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## EPAR summary for the public

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# Ulunar Breezhaler

indacaterol / glycopyrronium

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

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

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

Ulunar 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.

This medicine is the same as Ultibro Breezhaler, which is already authorised in the European Union (EU). The company that makes Ultibro Breezhaler has agreed that its scientific data can be used for Ulunar Breezhaler ('informed consent').

## How is Ulunar Breezhaler used?

Ulunar Breezhaler is available as capsules containing a powder for inhalation and 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 Ulunar Breezhaler device. The contents of the capsules must not be inhaled using any other device.

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

## How does Ulunar Breezhaler work?

The active substances in Ulunar 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 agonists are commonly combined in the management of COPD.

## What benefits of Ulunar Breezhaler have been shown in studies?

Ulunar Breezhaler has been studied in two main studies involving a total of 2,667 patients with COPD. While one study compared the effects of Ulunar Breezhaler with those of placebo (a dummy inhalation), or indacaterol or glycopyrronium alone, the other study compared Ulunar Breezhaler with fluticasone plus salmeterol, a standard treatment for COPD. In both studies, the main measure of effectiveness was how Ulunar Breezhaler improved patients' forced expiratory volumes (FEV<sub>1</sub>, 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 Ulunar Breezhaler was more effective than placebo and increased FEV<sub>1</sub> by an average of 200 ml more. Ulunar Breezhaler also increased FEV<sub>1</sub> by 70 ml more than indacaterol alone and 90 ml more than glycopyrronium alone. In the second study the average increase in FEV<sub>1</sub> was 140 ml more with Ulunar Breezhaler treatment than with treatment with fluticasone and salmeterol.

A third study investigated the effects of Ulunar 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 Ulunar Breezhaler than with tiotropium and glycopyrronium.

## What are the risks associated with Ulunar Breezhaler?

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

For the full list of all side effects and restrictions, see the package leaflet.

## Why is Ulunar Breezhaler approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Ulunar Breezhaler's benefits are greater than its risks and recommended that it be approved for use in the EU. The effects of Ulunar 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 use in reducing exacerbations. Regarding its safety, Ulunar 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 Ulunar Breezhaler?**

A risk management plan has been developed to ensure that Ulunar 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 Ulunar Breezhaler, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the [summary of the risk management plan](#).

## **Other information about Ulunar Breezhaler**

The European Commission granted a marketing authorisation valid throughout the European Union for Ulunar Breezhaler on 23 April 2014.

The full EPAR and risk management plan summary for Ulunar Breezhaler can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Ulunar Breezhaler, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2014.