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EPAR summary for the public

Elebrato Ellipta

fluticasone furoate / umeclidinium bromide / vilanterol

This is a summary of the European public assessment report (EPAR) for Elebrato Ellipta. 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 detailed practical advice on how to use Elebrato Ellipta.

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

What is Elebrato Ellipta and what is it used for?

Elebrato Ellipta is a medicine used 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.

Elebrato Ellipta is used in adults whose disease is not controlled well enough with a combination of inhaled medicines called corticosteroids and long-acting beta-2 agonists. Corticosteroids reduce inflammation in the airways and lungs, and long-acting beta-2 agonists widen the airways.

Elebrato Ellipta is used for maintenance (regular) treatment on a daily basis. It contains the active substances fluticasone furoate, umeclidinium bromide and vilanterol.

How is Elebrato Ellipta used?

Elebrato Ellipta can only be obtained with a prescription. It is available as an inhalation powder, which the patient inhales through the mouth using a portable inhaler device; the patient should inhale the medicine once a day at around the same time each day. For further information, see the package leaflet.

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How does Elebrato Ellipta work?

Elebrato Ellipta contains three active substances, which work in different ways to widen the airways and improve breathing in COPD.

Fluticasone furoate is a corticosteroid. It works in a similar way to naturally occurring corticosteroid hormones, reducing the activity of the immune system by attaching to receptors (targets) in various types of immune cells. This reduces the release of substances involved in the inflammation process, such as histamine, thereby reducing inflammation and helping to keep the airways clear and allowing the patient to breathe more easily.

Umeclidinium bromide is a muscarinic receptor antagonist. It works by blocking muscarinic receptors, which are involved in the contraction of muscles. When umeclidinium bromide is inhaled, it causes the muscles of the airways to relax.

Vilanterol is a long-acting beta-2 agonist. It works by attaching to beta-2 receptors in some types of muscle cells. When inhaled, vilanterol activates the beta-2 receptors in the airways. This 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 Elebrato Ellipta have been shown in studies?

A main study involving 1,810 patients whose COPD was not satisfactorily controlled with a daily maintenance treatment for their COPD found Elebrato Ellipta more effective at improving patients' breathing than an inhaled combination of budesonide, a corticosteroid, and formoterol, a long-acting beta-2 agonist.

After 24 weeks, patients taking Elebrato Ellipta had their FEV_1 (the maximum volume of air they could breathe out in one second) improve by 142 ml. This compares with an average reduction of 29 ml seen in patients taking the combination of budesonide and formoterol over the same period. Patients treated with Elebrato Ellipta also reported improved health compared with those treated with the comparator treatment.

What are the risks associated with Elebrato Ellipta?

The most common side effects with Elebrato Ellipta (which may affect up to 1 in 10 people) are nasopharyngitis (inflammation of the nose and throat), headache and upper respiratory tract infection (nose and throat infection). More serious side effects include pneumonia (which may affect up to 1 in 10 people).

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

Why is Elebrato Ellipta approved?

The European Medicines Agency decided that Elebrato Ellipta's benefits are greater than its risks and recommended that it be approved for use in the EU.

The Agency concluded that Elebrato Ellipta improves lung function as well as the quality of life of patients with moderate to severe COPD.

Regarding the safety profile of the medicine, the most frequent side effects reported with Elebrato Ellipta were similar to those with the individual active substances of the medicine and are well known.

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

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

Other information about Elebrato Ellipta

The European Commission granted a marketing authorisation valid throughout the European Union for Elebrato Ellipta on 15 November 2017.

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

This summary was last updated in 11 2017.