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EPAR summary for the public

Trimbow

beclometasone / formoterol / glycopyrronium bromide

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

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

What is Trimbow and what is it used for?

Trimbow is a medicine used in adults to relieve the symptoms of moderate to severe chronic obstructive pulmonary disease (COPD). COPD is a long-term disease in which the airways and air sacs inside the lungs become damaged or blocked, leading to difficulty breathing.

Trimbow is used for maintenance (regular) treatment in patients whose disease is not adequately controlled despite treatment with a combination of two other COPD medicines, a beta-2 agonist and an inhaled corticosteroid.

Trimbow contains the active substances beclometasone, formoterol and glycopyrronium bromide.

How is Trimbow used?

Trimbow is available as a liquid in a portable inhaler device. Each inhalation provides a fixed dose of the medicine. The recommended dose is two inhalations twice a day.

Patients should be shown how to use the inhaler correctly by a doctor or other healthcare professional, who should also regularly check that the patient's inhalation technique is correct.

The medicine can only be obtained with a prescription. For further information, see the package leaflet.

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How does Trimbow work?

The three active substances in Trimbow work by reducing inflammation and keeping the airways open by various mechanisms, so allowing the patient to breathe more easily.

Beclometasone belongs to a group of anti-inflammatory medicines known as corticosteroids. It works in a similar way to naturally occurring corticosteroid hormones, reducing the activity of the immune system by attaching to receptors in various types of immune cell. This leads to a reduction in the release of substances that are involved in the inflammation process, such as histamine, thereby helping to keep the airways clear and allowing the patient to breathe more easily.

Formoterol is a long-acting beta-2 agonist. It works by attaching to receptors known as beta-2 receptors (targets) found in the muscles of the airways. When it attaches to these receptors, it causes the muscles to relax, which keeps the airways open and helps with the patient's breathing.

Glycopyrronium bromide is a muscarinic receptor antagonist. This means that it opens the airways in another way, by blocking muscarinic receptors in muscle cells in the lungs. Because these receptors help control the contraction of muscles, when glycopyrronium 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.

What benefits of Trimbow have been shown in studies?

Trimbow has been shown to be effective at relieving symptoms of COPD in two main studies involving over 4,000 patients whose symptoms were not adequately controlled with a combination of two other COPD medicines.

In the first study lasting 26 weeks, Trimbow improved patients' FEV_1 (the maximum volume of air a person can breathe out in one second) by 82 ml before a dose and 261 ml after a dose. This was more than increases of 1 and 145 ml respectively in patients treated with a medicine containing only 2 of the active substances found in Trimbow (beclometasone plus formoterol).

In the second study, patients treated with Trimbow had 20% fewer exacerbations (flare-ups of symptoms) a year than patients treated with tiotropium (a muscarinic receptor antagonist). In this study, Trimbow was as effective as tiotropium in combination with beclometasone plus formoterol at reducing the number of exacerbations.

What are the risks associated with Trimbow?

Side effects with Trimbow include oral candidiasis (a fungal infection of the mouth caused by a yeast called *Candida*), muscles spasms and dry mouth.

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

Why is Trimbow approved?

Trimbow has been shown to be effective at reducing the frequency of exacerbations and improving lung function of patients with COPD. No major safety concerns have been reported with Trimbow, with side effects being manageable and similar to other COPD medicines. The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Trimbow's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

Other information about Trimbow

The European Commission granted a marketing authorisation valid throughout the European Union for Trimbow on 17 July 2017.

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

This summary was last updated in 08-2017.