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# Tovanor Breezhaler *(glycopyrronium bromide)*

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

## What is Tovanor Breezhaler and what is it used for?

Tovanor 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. Tovanor Breezhaler is used for maintenance (regular) treatment.

Tovanor Breezhaler contains the active substance glycopyrronium bromide.

## How is Tovanor Breezhaler used?

Tovanor Breezhaler capsules, which contain a powder for inhalation, are only used with the Tovanor 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.

Tovanor Breezhaler can only be obtained with a prescription.

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

## How does Tovanor Breezhaler work?

The active substance in Tovanor 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 Tovanor Breezhaler have been shown in studies?

Tovanor 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, Tovanor 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 Tovanor Breezhaler?

The most common side effects with Tovanor 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 Tovanor Breezhaler, see the package leaflet.

## Why is Tovanor Breezhaler authorised in the EU?

The European Medicines Agency noted that Tovanor 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 Tovanor Breezhaler, with side effects similar to other muscarinic receptor antagonist medicines. Therefore, the Agency decided that Tovanor 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 Tovanor Breezhaler?

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

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

## Other information about Tovanor Breezhaler

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

Further information on Tovanor Breezhaler can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

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