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

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

What is Anoro Ellipta and what is it used for?

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

Anoro Ellipta contains the active substances umeclidinium bromide and vilanterol.

How is Anoro Ellipta used?

Anoro Ellipta can only be obtained with a prescription. It is available as an inhalation powder in a portable inhaler device. Each inhalation provides 55 micrograms of umeclidinium (as umeclidinium bromide) and 22 micrograms of vilanterol.

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

How does Anoro Ellipta work?

The active substances in Anoro Ellipta, umeclidinium and vilanterol, work in different ways to widen the airways and improve breathing in COPD. Vilanterol is a long-acting beta-2 adrenergic agonist. It works by attaching to beta-2 adrenergic 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 causes the muscles of the airways to relax.

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

[1] Previously known as Anoro.

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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.

What benefits of Anoro Ellipta have been shown in studies?

Anoro Ellipta and a higher-dose combination of umeclidinium and vilanterol (113 micrograms/22 micrograms) were compared with placebo (a dummy treatment), vilanterol alone, umeclidinium alone or another COPD medicine called tiotropium in 5 main studies.

In all 5 studies, involving over 5,600 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 Anoro Ellipta improved lung function by an average FEV_1 of 167 ml more than placebo after 24 weeks of treatment. Anoro Ellipta also increased FEV_1 by an average of up to 95 ml more than vilanterol alone and by 52 ml more than umeclidinium bromide alone. The average increase in FEV_1 with Anoro Ellipta was 60, 90 and 112 ml more than with tiotropium after 24 weeks of treatment in the three studies where Anoro Ellipta was compared with tiotropium.

Anoro Ellipta was also shown to improve breathlessness when compared with placebo.

The higher dose combination of umeclidinium and vilanterol did not consistently lead to better improvements in lung function than Anoro Ellipta to justify its use.

What are the risks associated with Anoro Ellipta?

The most common side effects with Anoro 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 Anoro Ellipta authorised in the EU?

The European Medicines Agency decided that Anoro Ellipta's benefits are greater than its risks and it can be authorised for use in the EU. The Agency concluded that Anoro 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 Anoro 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 Anoro Ellipta?

As medicines of the same class as Anoro 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 for the safe and effective use of Anoro Ellipta have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Anoro Ellipta

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

Further information on Anoro 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.