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EPAR summary for the public

Duaklir Genuair

aclidinium bromide / formoterol fumarate dihydrate

This is a summary of the European public assessment report (EPAR) for Duaklir Genuair. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Duaklir Genuair.

For practical information about using Duaklir Genuair, patients should read the package leaflet or contact their doctor or pharmacist.

What is Duaklir Genuair and what is it used for?

Duaklir Genuair 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. Duaklir Genuair is used for maintenance (regular) treatment.

Duaklir Genuair contains two active substances: aclidinium bromide and formoterol fumarate dihydrate.

How is Duaklir Genuair used?

Duaklir Genuair is available as an inhalation powder in a portable inhaler device. The inhaler delivers 340 micrograms of aclidinium and 12 micrograms of formoterol fumarate dihydrate for each inhalation. The recommended dose of Duaklir Genuair is one inhalation twice a day. For detailed information on how to use the inhaler correctly, see the instructions in the package leaflet.

Duaklir Genuair can only be obtained with a prescription.

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How does Duaklir Genuair work?

The two active substances in Duaklir Genuair, aclinidium bromide and formoterol fumarate dihydrate, work by keeping the airways open and allowing the patient to breathe more easily.

Aclidinium bromide is a long-acting muscarinic antagonist. This means that it widens the airways by blocking some receptors in muscle cells in the lungs called muscarinic (also known as cholinergic) receptors, which control the contraction of muscles. When aclidinium bromide is inhaled, it causes the muscles of the airways to relax, helping to keep the airways open and allowing the patient to breathe more easily.

Formoterol is a long-acting beta-2 agonist. It works by attaching to receptors known as beta-2 receptors found in the muscles of the airways. When it attaches to these receptors, it causes the muscles to relax, which keeps the airways open and helps with the patient's breathing.

Long-acting muscarinic antagonists and long-acting beta-2 agonists are commonly combined in the management of COPD. Aclidinium bromide has been authorised in the EU as Bretaris Genuair and Eklira Genuair since July 2012; formoterol has been marketed in the EU since the 1990s.

What benefits of Duaklir Genuair have been shown in studies?

Duaklir Genuair has been studied in 2 main studies involving over 3,400 patients with COPD, in which it was compared with aclidinium alone, formoterol alone and placebo (a dummy treatment). The main measure of effectiveness was based on changes in patients' forced expiratory volumes (FEV_1, the maximum volume of air a person can breathe out in one second) after six months.

Results showed that, after six months of treatment, the increase in FEV_1 (measured one hour after an inhalation) was 293 milliliters (ml) more with Duaklir Genuair than with placebo and 118 ml more with Duaklir Genuair than with aclidinium alone. However the improvement over formoterol alone was small and not considered clinically significant: FEV_1 measured in the morning before the inhalation was 68 ml more with Duaklir Genuair than with formoterol alone. Duaklir Genuair was also shown to increase the percentage of patients who had an improvement in breathlessness compared with placebo.

What are the risks associated with Duaklir Genuair?

Side effects with Duaklir Genuair are similar to those with the individual components. The most common side effects (seen in around 7 patients in 100) are nasopharyngitis (inflammation of the nose and throat) and headache.

For the full list of all side effects and restrictions with Duaklir Genuair, see the package leaflet.

Why is Duaklir Genuair approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Duaklir Genuair's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP noted that Duaklir Genuair was shown to significantly improve lung function in patients with COPD compared with placebo, although the improvement observed when Duaklir Genuair was compared with one of the components on its own, formoterol, was small.

Regarding safety, the number of side effects reported with Duaklir Genuair was low and did not raise any major safety concern. In addition, the safety profile of the two components is well known, and there is no evidence that the combination is worse than the individual components.

What measures are being taken to ensure the safe and effective use of Duaklir Genuair?

A risk management plan has been developed to ensure that Duaklir Genuair is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Duaklir Genuair, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, as long-acting muscarinic antagonists may have an effect on the heart and blood vessels, the company that markets Duaklir Genuair will provide the results of studies to further evaluate the cardiovascular safety of the medicine.

Further information can be found in the summary of the risk management plan.

Other information about Duaklir Genuair

The European Commission granted a marketing authorisation valid throughout the European Union for Duaklir Genuair on 19 November 2014.

The full EPAR and risk management plan summary for Duaklir Genuair can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Duaklir Genuair, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2014.