

**PART III: CONSUMER INFORMATION**Pr **AVAMYS****fluticasone furoate nasal spray****FOR NASAL USE ONLY**

This leaflet is part III of a three-part "Product Monograph" published when AVAMYS was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AVAMYS. Contact your doctor or pharmacist if you have any questions about the drug. This medicine is for you. Only a doctor can prescribe it to you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

**ABOUT THIS MEDICATION****What the medication is used for:**

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

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

**What it does:**

When you spray AVAMYS into your nose, it helps reduce the symptoms of seasonal allergies, such as stuffiness, runniness, itching, sneezing, eye redness, itchy eyes, and watery eyes.

**When it should not be used:**

Do not use AVAMYS if you are allergic to it or any of its ingredients (see *What the medicinal and nonmedicinal ingredients are* below).

**What the medicinal ingredient is:**

fluticasone furoate

**What the nonmedicinal ingredients are:**

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

**What dosage forms it comes in:**

nasal spray; 27.5 mcg/metered spray

AVAMYS will deliver either 30 or 120 sprays.

**WARNINGS AND PRECAUTIONS**

This medicine is for use in the nose only. Do not spray it in your eyes or mouth.

**Before** you use AVAMYS talk to your doctor or pharmacist if you:

- Are pregnant (or planning to become pregnant).
- Are breastfeeding a baby.
- Are allergic to AVAMYS or any other corticosteroid.
- Are suffering from liver disease.
- Are exposed to chickenpox or measles.
- Are recovering from recent surgery, trauma or ulcers to your nose.
- Have tuberculosis or any untreated fungal, bacterial, or viral infections.
- Have untreated eye infections caused by herpes.

Drugs like AVAMYS can cause eye disorders:

- **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.

Contact your healthcare professional if you experience blurry vision or other vision problems. You should have regular eye exams.

This medicine has been prescribed for you by your doctor. **Do not** give this medicine to anyone else.

**INTERACTIONS WITH THIS MEDICATION**

Make sure that your doctor knows what other medicines you are taking (such as those for allergies, nervousness, depression, migraine, etc.), including those you can buy without a prescription as well as herbal and alternative 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

## PROPER USE OF THIS MEDICATION

Shake well before use.

### Usual dose:

**For patients 12 years and older**, the usual dosage is **2 sprays in each nostril once a day**. It doesn't matter when you take your dose but take it at the same time every day.

**For children aged 2 to less than 12 years**, the usual **starting dosage is 1 spray in each nostril, once a day**. Some people may need two sprays in each nostril once a day until their symptoms are properly controlled and then their doctor may reduce their dose. Always follow your doctor's recommendations.

It is important that you use AVAMYS as your doctor has told you. **Do not** take more of your medicine or take it more often than your doctor tells you. The prescription label will usually tell you how many sprays to take and how often. If it does not or if you are not sure, ask your doctor or pharmacist.

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.

Do not take extra doses of AVAMYS without telling your doctor. If your condition worsens after 24 hours of use, contact your doctor.

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, contact your doctor.

### Overdose:

If you think you have taken too much AVAMYS contact your doctor, pharmacist, 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.

### 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 doctor or pharmacist.

**Shake well before each use.**

AVAMYS is provided in an easy-to-use device. 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.

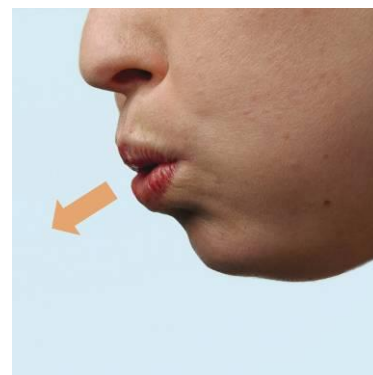
**2. Press**

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 number of sprays in each nostril as directed by your physician.

Put the cap back on the device after you have finished taking your dose.



Side effects that may occur with the use of corticosteroid nasal sprays are:

- Slower healing of wounds. Do not use AVAMYS until your nose has healed if you have a sore in your nose, if you have surgery on your nose, or if your nose has been injured.
- Worsening of the symptoms of infections such as existing tuberculosis, fungal, bacterial or parasitic infections or herpes of the eye.
- Slower growth in children (5-9 years of age) has occurred with use of AVAMYS. Slower growth in adolescents (12-17 years of age) may occur with use of corticosteroid nasal sprays. Your physician should monitor your growth regularly if you are in these age groups.

**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. If it does not work, consult with your pharmacist.



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



If any of these affects you severely, tell your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical assistance
		Only if severe	In all cases	
Rare	<b>Allergic Reactions:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
	Fungal infection in the nose.		✓	
Very Rare	<b>Decreased Adrenal Function:</b> tiredness, weakness, nausea and vomiting, low blood pressure.		✓	
	Slowed growth in children and adolescents.		✓	
	<b>Hyperglycemia</b> (ncreased amount of sugar in blood): Excessive thirst, frequent urination, dry skin, blurred vision and fatigue.		✓	
	<b>High Blood Pressure:</b> headaches, vision disorders, nausea and vomiting.		✓	
	<b>Nasal septum perforation:</b> small holes in the wall between the 2 nostrils		✓	

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Side effects may include:

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

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical assistance
		Only if severe	In all cases	
Unknown	<b>Cushing's Syndrome:</b> 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.		✓	
	<b>Glaucoma:</b> increased pressure in your eyes, eye pain.			✓
	<b>Cataract:</b> clouding of the lens in the eye, blurry vision, and/or eye pain.		✓	

*This is not a complete list of side effects. For any unexpected effects while taking AVAMYS, contact your doctor or pharmacist.*

**HOW TO STORE IT**

**Keep AVAMYS in a safe place where children cannot reach it. Your medicine may harm them.**

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

**REPORTING SUSPECTED 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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.gsk.ca> or by contacting the sponsor, GlaxoSmithKline Inc. 7333 Mississauga Road Mississauga, Ontario L5N 6L4 1-800-387-7374

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