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EPAR summary for the public

Eklira Genuair

aclidinium bromide

This is a summary of the European public assessment report (EPAR) for Eklira 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 Eklira Genuair.

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

What is Eklira Genuair and what is it used for?

Eklira Genuair is a medicine that is 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. Eklira Genuair is used for maintenance (regular) treatment.

Eklira Genuair contains the active substance aclidinium bromide.

How is Eklira Genuair used?

Eklira Genuair is available as an inhalation powder in a portable inhaler device. Each inhalation provides 375 micrograms of aclidinium bromide equivalent to 322 micrograms of aclidinium.

The recommended dose of Eklira Genuair is one inhalation twice a day. For detailed information on using the inhaler correctly, see the instructions in the package leaflet.

Eklira Genuair can only be obtained with a prescription.

How does Eklira Genuair work?

The active substance in Eklira Genuair, aclidinium bromide, is an antimuscarinic bronchodilator. This means that it widens the airways by blocking muscarinic receptors. Muscarinic receptors control the

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contraction of muscles and when aclidinium bromide is inhaled, it relaxes the muscles of the airways. This helps to keep the airways open and allows the patient to breathe more easily.

What benefits of Eklira Genuair have been shown in studies?

A main study involving 828 patients with COPD found that Eklira Genuair was more effective than placebo (a dummy treatment) at improving how well the lungs work. The study compared two doses of Eklira Genuair (200 and 400 micrograms) inhaled twice a day with placebo. The main measure of effectiveness was how Eklira Genuair improved patients' forced expiratory volumes (FEV_1, the maximum volume of air a person can breathe out in one second). On average, after six months of treatment, the FEV_1 in patients who used 200 and 400 micrograms Eklira Genuair increased compared with placebo by 99 ml and 128 ml respectively. The dose of 400 micrograms Eklira Genuair corresponds to an inhalation providing 322 micrograms of aclidinium.

What are the risks associated with Eklira Genuair?

The most common side effects with Eklira Genuair (which may affect more than 5 patients in 100) are headache and nasopharyngitis (inflammation of the nose and throat). Other common side effects (which may affect more than 1 patient in 100) are sinusitis (inflammation of the sinuses), cough, nausea (feeling sick) and diarrhoea. For the full list of all side effects and restrictions with Eklira Genuair, see the package leaflet.

Why is Eklira Genuair approved?

The CHMP noted that Eklira Genuair was shown to be effective at improving the symptoms of COPD, and its beneficial effects are maintained for up to a year. The CHMP also noted that there were no major safety concerns with Eklira Genuair, with side effects being reversible and similar to other antimuscarinic bronchodilator medicines. Therefore, the CHMP decided that Eklira Genuair's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of Eklira Genuair?

As antimuscarinic bronchodilator medicines may have an effect on the heart and blood vessels, the company will closely monitor the medicine's cardiovascular effects and will carry out a further study in patients to identify any potential risks.

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

Other information about Eklira Genuair

The European Commission granted a marketing authorisation valid throughout the European Union for Eklira Genuair on 20 July 2012.

The full EPAR for Eklira 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 Eklira Genuair, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2017.