EMA/595326/2018
EMEA/H/C/003754

Laventair Ellipta[1] (*umeclidinium bromide / vilanterol*)

An overview of Laventair Ellipta and why it is authorised for use in the EU

What is Laventair Ellipta and what is it used for?

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

Laventair Ellipta contains the active substances umeclidinium bromide and vilanterol.

How is Laventair Ellipta used?

Laventair Ellipta can only be obtained with a prescription. It 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) and 22 micrograms of vilanterol.

The recommended dose is one inhalation per day at the same time each day. For detailed information on using the inhaler correctly, see the instructions in the package leaflet or contact your doctor and pharmacist.

How does Laventair Ellipta work?

Laventair Ellipta contains two active substances. Vilanterol is a long-acting beta-2 agonist. It works by attaching to beta-2 receptors found in the muscle cells of many organs including the airways in the lungs. When inhaled, vilanterol reaches the receptors in the airways and activates them. This relaxes the muscles of the airways.

Umeclidinium bromide is a muscarinic receptor antagonist. It works by blocking other receptors called muscarinic receptors, which control the contraction of muscles. When umeclidinium bromide is inhaled, it relaxes the muscles of the airways.

The combined action of the two active substances helps to keep the airways open and allows the patient to breathe more easily. Muscarinic receptor antagonists and long-acting beta-2 agonists are commonly combined in the management of COPD.

[1] Previously known as Laventair.

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

What benefits of Laventair Ellipta have been shown in studies?

Laventair Ellipta and a higher-dose combination of umeclidinium bromide and vilanterol were compared with placebo (a dummy treatment), vilanterol alone, umeclidinium bromide alone and another COPD medicine called tiotropium in 4 main studies.

In all 4 studies, involving over 4,700 patients, the main measure of effectiveness was based on 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 Laventair Ellipta improved lung function by an average FEV_1 of 167 ml more than placebo after 24 weeks of treatment. Laventair Ellipta also increased FEV_1 by an average of 95 ml more than vilanterol alone and by 52 ml more than umeclidinium bromide alone. The average increase in FEV_1 with Laventair Ellipta was 90 ml more than with tiotropium after 24 weeks of treatment.

Laventair Ellipta was also shown to improve symptoms such as breathlessness and wheezing.

The results for the higher dose combination of umeclidinium bromide and vilanterol did not consistently show relevant improvements in lung function to justify its use.

What are the risks associated with Laventair Ellipta?

The most common side effects with Laventair Ellipta (which may affect up to 1 in 10 people) are upper respiratory tract infections (nose and throat infection), urinary tract infections (infection of the structures that carry urine), pharyngitis (inflammation of the throat), sinusitis (inflammation of the sinuses), nasopharyngitis (inflammation of the nose and throat), headache, cough, oropharyngeal pain (pain in the mouth and throat), constipation and dry mouth.

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

Why is Laventair Ellipta authorised in the EU?

The European Medicines Agency decided that Laventair Ellipta's benefits are greater than its risks and recommended that it can be authorised for use in the EU. The Agency concluded that Laventair Ellipta was shown to be effective at improving lung function and the symptoms of COPD when compared with placebo or the single components as well as with tiotropium. The Agency also noted that there were no major safety concerns with Laventair Ellipta, with side effects being manageable, although the long-term safety data so far are limited. To investigate this further the Agency recommended that a study be carried out.

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

As medicines of the same class as Laventair Ellipta may have an effect on the heart and blood vessels in the brain, the company that markets the medicine 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 have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Laventair Ellipta

Laventair Ellipta received a marketing authorisation valid throughout the EU on 8 May 2014.

Further information on Laventair 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.