PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

AVAMYS 27,5 µg/spray, nasal spray suspension

Fluticasone furoate

Read all of this leaflet carefully before you start using AVAMYS.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- AVAMYS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

1. What AVAMYS is and what it is used for

AVAMYS contains the medicine fluticasone furoate. It is a steroid which helps decrease inflammation in the nose and irritation of the eyes caused by allergies (rhinitis). The effects

are usually felt within the first day, although some people will not feel the full effects until several days after first using AVAMYS.

The doctor has prescribed AVAMYS to help treat symptoms caused by allergies, including watery and itchy eyes, stuffy or runny nose, and sneezing. Symptoms can occur at specific times of the year and be caused by allergies to pollen from grass or trees (hayfever) or they can occur all year around and be caused by allergies to animals, house-dust mites or moulds. Using AVAMYS once daily will help prevent both daytime and night time symptoms.

AVAMYS is delivered into the nose as a fine mist spray. AVAMYS is not for use in the eyes.

There is a window on the side of the outer plastic cover of AVAMYS so that you can see how much medicine is left in the nasal spray bottle. Ask your doctor for more medicine when the amount of medicine left is getting low.

2. What you need to know before you use AVAMYS

Do not use AVAMYS if:

You are allergic (hypersensitive) to fluticasone furoate or any of the other ingredients of AVAMYS (listed in section 6 of this leaflet).

Warnings and precautions:

Tell your doctor or health care provider, before using AVAMYS if you or your child:

- Nasal corticosteroids can affect the normal production of hormones in your body, particularly if you use high doses for a long time

Take special care with AVAMYS:

- if you experience blurred vision or other visual disturbances, speak to your doctor.

Children and adolescents:

When using AVAMYS for a long time, this may cause children to grow slowly. The doctor will check your child's height regularly and make sure your child is using the lowest possible dose.

AVAMYS is not recommended for use in children below 2 years of age.

Other medicine and AVAMYS:

Always tell your health care provider if you are taking any other medicine. (This includes complementery or traditional medicines.)

Some medicines may affect how AVAMYS works, or make it more likely that you will have side effects.

Tell your doctor or pharmacist if you are taking:

- medicines for asthma
- any medicnes containing a steroid. These may include some eczema creams, injections, tablets, nasal sprays and eye or nose drops
- ritonavir (a medicine used in the treatment of HIV)
- ketoconazole (a medicine used to treat fungal infections).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice, before using AVAMYS.

Driving and using machines:

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

AVAMYS contains benzalkonium chloride:

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How to use AVAMYS

Do not share medicines precribed for you with any other person.

Always use AVAMYS exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Use your AVAMYS once every day as close to the same time of day as possible, to treat your symptoms throughout the day and night.

AVAMYS is sprayed into the nose as a fine mist.

Adults and adolescents 12 years and older:

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 (2 to 11 years of age):

In children aged 2 to 11 years the usual starting dose is 1 spray in each nostril once every day.

If symptoms are very bad the doctor may increase the dose to 2 sprays in each nostril once every day until symptoms are under control. It may then be possible for the dose to be reduced to 1 spray in each nostril once every day.

If you have the impression that the effect of AVAMYS is too strong or too weak, tell your doctor or pharmacist.

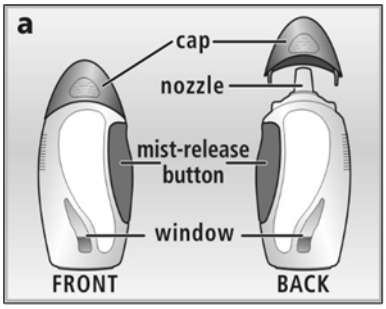
Instructions for use:

This section includes the following information:

- The nasal spray
- Six important things you need to know about AVAMYS
- Preparing the nasal spray
- Using the nasal spray
- Cleaning the nasal spray.

The nasal spray:

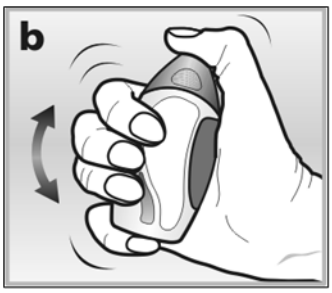
- AVAMYS comes in a brown glass bottle inside a plastic casing. It will contain either 30, 60 or 120 sprays, depending on the pack size that has been prescribed for you. **(picture a).**
- A window in the plastic casing allows you to see how much medicine is left. You will be able to see the liquid level for a new 30 or 60 spray bottle (**picture a**), but not for a new 120 spray bottle because the liquid level is above the window.



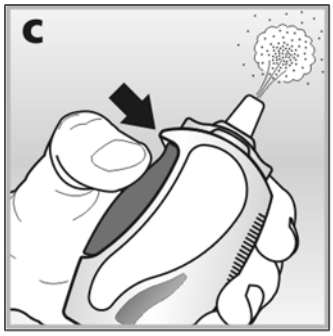
- The medicine sprays out of the nozzle when the button on the side is pressed firmly all the way in.
- A removable cap protects the nozzle from dust and prevents it from blocking up.

Six important things you need to know about AVAMYS:

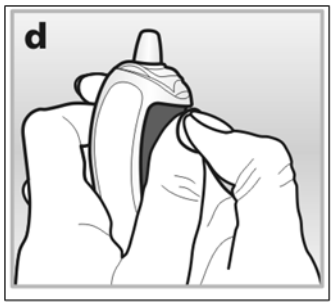
1. The nasal spray comes in a brown glass bottle. To check how much is left, **hold the nasal spray upright against a bright light**. You will then be able to see the level through the window.
2. When you **first use the nasal spray you must shake it vigorously** with the cap on for about 10 seconds. 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 cannot 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:

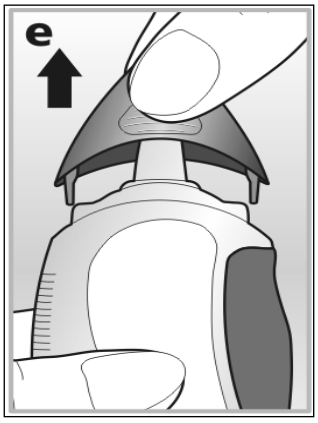
- before you use it for the first time
- if you have left the cap off.

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

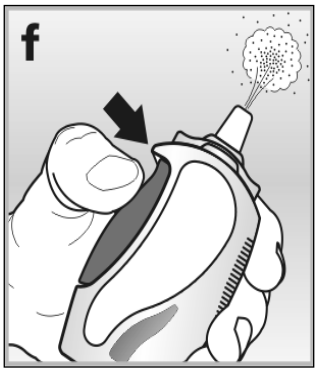
Follow these steps:

- 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.

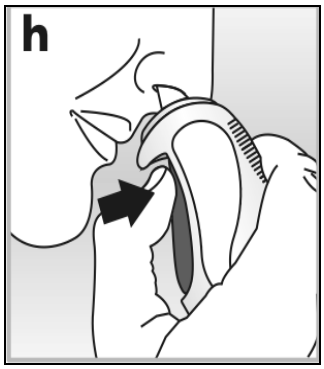
4. Hold the nasal spray upright and carefully place the nozzle in one of your nostrils **(picture g)**.



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)**.

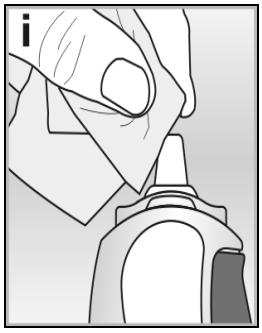


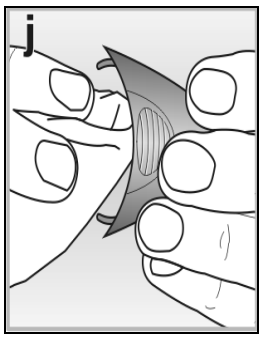
7. Be careful not to get any spray in your eyes. If you do, rinse your eyes with water.
8. Take the nozzle out and breathe out through your mouth.
9. If your doctor has told you to take two sprays per nostril, repeat steps 4 to 6.
10. Repeat steps 4 to 6 for your other nostril.
11. **Replace the cap** on the nasal spray.

Cleaning the nasal spray:

After each use:

- Wipe the nozzle and the inside of the cap **(picture i and j)**. Do not 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, **do not use a pin** or anything sharp to clear it.

Try to re-set the nasal spray 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.

If you use more AVAMYS than you should:

It is important to use AVAMYS as you have been instructed.

If you accidently use more than the recommended number of sprays, talk to your doctor or pharmacist.

If you forget to use AVAMYS:

If you miss a dose, use it when you remember. If it is nearly time for your next dose, wait until then. Do not use a double dose.

If you have any further questions on the use of AVAMYS, ask your doctor or pharmacist.

4. Possible side effects

AVAMYS can have side effects.

Not all side effects reported for AVAMYS are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using AVAMYS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using AVAMYS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- difficulty breathing
- swelling of the face, neck, tongue or throat and a skin rash (severe allergic reactions)
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to AVAMYS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- slowing of growth of children
- small holes (perforations) in the ridge inside the nose that separates the nostrils.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects include:

- minor nosebleeds – nosebleeds are more likely to occur if you use AVAMYS for more than 6 weeks continuously
- nasal ulceration – which may cause irritation or discomfort in your nose

  You may also get streaks of blood when you blow your nose.
- headache.

Less frequent side effects include:

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under

SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AVAMYS.

5. How to store AVAMYS

Store all medicines out of reach of children.

Store at or below 30 ºC in the container specified.

Do not keep AVAMYS in the fridge or freezer.

Always keep the cap on.

Once opened, you can use AVAMYS up until the last day of the month of the expiry date. Do not use AVAMYS after the expiry date which is stated on the label or carton.

Medicines should not be disposed of via wastewater or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What AVAMYS contains:

The active substance is fluticasone furoate. Each 50 µl of nasal spray contains 27,5 µg of fluticasone furoate.

The other ingredients are glucose anhydrous, dispersible cellulose, polysorbate 80, benzalkonium chloride (preservative), disodium edetate (preservative) and purified water.

What AVAMYS looks like and contents of the pack:

A uniform white suspension.

The nasal spray container consists of an inner container within an outer device. The inner container consists of a Type I or Type III amber glass bottle, closed with a metering spray

pump. The outer device is a mostly off-white side-actuated plastic delivery system with a light blue lever and lid containing a stopper. The outer plastic cover has a window for viewing the bottle contents.

AVAMYS is available in three pack sizes:

- 30 sprays with a target net content of 4,5 g
- 60 sprays with a target net content of 6,5 g
- 120 sprays with a target net content of 10 g.

Not all pack sizes may be marketed.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

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