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EPAR summary for the public

Rolufta

umeclidinium bromide

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

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

What is Rolufta and what is it used for?

Rolufta is a medicine used to relieve the 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. Rolufta is used for maintenance (regular) treatment.

Rolufta contains the active substance umeclidinium bromide.

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

How is Rolufta used?

Rolufta is available as an inhalation powder in a portable inhaler device. The inhaler delivers 65 micrograms of umeclidinium bromide equivalent to 55 micrograms of umeclidinium for each inhalation. The recommended dose is one inhalation per day at the same time each day. For detailed information on how to use the inhaler correctly, see the instructions in the package leaflet.

The medicine can only be obtained with a prescription.

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

How does Rolufta work?

The active substance in Rolufta, umeclidinium bromide, is a muscarinic receptor antagonist. It works by blocking the action of so-called muscarinic receptors, which control the contraction of muscles. When umeclidinium bromide 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 Rolufta have been shown in studies?

Rolufta was investigated in four main studies involving over 4,000 patients. Three studies compared Rolufta with placebo (a dummy treatment), while one study compared Rolufta with tiotropium (another medicine for COPD). The main measure of effectiveness was based on changes in the patients' forced expiratory volumes (FEV_1, the maximum volume of air a person can breathe out in one second). Results showed that Rolufta at a dose of equivalent to 55 micrograms of umeclidinium improved lung function by an average FEV_1 by 127 ml more than placebo after 12 weeks of treatment and by 115 ml after 24 weeks of treatment. Rolufta given at double that dose only showed small improvements compared with the lower dose, which were not considered relevant. In the study comparing Rolufta with tiotropium, FEV_1 improvements over 24 weeks were similar for both medicines.

The studies also showed an improvement in symptoms such as breathlessness and wheezing.

What are the risks associated with Rolufta?

The most common side effects with Rolufta (seen in between 1 and 10 patients in 100) are headache, nasopharyngitis (inflammation of the nose and throat), upper respiratory tract infection (cold), sinusitis, cough, urinary tract infection, and tachycardia (increased heart rate).

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

Why is Rolufta approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Rolufta's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP concluded that Rolufta was shown to be effective at improving the lung function and symptoms of COPD. The CHMP also noted that there were no major safety concerns with Rolufta, with side effects being manageable and similar to other antimuscarinic bronchodilator medicines.

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

As antimuscarinic bronchodilator medicines may have an effect on the heart and blood vessels, the company that markets Rolufta will continue to closely monitor the medicine's cardiovascular effects and will carry out a further study in patients to identify any potential risks.

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

Other information about Rolufta

The European Commission granted a marketing authorisation valid throughout the European Union for Rolufta on 20 March 2017.

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

This summary was last updated in 03-2017.