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Trelegy Ellipta (*fluticasone furoate / umeclidinium bromide / vilanterol*)

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

What is Trelegy Ellipta and what is it used for?

Trelegy 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.

Trelegy Ellipta is used in adults whose disease is not controlled well enough with a combination of inhaled medicines consisting of a long-acting beta-2 agonist plus either a corticosteroid or a long-acting muscarinic antagonist. Long-acting beta-2 agonists widen the airways; corticosteroids reduce inflammation in the airways and lungs; and muscarinic receptor antagonists cause the muscles of the airways to relax.

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

How is Trelegy Ellipta used?

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

How does Trelegy Ellipta work?

Trelegy 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.

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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 Trelegy Ellipta have been shown in studies?

Trelegy Ellipta was shown to improve patients' breathing and reduce exacerbations (flare-ups) of the disease in 2 main studies.

A study compared Trelegy Ellipta with either vilanterol given with fluticasone furoate or vilanterol with umeclidinium bromide, in 10,355 patients with advanced COPD who were at risk of exacerbations and whose disease was not satisfactorily controlled with a daily maintenance treatment.

In this study, Trelegy Ellipta reduced the rate of moderate and severe exacerbations over one year by 15% compared with treatment with vilanterol and fluticasone furoate, and by 25% compared with treatment with vilanterol and umeclidinium bromide.

Another study involving 1,810 patients whose COPD was not satisfactorily controlled with a daily maintenance treatment for their COPD found Trelegy 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 Trelegy 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 Trelegy Ellipta also reported improved health compared with those treated with the comparator treatment.

What are the risks associated with Trelegy Ellipta?

The most common side effects with Trelegy 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 side effects and restrictions with Trelegy Ellipta, see the package leaflet.

Why is Trelegy Ellipta authorised in the EU?

Trelegy 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 Trelegy Ellipta were similar to those with the individual active substances of the medicine and are well known. The European Medicines Agency therefore decided that Trelegy Ellipta'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 Trelegy Ellipta?

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

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

Other information about Trelegy Ellipta

Trelegy Ellipta received a marketing authorisation valid throughout the EU on 15 November 2017.

Further information on Trelegy Ellipta can be found on the Agency's website: ema.europa.eu/medicines/Human/EPAR/Trelegy-Ellipta.

This overview was last updated in 10-2018.