EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Avamys

fluticasone furoate

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AUTHORISED
This medicine is authorised for use in the European Union.

Overview

This 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 its 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 Avamys?

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

What is Avamys used for?

Avamys 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. Avamys is for use in patients aged six years and over.

The medicine can only be obtained with a prescription.

How is Avamys used?

The recommended dose of Avamys 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. Avamys 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 Avamys work?

The active substance in Avamys, 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 Avamys been studied?

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

Avamys was compared with placebo (a dummy treatment) in six main studies involving almost 2,500 patients. The first four studies looked at Avamys 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 Avamys shown during the studies?

Avamys 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, Avamys 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, Avamys 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 Avamys worked in children below the age of six years, because there were too few children below this age included the studies.

What is the risk associated with Avamys?

The most common side effect with Avamys (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 Avamys for more than six weeks. For the full list of all side effects reported with Avamys, see the package leaflet.

Avamys should not be used in people who are allergic to fluticasone furoate or any of the other ingredients.

Why has Avamys been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Avamys'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 Avamys be given marketing authorisation.

Other information about Avamys

The European Commission granted a marketing authorisation valid throughout the European Union for Avamys to Glaxo Group Ltd on 11 January 2008.

Avamys : EPAR - Summary for the public (PDF/32.82 KB)

First published: 06/07/2009
Last updated: 06/07/2009

Available languages (21)

More detail is available in the summary of product characteristics

This EPAR was last updated on 14/05/2019

Authorisation details

Name

Avamys

Agency product number

EMEA/H/C/000770

Active substance

Fluticasone furoate

International non-proprietary name (INN) or common name

Fluticasone furoate

Therapeutic area (MeSH)

- Rhinitis, Allergic, Seasonal
- Rhinitis, Allergic, Perennial

Anatomical therapeutic chemical (ATC) code

R01AD12

Marketing-authorisation holder

GlaxoSmithKline (Ireland) Limited

Revision

18

Date of issue of marketing authorisation valid throughout the European Union

11/01/2008

Contact address

12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

Product information

06/12/2018 Avamys - EMEA/H/C/000770 - T/0037

Avamys : EPAR - Product Information (PDF/543.85 KB)

First published: 09/07/2009
Last updated: 14/05/2019

Available languages (24)

Contents

- Annex I - Summary of product characteristics
- Annex IIA - Manufacturing-authorisation holder responsible for batch release
- Annex IIB - Conditions of the marketing authorisation
- Annex IIIA - Labelling
- Annex IIIB - Package leaflet

Please note that the size of the above document can exceed 50 pages.

You are therefore advised to be selective about which sections or pages you wish to print.

Avamys : EPAR - All Authorised presentations (PDF/11.53 KB)

First published: 24/01/2008
Last updated: 24/01/2008

Available languages (22)

Pharmacotherapeutic group

- NASAL PREPARATIONS
- Corticosteroids

Therapeutic indication

Adults, adolescents (12 years and over) and children (6-11 years). Avamys is indicated for the treatment of the symptoms of allergic rhinitis.

Assessment history

Changes since initial authorisation of medicine

Avamys : EPAR - Procedural steps taken and scientific information after authorisation (PDF/148.62 KB)

First published: 18/01/2010
Last updated: 14/05/2019

Avamys-H-C-770-P46-0023 : EPAR - Assessment Report (PDF/471.41 KB)

Adopted

First published: 20/12/2012
Last updated: 20/12/2012
EMA/813446/2012

Initial marketing-authorisation documents

Avamys : EPAR - Procedural steps taken before authorisation (PDF/22.87 KB)

First published: 24/01/2008
Last updated: 24/01/2008

Avamys : EPAR - Scientific Discussion (PDF/337.79 KB)

First published: 24/01/2008
Last updated: 24/01/2008

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