

AVAMYS

Fluticasone furoate (27.5 micrograms)

What is in this leaflet

1. What AVAMYS is used for
2. How AVAMYS works
3. Before you use AVAMYS
4. How to use AVAMYS
5. While you are using it
6. Side effects
7. Storage and disposal of AVAMYS
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What AVAMYS is used for

AVAMYS nasal spray is used to treat allergic symptoms which include:

- Stuffy, runny or itchy nose
- Sneezing
- Water, itchy or red eyes

Symptoms can be seasonal. These are caused by allergies to pollen from grass or trees (hayfever). They can also occur throughout the year and can be caused by animal allergies, house-dust mites or moulds.

How AVAMYS works

AVAMYS belongs to a group of medicines called glucocorticoids. AVAMYS decreases inflammation in the nose and irritation of the eyes caused by allergies (rhinitis).

Before you use AVAMYS

When you must not use it

If you are allergic (*hypersensitive*) to fluticasone furoate or any other ingredients of AVAMYS.

Before you start to use it

Before you use AVAMYS your doctor needs to know:

- If you have liver disease, your doctor may lower your dose of AVAMYS
- Check with your doctor if you think this may apply to you.

If you are pregnant, or think you could be, or if you are planning to become pregnant, don't take AVAMYS without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking AVAMYS while you're pregnant.

It is not known whether the ingredients of AVAMYS can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take AVAMYS.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicine bought without a prescription.

Some medicines may affect how AVAMYS works, or make it more likely that you'll have side effects. These include:

- Ritonavir (used to treat HIV)
- Ketoconazole (used to treat fungal infections)

Tell your doctor or pharmacist if you are taking any of these.

How to use AVAMYS

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 reduce your dose to 1 spray in each nostril, once a day

Children 2 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 a day

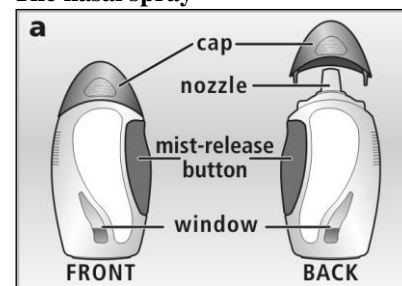
- Do not use in children under 2 years old.

AVAMYS is sprayed into the nose as a fine mist. It has virtually no taste.

The first time you use the spray, you must test that it is working properly.

Step-by-step instructions:

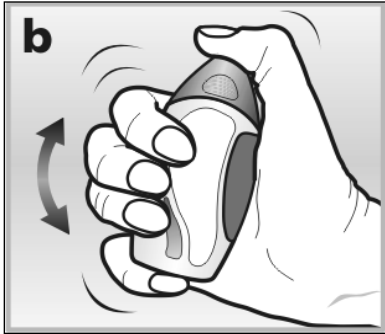
The nasal spray



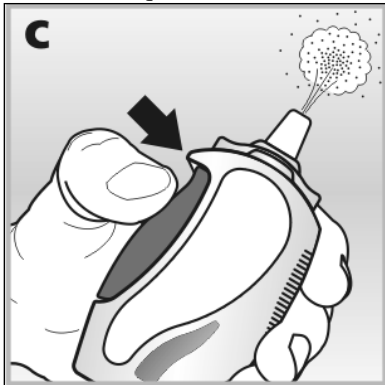
- Your medicine comes in a brown glass bottle inside a plastic casing. It will contain either 30, 60 or 120 sprays, depending on the pack size that has been prescribed for you. (picture a)
- A window in the plastic casing allows you to see how much medicine is left. You will be able to see the liquid level for a new 30 or 60 spray bottle (picture 1), but not for a new 120 spray bottle because the liquid level is above the window.
- The medicine sprays out of the nozzle when the button on the side is pressed firmly all the way in.
- A removable cap protects the nozzle from dust and prevents it from blocking up.

Six important things you need to know about AVAMYS

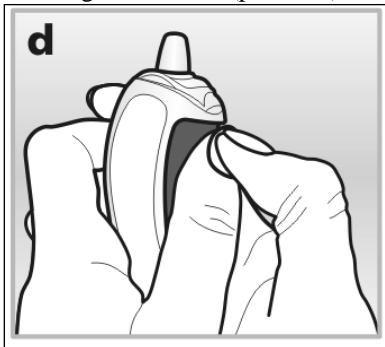
1. The nasal spray comes in a brown glass bottle. To check how much is left hold the nasal spray upright against a bright light. You will then be able to see the level through the window.



2. When you first use the nasal spray you must shake it vigorously with the cap on for about 10 seconds. This is important as AVAMYS is very thick and becomes more liquid when you shake it well (picture b). It will only spray when it becomes liquid.



3. The button on the side must be pressed firmly all the way in, to release a spray through the nozzle (picture c).



4. If you have difficulty pressing the button with your thumb, you can use two hands (picture d).
5. 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 button on the side can't be pressed accidentally.

6. Never use a pin or anything sharp to clear the nozzle. It will damage the nasal spray.

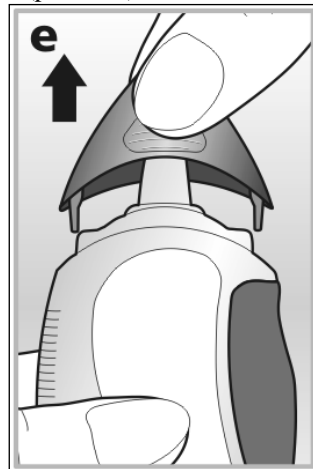
Preparing the Nasal Spray

You must prepare the nasal spray:

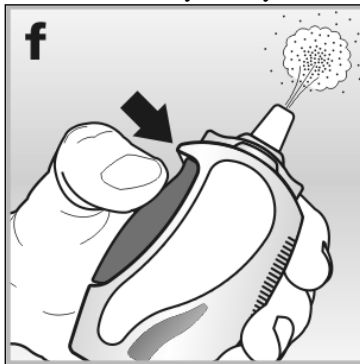
- Before you use it for the first time
- If you have left the cap off

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

- With the cap on, shake the nasal spray vigorously for about 10 seconds.
- Remove the cap by gently squeezing the sides of the cap with your thumb and forefinger and pulling it straight off (picture e).



- Hold the nasal spray upright and point the nozzle away from you.

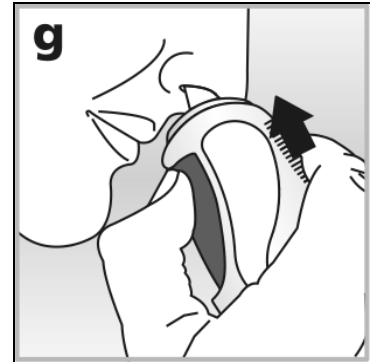


- Press the button firmly all the way in. Do this at least 6 times to release a fine spray into the air (picture f)
- The nasal spray is now ready for use.

Using the nasal spray

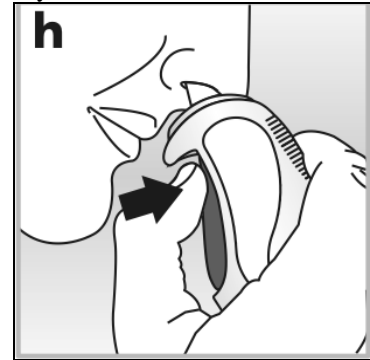
1. Shake the nasal spray vigorously.
2. Remove the cap.

3. Blow your nose to clear your nostrils, and then tilt your head forward a little bit.



4. Hold the nasal spray upright and carefully place the nozzle in one of your nostrils (picture g).

5. Point the end of the nozzle toward the outside of your nose, away from the centre ridge of your nose. This helps direct the medicine to the right part of your nose.



6. As you breathe in through your nose, press the button once firmly all the way in (picture h).

7. Be careful not to get any spray in your eyes. If you do, rinse your eyes with water.

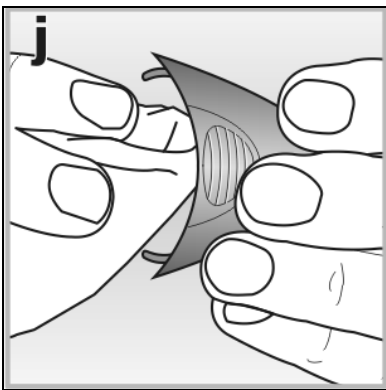
8. Take the nozzle out and breath out through your mouth.

9. If your doctor has told you to take 2 sprays per nostril, repeat steps 4 to 6.

10. Repeat steps 4 to 6 for your other nostril.

11. Replace the cap on the nasal spray.

Cleaning the nasal spray
After each use:



- Wipe the nozzle and the inside of the cap (picture I and j). Don't use water to do this. Wipe with a clean, dry tissue.
- Never use a pin or anything sharp on the nozzle.
- Always replace the cap once you have finished to keep out dust, seal in the pressure and stop the nozzle from blocking up.

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 anything other than a fine mist (such as a jet of liquid), or if you feel any discomfort using the spray, return it to your pharmacist.

When to use it

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

This will treat your symptoms throughout the day and night.

How long to use it

Don't stop AVAMYS without advice. Most people will feel the effects of AVAMYS within 8 hours. However, some people will not feel the full effects until several days after first using AVAMYS. Take AVAMYS for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you forget to use it

Don't take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

If you use too much (overdose)

If you take too much AVAMYS, contact your doctor or pharmacist for advice. If possible, show them the AVAMYS pack.

While you are using it

Things you must do

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

Things you must not do

This medicine has been prescribed for you personally. Don't pass it on to other people – it may harm them even if their symptoms seem to be the same as yours.

Things to be careful of

Conditions you need to look out for

Allergic reactions: These are rare in people taking AVAMYS. Signs include:

- Skin rash (*hives*) or redness
- Swelling, sometimes of the face or mouth (*angioedema*)

- Becoming very wheezy, coughing or having difficulty in breathing
- Suddenly feeling weak or light headed (may lead to collapse or loss of consciousness)

Contact a doctor immediately if you get any of these symptoms. Stop taking AVAMYS.

Side effects

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

Very common side effects

These may affect more than 1 in 10 people:

- Nosebleeds are generally minor. Nosebleeds are more likely to occur if you use AVAMYS for more than 6 weeks continuously

Common side effects

These 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

These may affect up to 1 in 100 people:

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

Rare side effects

These may affect up to 1 in 1,000 people:

- Allergic reactions

Very rare side effects

These may affect up to 1 in 10,000 people:

- Nasal septum perforation (hole in the nasal septum)

Not known

Cannot be estimated from the available data:

- Slowing of growth in children

If you get side effects

- Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of AVAMYS

Storage

Keep out of the reach and sight of children. Do not use AVAMYS after the expiry date shown on the pack. Do not store AVAMYS above 30°C. Do not refrigerate or freeze. Always keep the cap on.

Disposal

If you have any unwanted AVAMYS nasal sprays, don't dispose of them in your wastewater or household rubbish. Ask your pharmacist how to dispose of

medicines no longer required. This will help to protect the environment.

Product description

What it looks like

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 blue side-actuated lever and a lid which contains a stopper.

Ingredients

Active ingredient(s)

Each spray delivers 27.5 micrograms of fluticasone furoate.

Inactive ingredient(s)

Glucose anhydrous, dispersible cellulose, polysorbate 80, benzalkonium chloride, disodium edetate, purified water.

MAL number

MAL20081823ARZ

Manufacturer

Glaxo Wellcome S.A.
Avenida De Extremadura 3
09400 Aranda De Duero
Burgos
Spain

Product Registration Holder

GlaxoSmithKline Pharmaceutical Sdn.
Bhd.
HZ.01, Horizon Penthouse,
1 Powerhouse,
1, Persiaran Bandar Utama,
Bandar Utama,
47800 Petaling Jaya
Selangor, Malaysia

Date of revision

30/06/2023

Serial Number

NPRA (R1/2)04112020/193