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Riarify (*beclomethasone / formoterol / glycopyrronium bromide*)

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

What is Riarify and what is it used for?

Riarify 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.

Riarify 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.

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

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

How is Riarify used?

Riarify 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 more information about using Riarify, see the package leaflet or contact your doctor or pharmacist.

How does Riarify work?

The three active substances in Riarify 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

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system by attaching to receptors (targets) 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 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 Riarify have been shown in studies?

Riarify 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 at 26 weeks, Riarify 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 Riarify (beclometasone plus formoterol).

In the second study, patients treated with Riarify had 20% fewer exacerbations (flare-ups of symptoms) per year than patients treated with tiotropium (a muscarinic receptor antagonist). In this study, Riarify also had a comparable effect on reducing the number of exacerbations to a combination of tiotropium, beclometasone and formoterol.

What are the risks associated with Riarify?

Side effects with Riarify 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 Riarify, see the package leaflet.

Why is Riarify authorised in the EU?

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

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

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

Other information about Riarify

Riarify received a marketing authorisation valid throughout the EU on 23 April 2018.

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

This overview was last updated in 04-2018.