



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/229136/2019  
EMA/H/C/004257

## Trimbow (*beclometasone / formoterol / glycopyrronium bromide*)

An overview of Trimbow and why it is authorised in the EU

### What is Trimbow and what is it used for?

Trimbow is a medicine used in adults for treating moderate to severe chronic obstructive pulmonary disease (COPD) and asthma.

In COPD, Trimbow is used for maintenance (continuing) treatment in patients whose disease is not adequately controlled despite treatment with a combination of two medicines consisting of a long-acting beta-2 agonist plus either an inhaled corticosteroid or a long-acting muscarinic receptor antagonist. Beta-2 agonists and muscarinic receptor antagonists help to widen the airways; corticosteroids reduce inflammation in the airways and lungs.

In asthma, Trimbow is used for maintenance treatment in adults whose disease is not adequately controlled despite treatment with a long-acting beta-2 agonist plus a medium or high dose of inhaled corticosteroid, and who had one or more exacerbations (flare-ups) in the past year.

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. Patients should take two inhalations twice a day. Trimbow is available in two strengths. The doctor will decide which strength the patient should use based on whether Trimbow is used for asthma or for COPD, and, for asthma, on whether patients had been using a medium or high dose of inhaled corticosteroid.

Patients should be shown how to use the inhaler correctly by a doctor or another 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 more information about using Trimbow, see the package leaflet or contact your doctor or pharmacist.

### How does Trimbow work?

The three active substances in Trimbow work in different ways to reduce inflammation and keep the

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airways open, 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. This leads to a reduction in the release of substances 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 attaches to receptors (targets) known as beta-2 receptors in the muscles of the airways. By attaching 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 long-acting muscarinic receptor antagonist. It opens the airways by blocking muscarinic receptors in muscle cells in the lungs. Because these receptors help control the contraction of the airway muscles, blocking them causes the muscles 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?**

### **COPD**

Trimbow has been shown to be effective at relieving symptoms of COPD in three main studies involving over 5,500 patients whose symptoms were not controlled well enough either by combinations of two other COPD medicines or by a long-acting muscarinic receptor antagonist alone.

In the first study lasting a year, after 26 weeks of treatment Trimbow improved patients' FEV<sub>1</sub> (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. By comparison, the FEV<sub>1</sub> increased by 1 and 145 ml before and after dosing in patients treated with a medicine containing only 2 of the active substances found in Trimbow (beclometasone plus formoterol).

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

In the third study lasting a year, patients treated with Trimbow had 15% fewer exacerbations a year than patients treated with a combination of indacaterol (a long-acting beta-2 agonist) and glycopyrronium bromide.

### **Asthma**

A main study involved over 1,000 patients with asthma whose disease was not adequately controlled on medium doses of inhaled corticosteroids in combination with long-acting beta-2 agonists. Patients had at least one asthma exacerbation in the previous year. After 26 weeks of treatment, Trimbow (medium strength) improved patients' FEV<sub>1</sub> before dosing by 185 ml compared with 127 ml with a combination of beclometasone plus formoterol. In addition, patients treated with Trimbow for up to one year had 15% fewer moderate and severe exacerbations a year than patients treated with beclometasone plus formoterol.

In a second study in over 1,000 patients with asthma whose disease was not adequately controlled on high doses of inhaled corticosteroids in combination with long-acting beta-2 agonists, Trimbow (higher strength) improved patients' FEV<sub>1</sub> before dosing by 229 ml compared with 157 ml for beclometasone plus formoterol after 26 weeks of treatment. The 12% reduction in the yearly rate of moderate to

severe exacerbations was not statistically different (meaning that it may be due to chance) between the 2 groups. However, a higher reduction in the number of these exacerbations per year was seen with Trimbow in a sub-group of patients with persistent airflow limitation, representing almost two thirds of patients analysed. When looking at the results from the 2 studies together, Trimbow was found to have a beneficial effect on the rate of severe exacerbations.

### **What are the risks associated with Trimbow?**

Side effects with Trimbow (which may affect up to 1 in 10 people) include dysphonia (changes in the sound of the voice), oral candidiasis (a fungal infection of the mouth caused by a yeast called *Candida*), muscle spasms and dry mouth. In asthma, side effects tend to occur in the first 3 months after start of treatment and then become less frequent.

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

### **Why is Trimbow authorised in the EU?**

Trimbow has been shown to be effective at reducing the frequency of exacerbations and improving lung function of patients with COPD and asthma. No major safety concerns have been reported with Trimbow, with side effects being manageable and similar to other COPD and asthma medicines. The European Medicines Agency therefore decided that Trimbow'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 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.

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

### **Other information about Trimbow**

Trimbow received a marketing authorisation valid throughout the EU on 17 July 2017.

Further information can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/trimbow](http://ema.europa.eu/medicines/human/EPAR/trimbow).

This overview was last updated in 11-2020.