EMA/188679/2019
EMEA/H/C/004836

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 (continuing) treatment in patients whose disease is not adequately controlled despite treatment with a combination of two COPD 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.

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. The recommended dose is two inhalations twice a day.

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 Riarify, see the package leaflet or contact your doctor or pharmacist.

How does Riarify work?

The three active substances in Riarify work in different ways to reduce inflammation and keep the airways open, allowing the patient to breathe more easily.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Beclometasone belongs to 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 Riarify have been shown in studies?

Riarify 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 muscarinic receptor antagonist alone.

In the first study lasting a year, after 26 weeks of treatment 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. By comparison, the FEV_1 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 Riarify (beclometasone plus formoterol).

In the second study lasting a year, patients treated with Riarify had 20% fewer exacerbations (flare-ups of symptoms) per year than patients treated with tiotropium (a long-acting muscarinic receptor antagonist). In this study, Riarify 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 Riarify had 15% fewer exacerbations a year than patients treated with a combination of indacaterol (a long-acting beta-2 agonist) and glycopyrronium bromide.

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*), muscle spasms and dry mouth.

For the full list of 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: https://www.ema.europa.eu/en/medicines/human/EPAR/riarify-previously-chf-5993-chiesi-farmaceutici-spa.

This overview was last updated in 03-2019.