EMA/120112/2018
EMEA/H/C/002673

Relvar Ellipta (*fluticasone furoate / vilanterol*)

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

What is Relvar Ellipta and what is it used for?

Relvar Ellipta is an inhaler for treating asthma and chronic obstructive pulmonary disease (COPD).

In asthma, it is used for regular treatment of patients from 12 years of age:

- whose symptoms are not controlled with an inhaled corticosteroid and an inhaled short-acting beta-2 agonist;
- whose symptoms are adequately controlled with both inhaled corticosteroids and a long-acting beta-2 agonist.

In COPD, it is used in adults who have flare-ups of the disease despite regular bronchodilator treatment (treatment to widen the airways).

Relvar Ellipta contains the active substances fluticasone furoate and vilanterol.

How is Relvar Ellipta used?

Relvar Ellipta is available as an inhaler in two strengths (92/22 micrograms and 184/22 micrograms). The doctor will decide which inhaler the patient should use. The dose is one inhalation ('puff') into the mouth once a day at the same time each day.

Relvar Ellipta can only be obtained with a prescription. For more information about using Relvar Ellipta, see the package leaflet or contact your doctor or pharmacist.

How does Relvar Ellipta work?

Relvar Ellipta contains two active substances that work in different ways to improve breathing in patients with asthma and COPD.

Fluticasone furoate is a corticosteroid. It works on various types of immune cells, blocking the release of substances involved in inflammation. This reduces inflammation in the airways and improves the patient's breathing.

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

Vilanterol is a long-acting beta-2 agonist. It attaches to beta-2 receptors in the airways and causes the muscles of the airways to relax and widen, allowing the patient to breathe more easily.

What benefits of Relvar Ellipta have been shown in studies?

Asthma

Three studies in over 3,200 patients showed that Relvar Ellipta improves breathing and reduces flare-ups in patients with asthma.

In two of the studies, Relvar Ellipta 92/22 increased the volume of air a patient could breathe out in one second (FEV_1) by 36 ml more than fluticasone furoate alone and 172 ml more than placebo (a dummy treatment). Relvar Ellipta 184/22 also improved FEV_1 by 193 ml more than fluticasone furoate and 210 ml more than another inhaler containing fluticasone propionate.

In a third study, fewer patients taking Relvar Ellipta 92/22 had at least one severe flare-up after a year of treatment than those taking fluticasone furoate alone (13% versus 16%).

A fourth study in 1,522 patients showed that Relvar Ellipta was as effective as another medicine containing a corticosteroid (fluticasone propionate) and a long-acting beta-2 agonist (salmeterol). These patients were already well controlled with the comparator medicine and Relvar Ellipta treatment was able to maintain their FEV_1.

COPD

Four studies in over 5,500 patients showed that Relvar Ellipta improves breathing and reduces flare-ups of symptoms in patients with COPD.

The first study showed that Relvar Ellipta 92/22 improved average FEV_1 by 115 ml more than placebo, and a second study showed that Relvar Ellipta 184/22 improved average FEV_1 by 131 ml more than placebo.

In two further studies, Relvar Ellipta reduced the number of flare-ups by between 13 and 34% more than vilanterol alone.

What are the risks associated with Relvar Ellipta?

The most common side effects with Relvar Ellipta (which may affect more than 1 in 10 people) are headache and nasopharyngitis (inflammation of the nose and throat). More serious side effects include pneumonia and fractures (seen in up to 1 in 10 people), which were reported more often in patients with COPD than those with asthma. For the full list of side effects of Relvar Ellipta, see the package leaflet.

Why is Relvar Ellipta authorised in the EU?

Relvar Ellipta improves breathing and reduces flare ups of symptoms in patients with asthma and COPD. Regarding its safety, the most frequent side effects reported with Relvar Ellipta were similar to those seen with other COPD and asthma treatments; an increased incidence of pneumonia was observed in patients with COPD.

The European Medicines Agency concluded that Relvar 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 Relvar Ellipta?

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

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

Other information about Relvar Ellipta

Relvar Ellipta received a marketing authorisation valid throughout the EU on 13 November 2013.

Further information on Relvar 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 02-2018.