or any of the other ingredients.

Why has Seebri Breezhaler been approved?

The CHMP noted that Seebri Breezhaler had a modest but relevant benefit for patients in terms of improving lung function, and was also seen to improve the symptoms of COPD. The CHMP also noted that the fact that the medicine is used once a day may help patients to comply with their treatment. In addition, there were no major safety concerns with Seebri Breezhaler, with side effects being similar to other anticholinergic bronchodilator medicines. Therefore, the CHMP decided that Seebri 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 use of Seebri Breezhaler?

As anticholinergic bronchodilator medicines may have an effect on the heart and blood vessels, the company will continue to closely monitor the medicine's cardiovascular effects and will carry out a further study in patients to identify any potential risks.

Other information about Seebri Breezhaler

The European Commission granted a marketing authorisation valid throughout the European Union for Seebri Breezhaler on 28 September 2012.

The full EPAR for 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 summary was last updated in 07-2012.