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Rolufta Ellipta[1] (*umeclidinium bromide*)

An overview of Rolufta Ellipta and why it is authorised in the EU

What is Rolufta Ellipta and what is it used for?

Rolufta Ellipta 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 Ellipta is used for maintenance (regular) treatment.

Rolufta Ellipta contains the active substance umeclidinium bromide.

How is Rolufta Ellipta used?

Rolufta Ellipta is available as an inhalation powder in a portable inhaler device. Each inhalation provides 65 micrograms of umeclidinium bromide equivalent to 55 micrograms of umeclidinium. 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 or contact your doctor or pharmacist.

The medicine can only be obtained with a prescription.

How does Rolufta Ellipta work?

The active substance in Rolufta Ellipta, 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 relaxes the muscles of the airways. This helps to keep the airways open and allows the patient to breathe more easily.

What benefits of Rolufta Ellipta have been shown in studies?

Rolufta Ellipta was investigated in four main studies involving over 4,000 patients. Three studies compared Rolufta Ellipta with placebo (a dummy treatment), while one study compared Rolufta Ellipta with tiotropium (another medicine for COPD). The main measure of effectiveness was based on

[1] Previously known as Rolufta.

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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 Ellipta 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. A double dose of Rolufta Ellipta only showed small improvements compared with a single dose, which were not considered relevant. In the study comparing Rolufta Ellipta 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 Ellipta?

The most common side effects with Rolufta Ellipta (which may affect up to 1 in 10 people) are headache, nasopharyngitis (inflammation of the nose and throat), upper respiratory tract infection (nose and throat infection), sinusitis (inflammation of the sinuses), cough, urinary tract infection (infection of the structures that carry urine), and tachycardia (increased heart rate).

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

Why is Rolufta Ellipta authorised in the EU?

The European Medicines Agency decided that Rolufta Ellipta's benefits are greater than its risks and it can be authorised for use in the EU. The Agency concluded that Rolufta Ellipta was shown to be effective at improving the lung function and symptoms of COPD. The Agency also noted that there were no major safety concerns with Rolufta Ellipta, with side effects being manageable and similar to other medicines of the same class (antimuscarinic bronchodilators).

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

As medicines of the same class as Rolufta Ellipta may have an effect on the heart and blood vessels, the company that markets Rolufta Ellipta will carry out a long-term study in patients to collect further information on its safety in comparison with tiotropium.

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

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

Other information about Rolufta Ellipta

Rolufta Ellipta received a marketing authorisation valid throughout the EU on 20 March 2017. This authorisation was based on the authorisation granted to Incruse Ellipta in 2014 ('informed consent').

Further information on Rolufta Ellipta 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 09-2018.