

**Alisade<sup>1</sup>**  
*fluticasone furoate***EPAR summary for the public**

*This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.*

*If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).*

**What is Alisade?**

Alisade is a nasal spray that contains the active substance fluticasone furoate.

**What is Alisade used for?**

Alisade is used to treat the symptoms of allergic rhinitis. This is inflammation of the nasal passages caused by an allergy, resulting in runny nose, blocked nose, itching and sneezing. It is often accompanied by symptoms affecting the eyes, such as irritation, watering or redness. Alisade is for use in patients aged six years and over.

The medicine can only be obtained with a prescription.

**How is Alisade used?**

The recommended dose of Alisade for patients aged 12 years and over is two sprays in each nostril once a day. This can be reduced to one spray in each nostril once symptoms are controlled. The lowest effective dose that keeps symptoms controlled should be used.

For children between six and 12 years of age, the recommended dose is one spray in each nostril once a day, although this can be increased to two sprays if symptoms are not controlled.

To get the most benefit from the medicine, it should be used regularly and at the same time every day. It usually starts to work from eight hours after the first spray, but it may take several days to get the maximum benefit. Alisade should only be used for as long as the patient is exposed to the allergen, such as pollen, house dust mites or other animals.

**How does Alisade work?**

The active substance in Alisade, fluticasone furoate, is a corticosteroid. It works in a similar way to naturally occurring corticosteroid hormones, reducing the activity of the immune system by attaching to receptors in various types of immune cell. This leads to a reduction the release of substances that are involved in the inflammation process, such as histamine, reducing the symptoms of allergy.

**How has Alisade been studied?**

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

<sup>1</sup> Previously known as Fluticasone Furoate GSK.

Alisade was compared with placebo (a dummy treatment) in six main studies involving almost 2,500 patients. The first four studies looked at Alisade used in patients aged 12 years or over: three were short-term studies lasting two weeks and involved a total of 886 patients with seasonal allergic rhinitis (hay fever), while the fourth lasted four weeks and involved 302 patients with perennial (non-seasonal) allergies, such as allergies to animals. The other two studies were carried out in children aged between two and 11 years: the first involved 558 children with perennial allergic rhinitis and the second involved 554 children with seasonal allergic rhinitis.

In all of the studies, the main measure of effectiveness was the change in four symptoms of allergy affecting the nose. Each symptom was measured on a scale from 0 to 3, with a maximum total score of 12.

#### **What benefit has Alisade shown during the studies?**

Alisade was more effective than placebo at reducing symptoms of allergic rhinitis in patients aged six years and over. In the studies of seasonal allergic rhinitis in patients aged 12 years or over, Alisade reduced symptom scores from around 9 points at the start of the study by between 3.6 and 5.4 points over two weeks, compared with a reduction of 2.3 to 3.7 points with placebo. In the study of perennial allergic rhinitis, Alisade had reduced scores by 3.6 points after four weeks, compared with a reduction of 2.8 points with placebo.

Similar results were seen in children aged six years and above. However, it was not possible to determine if Alisade worked in children below the age of six years, because there were too few children below this age included in the studies.

#### **What is the risk associated with Alisade?**

The most common side effect with Alisade (seen in more than 1 patient in 10) is epistaxis (nosebleeds). This is generally mild or moderate and tends to affect adults who have used Alisade for more than six weeks. For the full list of all side effects reported with Alisade, see the Package Leaflet. Alisade should not be used in people who are allergic to fluticasone furoate or any of the other ingredients.

#### **Why has Alisade been approved?**

The Committee for Medicinal Products for Human Use (CHMP) decided that Alisade's benefits are greater than its risks for the treatment of the symptoms of allergic rhinitis in patients aged six years or over. The Committee recommended that Alisade be given marketing authorisation.

#### **Other information about Alisade:**

The European Commission granted a marketing authorisation valid throughout the European Union for Fluticasone Furoate GSK to Glaxo Group Ltd on 6 October 2008. This authorisation was based on the authorisation granted to Avamys in January 2008 ('informed consent'). The name of the medicine was changed to Alisade on 25 March 2009.

The full EPAR for Alisade can be found [here](#).

**This summary was last updated in 05-2009.**