EMA/398097/2013
EMEA/H/C/002706

EPAR summary for the public

Bretaris Genuair

aclidinium bromide

This is a summary of the European public assessment report (EPAR) for Bretaris Genuair. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Bretaris Genuair.

What is Bretaris Genuair?

Bretaris Genuair is a medicine that contains the active substance aclidinium bromide. It is available as an inhalation powder in a portable inhaler device. The inhaler delivers 375 micrograms of aclidinium bromide equivalent to 322 micrograms of aclidinium for each inhalation.

What is Bretaris Genuair used for?

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

The medicine can only be obtained with a prescription.

How is Bretaris Genuair used?

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

How does Bretaris Genuair work?

The active substance in Bretaris Genuair, aclidinium bromide, is an anticholinergic bronchodilator. This means that it widens the airways by blocking some receptors in muscle cells in the lungs called

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

muscarinic 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.

How has Bretaris Genuair been studied?

The effects of Bretaris Genuair were first tested in experimental models before being studied in humans.

In the main study involving 828 patients with COPD, two different doses of Bretaris Genuair (200 and 400 micrograms) given twice a day were compared with placebo (a dummy treatment). The main measure of effectiveness was how Bretaris Genuair improved patients' forced expiratory volumes (FEV_1, the maximum volume of air a person can breathe out in one second) after six months.

What benefit has Bretaris Genuair shown during the studies?

Bretaris Genuair was more effective than placebo at improving how well the lungs work in patients with COPD. On average, after six months of treatment the increase in FEV_1 in patients who received 200 and 400 micrograms Bretaris Genuair was 99 ml and 128 ml compared with placebo, respectively. 400 micrograms of Bretaris Genuair corresponds to the amount of aclidinium bromide contained in the inhaler which delivers 322 micrograms of aclidinium.

What is the risk associated with Bretaris Genuair?

The most common side effects with Bretaris Genuair (seen in between 1 and 10 patients in 100) are sinusitis (inflammation of the sinuses), nasopharyngitis (inflammation of the nose and throat), headache, cough and diarrhoea. For the full list of all side effects reported with Bretaris Genuair, see the package leaflet.

Bretaris Genuair must not be used in people who are hypersensitive (allergic) to aclidinium bromide, atropine, other related anticholinergic bronchodilator medicines, or any of the other ingredients.

Why has Bretaris Genuair been approved?

The CHMP noted that Bretaris 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 Bretaris Genuair, with side effects being reversible and similar to other anticholinergic bronchodilator medicines. Therefore, the CHMP decided that Bretaris 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 Bretaris Genuair?

As anticholinergic 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.

Other information about Bretaris Genuair

The European Commission granted a marketing authorisation valid throughout the European Union for Bretaris Genuair on 24 July 2012.

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

This summary was last updated in 07-2013.