

Package leaflet: Information for the user

Avamys® 27.5 micrograms per spray nasal spray suspension Fluticasone furoate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Never pass it on to others. It may harm them, even if their signs of illness seem the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Avamys is and what it is used for
2. What you need to know before you use Avamys
3. How to use Avamys
4. Possible side effects
5. How to store Avamys
6. Contents of the pack and other information
Step-by-step guide to using the nasal spray

1. What Avamys is and what it is used for

Avamys (fluticasone furoate) belongs to a group of medicines called *glucocorticoids*. Avamys works to decrease inflammation caused by allergy (*rhinitis*) and therefore reduce symptoms of allergy.

Avamys nasal spray is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing and watery, itchy or red eyes, in adults and children aged 6 years and over.

Allergy symptoms can occur at specific times of the year and be caused by allergy to pollen from grass or trees (hayfever), or they can occur all year round and be caused by allergy to animals, house-dust mites or moulds to name some of the most common.

2. What you need to know before you use Avamys

Do not use Avamys:

- **If you are allergic** to fluticasone furoate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

If you have any liver problems, tell your doctor or pharmacist.

Children and adolescents

Do not use in children under 6 years old.

Taking Avamys:

- may when taken for a long time cause children to grow more slowly. The doctor will check your child's height regularly, and make sure he or she is taking the lowest possible effective dose.
- may cause eye conditions such as glaucoma (increase in pressure in the eye) or cataracts (clouding of the lens of the eye). Tell your doctor if you had these conditions in the past, or if you notice any change in your vision while you are taking Avamys.

Other medicines and Avamys

Tell your doctor or pharmacist if you are taking, or have recently taken, or might take any other medicines.

It is especially important to tell your doctor if you are taking, or have recently taken any of the following medicines:

- steroid tablets or injected steroids
- steroid creams
- medicines for **asthma**
- ritonavir, used to treat **HIV**
- ketoconazole, used to treat **fungal infections**

Your doctor will assess whether you should take Avamys with these medicines.

Avamys should not be used at the same time with other nasal sprays containing steroids.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not use Avamys if you are pregnant, or planning to become pregnant, unless your doctor or pharmacist tells you to.

Do not use Avamys if you are breast feeding unless your doctor or pharmacist tells you to.

Driving and using machines

Avamys is unlikely to affect your ability to drive and use machines.

Avamys contains benzalkonium chloride

In some patients benzalkonium chloride can cause irritation in the inside of the nose. Tell your doctor or pharmacist if you feel discomfort when using the spray.

3. How to use Avamys

Always use this medicine exactly as your doctor or pharmacist has told you. Don't exceed the recommended dose. Check with your doctor or pharmacist if you're not sure.

When to use Avamys

- Use once a day
- Use at the same time each day.

This will treat your symptoms throughout the day and night.

How long Avamys takes to work

Some people will not feel the full effects until several days after first using Avamys. However, it is usually effective within 8 to 24 hours of use.

How much to use

Adults and children 12 years and over

- **The usual starting dose** is 2 sprays in each nostril once every day.
- Once symptoms are controlled you may be able to decrease your dose to 1 spray in each nostril, once every day.

Children 6 to 11 years

- **The usual starting dose** is 1 spray in each nostril once a day.
- If symptoms are very bad your doctor may increase the dose to 2 sprays in each nostril once every day until the symptoms are under control. It may then be possible for the dose to be reduced to 1 spray in each nostril once every day.

How to use the nasal spray

Avamys has virtually no taste or smell. It is sprayed into the nose as a fine mist. Be careful not to get any spray into your eyes. If you do, rinse your eyes with water.

There is a step-by-step guide to using the nasal spray after Section 6 of this leaflet. Follow the guide carefully to get full benefit from using Avamys

➤ **See *Step-by-step guide to using the nasal spray*, after Section 6.**

If you use more Avamys than you should

Talk to your doctor or pharmacist.

If you forget to use Avamys

If you miss a dose, take it when you remember.

If it is nearly the time for your next dose, wait until then. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, or if you have any discomfort using the nasal spray ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions: get a doctor's help straight away

Allergic reactions to Avamys are rare and affect less than 1 person in 1,000. In a small number of people, allergic reactions can develop into a more serious, even life-threatening problem if not treated. Symptoms include:

- becoming very wheezy, coughing or having difficulty with breathing
- suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness)
- swelling around the face
- skin rashes or redness.

In many cases, these symptoms will be signs of less serious side effects. **But you must be aware that they are potentially serious** — so, if you notice any of these symptoms:

Contact a doctor as soon as possible.

Very common side effects (may affect more than 1 in 10 people)

- Nosebleeds (generally minor), particularly if you use Avamys for more than 6 weeks continuously.

Common side effects (may affect up to 1 in 10 people)

- Nasal ulceration – which may cause irritation or discomfort in your nose. You may also get streaks of blood when you blow your nose.
- Headache.

Uncommon side effects (may affect up to 1 in 100 people)

- Pain, burning, irritation, soreness or dryness in the inside of the nose.

Not known (frequency cannot be estimated from the available data)

- Slowing of growth in children.
- Temporary changes to vision with long term use.

Nasal corticosteroids can affect the normal production of hormones in your body, particularly if you use high doses for a long time. In children this side effect can cause them to grow more slowly than others.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

FREEPOST

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

Malta

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

203 Level 3, Rue D'Argens

GŻR-1368 Gżira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Avamys

Keep this medicine out of the sight and reach of children.

It is best to store your Avamys nasal spray upright. Always keep the cap on.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of the month. Avamys nasal spray should be used within 2 months after first opening.

Do not refrigerate or freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Avamys contains

The active substance is fluticasone furoate. Each spray delivers 27.5 micrograms of fluticasone furoate. The other ingredients are glucose anhydrous, dispersible cellulose, polysorbate 80, benzalkonium chloride, disodium edetate, purified water (see section 2).

What Avamys looks like and contents of the pack

The medicine is a white nasal spray suspension contained in an amber glass bottle, fitted with a pump. The bottle is in an off-white plastic casing with a light blue cap and side-actuated lever. The casing has a window for viewing the bottle contents. Avamys is available in pack sizes 30, 60 and 120 sprays. Not all pack sizes may be marketed.

Marketing authorisation holder

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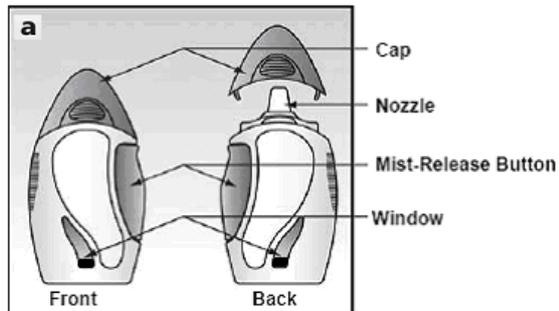
Detailed information on this medicine is available on the European Medicines Agency website:
<http://www.ema.europa.eu>

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STEP-BY-STEP GUIDE TO USING THE NASAL SPRAY

What the nasal spray looks like

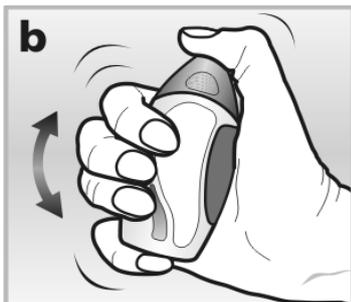
The nasal spray comes in an amber glass bottle inside a plastic casing - see picture **a**. It will contain either 30, 60 or 120 sprays, depending on the pack size that has been prescribed for you.



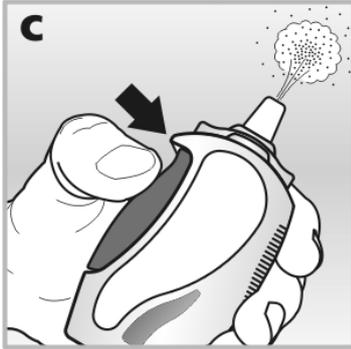
The window in the plastic casing lets you see how much Avamys is left in the bottle. You will be able to see the liquid level for a new 30 or 60 spray bottle, but not in a new 120 spray bottle because the liquid level is above the window.

Six important things you need to know about using the nasal spray

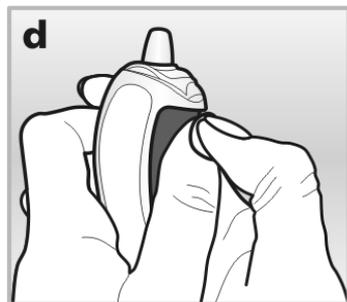
- Avamys comes in an amber glass bottle. If you need to check how much is left **hold the nasal spray upright against a bright light**. You will then be able to see the level through the window.
- When you **first use the nasal spray** you will need to **shake it vigorously** with the cap on for about 10 seconds. This is important as Avamys is a thick suspension that becomes liquid when you shake it well - see picture **b**. It will only spray when it becomes liquid.



- The mist-release button must be **pressed firmly all the way in**, to release the mist through the nozzle - see picture **c**.



- If you have difficulty pressing the button with your thumb, you can use two hands – see picture **d**



- **Always keep the cap on the nasal spray** when you are not using it. The cap keeps the dust out, seals in the pressure and stops the nozzle from blocking up. When the cap is in place the mist-release button cannot be pressed accidentally.
- **Never use a pin** or anything sharp to clear the nozzle. It will damage the nasal spray

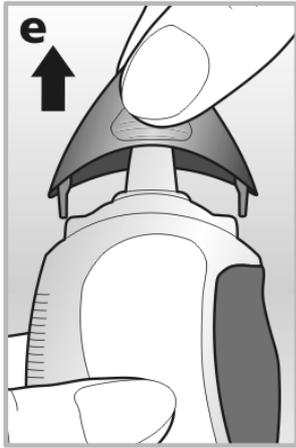
Preparing the nasal spray for use

You must prepare the nasal spray:

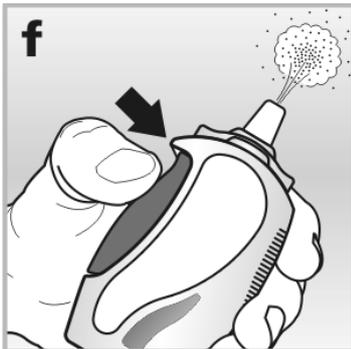
- before you use it for the first time
- if you have left the cap off for 5 days or the intranasal device has not been used for 30 days or more.

Preparing the nasal spray helps to make sure you always get the full dose of medicine. Follow these steps:

- 1 **Shake the nasal spray vigorously** with the cap on for about 10 seconds.
- 2 Remove the cap by squeezing firmly on the sides of the cap with your thumb and forefinger– see picture e.



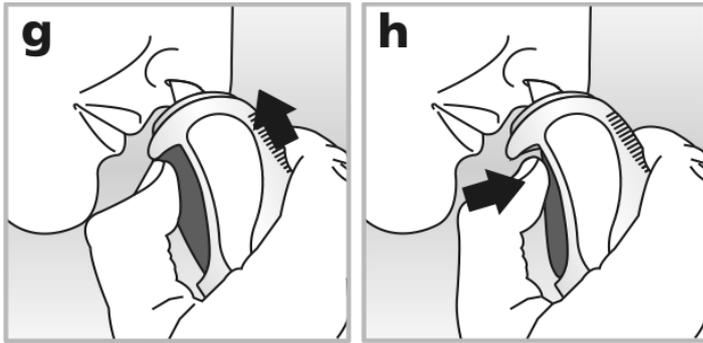
- 3 Hold the nasal spray upright, then tilt and **point the nozzle away from you**.
- 4 **Press the button firmly** all the way in. **Do this at least 6 times** until it releases a fine mist of spray into the air – see picture f.



The nasal spray is now ready for use.

Using the nasal spray

- 1 **Shake the nasal spray** vigorously.
- 2 **Remove the cap**.
- 3 **Blow your nose** to clear your nostrils, then tilt your head forward a little bit.
- 4 Place the nozzle in one of your nostrils – see picture g. Point the end of the nozzle slightly outwards, away from the centre ridge of your nose. This helps to get the medicine to the correct part of your nose.
- 5 Press the **button firmly** all the way in, **while you breathe in through your nose** – see picture h.



- 6 Take the nozzle out and **breathe out through your mouth.**
- 7 If your dose is 2 sprays in each nostril repeat steps 4 to 6.
- 8 Repeat steps 4 to 7 to treat the other nostril.
- 9 **Replace the cap** on the nasal spray.

Cleaning the nasal spray

After each use:

- 1 Wipe the nozzle and inside of the cap with a clean, dry tissue – see pictures **i** and **j**.



- 2 Do not use water to clean it.
- 3 **Never use a pin** or anything sharp on the nozzle.
- 4 **Always replace the cap** once you have finished.

If the nasal spray does not seem to be working:

- Check you still have medicine left. Look at the level through the window. If the level is very low there may not be enough left to work the nasal spray.
- Check the nasal spray for damage
- If you think the nozzle may be blocked, **don't use a pin** or anything sharp to clear it.
- Try to reset it by following the instructions under 'Preparing the nasal spray for use'.
- If it is still not working, or if it produces a jet of liquid, take the nasal spray back to the pharmacy to get advice.