

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrAVAMYS

fluticasone furoate nasal spray

Read this carefully before you start taking **AVAMYS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **AVAMYS**.

What is AVAMYS used for?

AVAMYS is used in adults, adolescents and children 2 years of age and older, to treat the symptoms of:

- **Seasonal allergic rhinitis:** also called “hay fever”;
- **Perennial allergic rhinitis:** year round allergies.

How does AVAMYS work?

AVAMYS belongs to a group of medicines called glucocorticoids and works by decreasing inflammation caused by seasonal allergies. When you spray AVAMYS into your nose it helps to reduce symptoms such as stuffiness, runniness, itching, sneezing, eye redness, itchy eyes, and watery eyes.

What are the ingredients in AVAMYS?

Medicinal ingredients: fluticasone furoate

Non-medicinal ingredients: 0.015% w/w benzalkonium chloride, carboxymethylcellulose sodium, dextrose anhydrous, edetate disodium, microcrystalline cellulose, polysorbate 80 and purified water.

AVAMYS comes in the following dosage forms:

Nasal spray; 27.5 mcg/metered spray.

Do not use AVAMYS if:

- You are allergic to fluticasone furoate or to any of the other ingredients in AVAMYS (see **What are the ingredients in AVAMYS** above).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AVAMYS. Talk about any health conditions or problems you may have, including if you:

- Are recovering from recent surgery, trauma or sores to your nose.
- Are pregnant, think you are pregnant, or are planning to become pregnant.
- Are breastfeeding or planning to breastfeed.
- Have asthma.
- Have liver disease or liver problems.
- Have been exposed to chickenpox or measles.
- Are taking any other corticosteroid medications.
- Have or have ever had tuberculosis.
- Have any untreated fungal, bacterial, viral or parasitic infections.
- Have an untreated eye infection caused by herpes.
- Have or have a history of any eye disorders such as glaucoma, cataracts or central serous

chorioretinopathy.

Other warnings you should know about:

Eye disorders: Drugs like AVAMYS can cause eye disorders such as:

- **Cataracts:** Clouding of the lens in the eye, blurry vision, eye pain;
- **Glaucoma:** An increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss;
- **Central serous chorioretinopathy (CSCR):** blurry vision or other changes in vision.

If you have any changes in your vision, tell your healthcare professional **right away**. You should have regular eye exams.

Monitoring: During treatment with AVAMYS, your doctor may monitor:

- The function of your eyes and nose.
- Growth; slower growth can occur in children and adolescents using AVAMYS.
- The effects of corticosteroid therapy on your body, especially if you have liver problems.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with AVAMYS:

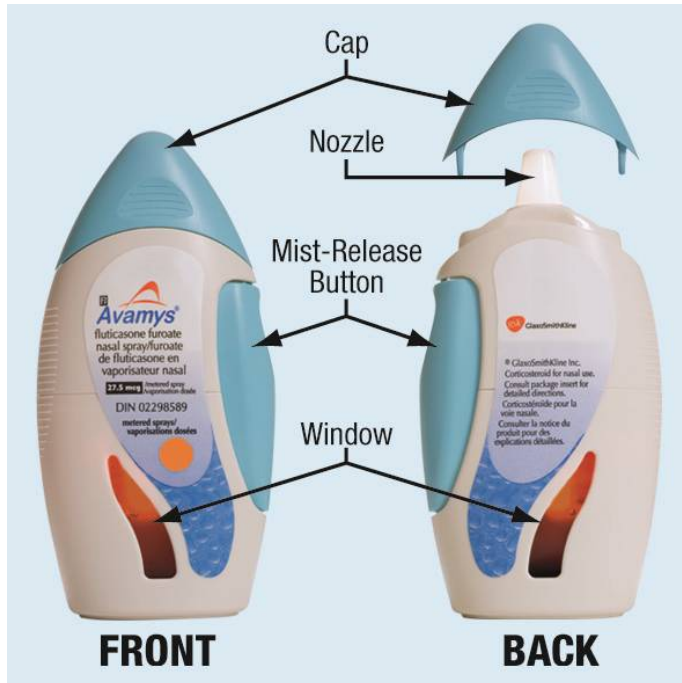
- steroid tablets, steroid creams or injected steroids
- medicines for asthma
- ritonavir, used to treat HIV
- ketoconazole, used to treat fungal infections

How to take AVAMYS:

- **Shake well before use.**
- This medicine is for use in the nose only. Do **not** spray it in your eyes or mouth.
- Use exactly as directed, do not take more or take it more often than your healthcare professional has told you to.
- You can take AVAMYS at any time of the day, but take it at the same time each day.
- Read the information below to learn how to use your AVAMYS device.

The parts of AVAMYS:

AVAMYS comes in an easy-to-use nasal spray device which contains a glass bottle.



The **Cap** keeps the **Mist-Release Button** from being pressed by mistake. It also helps keep the nozzle clean. Do not throw the cap away. Always keep the cap on when you are not using it.

The **Nozzle** is small and short, so it will fit comfortably inside your nose. The medicine comes out from the nozzle.

Pressing the **Mist-Release Button** sprays a measured amount of medicine from the nozzle as a gentle, fine mist. Because the button is on the side of the device, it is easy for you to keep the nozzle in the right place in your nose while you press the button.

AVAMYS comes in a brown glass bottle inside a plastic casing. The **Window** in the plastic casing lets you see how much medicine is left in the bottle. To check how much is left **hold the nasal spray upright against a bright light**; you will be able to see the liquid level if it is low. Bottles containing 30 sprays will not appear full when you first receive them.

How to prime AVAMYS (i.e. How to make AVAMYS ready to use):

Prime AVAMYS before using it for the first time. This helps to make sure you always get the same full dose of medicine:

1. With the cap on, shake AVAMYS well.
2. Take the cap off by squeezing the finger grips and pulling it straight off. Do not press the button while you take off the cap



3. Hold the device with the nozzle pointing up and away from you. Firmly press the button on the side all the way in to release a spray through the nozzle. If you have difficulty pressing the button with your thumb, you can use both hands. Press and release the button 6 times or until a fine mist is sprayed from the nozzle. AVAMYS is now ready to use.



4. Remember to prime AVAMYS whenever:
 - You use a new bottle for the first time.
 - You have not used AVAMYS for 30 days or longer.
 - The cap has been left off the bottle for 5 days or longer.
5. If you accidentally drop AVAMYS check it for damage and prime it again. If the device is damaged, or if it produces anything other than a fine mist (such as a jet of liquid) or if you feel any discomfort while using the spray, do not use it. Consult with your pharmacist.

How to use AVAMYS:

Follow the instructions below. If you have any questions, ask your healthcare professional.

Shake well before each use.

Before taking a dose of AVAMYS, gently blow your nose to clear your nostrils. Then do these 3 simple steps: Place, Press, Repeat.

1. Place

Tilt your head forward a little bit. Hold AVAMYS upright. **Place** the nozzle in one of your nostrils.

Point the end of the nozzle toward the side of your nose, away from the center of your nose. This helps get the medicine to the right part of your nose.



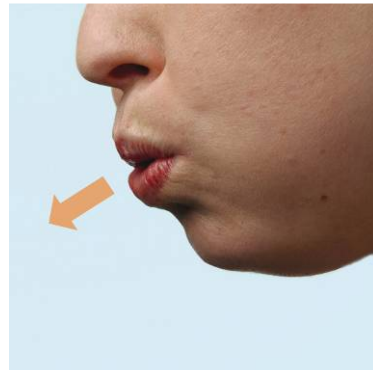
2. Press

Firmly **Press** the button 1 time to spray the medicine in your nose while you are breathing in through your nose.

Do not get any spray in your eyes. If you do, rinse your eyes well with water.



Take the nozzle out of your nose. Breathe out through your mouth.



3. Repeat

Steps 1 and 2 in the **other nostril**.

Take as many sprays as your healthcare professional has told you to.

When you are finished taking your dose, clean the nozzle (see **How to clean AVAMYS** below), and put the cap back on the device.



How to clean AVAMYS:

1. After each use, wipe the nozzle with a clean, dry tissue. If the spray becomes blocked, never try to clean the nozzle with a pin or anything sharp because this may damage the spray mechanism. Talk to your healthcare professional if it does not work.



2. Once a week, clean the inside of the cap with a clean, dry tissue. This will help keep the nozzle from getting blocked.



Usual dose:

Adults and adolescents (12 years and older), the usual dosage is **2 sprays in each nostril once a day.**

Children (2 to 11 years), the usual starting dosage is **1 spray in each nostril, once a day.** If your child continues to have symptoms, talk to your doctor. They may suggest that the dosage change to 2 sprays in each nostril once a day. Once the symptoms are under control, your doctor may reduce the dose. Always follow your doctor's recommendations.

Do not use AVAMYS for more than the number of sprays printed on the label even though the bottle is not completely empty. After the labelled number of sprays, the amount of drug delivered per spray may not be consistent.

AVAMYS may begin to work within 8 to 24 hours after you take your first dose. However, it may take several days of treatment to achieve its greatest effect. You will get the best results if you keep using AVAMYS regularly each day without missing a dose. If your symptoms do not improve, talk to your doctor.

Overdose:

If you think you, or a person you are caring for, have taken too much AVAMYS, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose by several hours, just take your next dose at the usual time. **Do not** take an extra dose.

What are possible side effects from using AVAMYS?

These are not all the possible side effects you may have when taking AVAMYS. If you experience any side effects not listed here, tell your healthcare professional.

- nose bleeds; nasal ulcers; pain, burning, irritation, soreness or dryness inside of the nose
- sore throat, upper respiratory tract infection, fever, bronchitis, cough, stuffy nose
- dry throat
- headache
- nausea
- back pain
- dizziness
- shortness of breath
- a feeling that your heart is racing

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Allergic Reactions: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, wheezing.			✓
Fungal infection in the nose.		✓	
VERY RARE			
Decreased Adrenal Function: tiredness, weakness, nausea and vomiting, low blood pressure.		✓	
Slowed growth in children and adolescents.		✓	
Hyperglycemia (increased amount of sugar in blood): Excessive thirst, frequent urination, dry skin, blurred vision and fatigue.		✓	
Hypertension (High Blood Pressure): headaches, vision disorders, nausea and vomiting.		✓	
Nasal septum perforation: (small holes in the wall between the 2 nostrils): constant whistling sound		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
when you breathe from your nose.			
UNKNOWN			
Cushing's Syndrome: rapid weight gain especially around the body and face. Round "moon face", excess sweating, and thinning of the skin with easy bruising and dryness, muscle and bone weakness.		✓	
Glaucoma: increased pressure in your eyes, eye and head pain, swelling or redness in or around the eye, changes in vision, hazy or blurred vision, sudden sight loss.			✓
Cataract: clouding of the lens in the eye, blurry vision, and/or eye pain.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects
 You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>|<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store AVAMYS between 4°C and 30°C. Keep the device in an upright position with the cap in place. Do not refrigerate or freeze.

Keep out of reach and sight of children.

If you want more information about AVAMYS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.gsk.ca, or by calling 1-800-387-7374.

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