EMA/247773/2019
EMEA/H/C/005254

Temybric Ellipta (*fluticasone furoate / umeclidinium / vilanterol*)

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

What is Temybric Ellipta and what is it used for?

Temybric 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 in the lungs become damaged or blocked, leading to difficulty breathing.

Temybric 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 and muscarinic receptor antagonists cause the muscles of the airways to relax which leads to a widening of the airways. Corticosteroids reduce inflammation in the airways and lungs.

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

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

How is Temybric Ellipta used?

Temybric 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 Temybric Ellipta, see the package leaflet or contact your doctor or pharmacist.

How does Temybric Ellipta work?

Temybric 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,

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 long-acting 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 Temybric Ellipta have been shown in studies?

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

A study compared Temybric 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. Temybric 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 daily maintenance treatment for their COPD found Temybric 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, the FEV_1 (the maximum volume of air they could breathe out in one second) of patients taking Temybric Ellipta increased by 142 ml. This compares with an average reduction of 29 ml in patients taking the combination of budesonide and formoterol over the same period. Patients treated with Temybric Ellipta also reported improved health compared with those treated with the comparator treatment.

What are the risks associated with Temybric Ellipta?

The most common side effects with Temybric 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 Temybric Ellipta, see the package leaflet.

Why is Temybric Ellipta authorised in the EU?

Temybric Ellipta improves lung function as well as the quality of life of patients with moderate to severe COPD. The most frequent side effects reported with Temybric Ellipta were similar to those with the individual active substances of the medicine and are well known. The European Medicines Agency therefore decided that Temybric 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 Temybric Ellipta?

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

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

Other information about Temybric Ellipta

Temybric Ellipta received a marketing authorisation valid throughout the EU on 12 June 2019.

Further information on Temybric Ellipta can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/temybric-ellipta.

This overview was last updated in 06-2019.