

**AVAMYS™**  
(fluticasone furoate)  
**Nasal Spray**  
**For Intranasal Use Only**

Read the Patient Information that comes with AVAMYS Nasal Spray carefully before you start using it and each time you get a refill. There may be new information. Keep the leaflet for reference because it gives you a summary of important information about AVAMYS Nasal Spray. This leaflet does not take the place of talking to your healthcare provider about your medical condition or your treatment.



**What is AVAMYS Nasal Spray?**  
AVAMYS Nasal Spray is a medicine that treats seasonal and year-round allergy symptoms in adults and children 2 years old and older.

AVAMYS Nasal Spray contains fluticasone furoate, which is a man-made (synthetic) corticosteroid. When you spray AVAMYS Nasal Spray into your nose, it helps reduce the nasal symptoms of allergic rhinitis (inflammation of the lining of the nose), such as stuffy nose, runny nose, nasal itching, and sneezing. AVAMYS Nasal Spray may also help red, itchy, and watery eyes in adults and teenagers with seasonal allergic rhinitis.

Your healthcare provider has prescribed AVAMYS Nasal Spray to treat your symptoms of allergic rhinitis.

It is not known if AVAMYS Nasal Spray is safe and effective in children under 2 years of age.

**Who should not use AVAMYS Nasal Spray?**

**Do not use AVAMYS Nasal Spray** if you are allergic to fluticasone furoate or any of the ingredients in AVAMYS Nasal Spray. See the end of this Patient Information leaflet for a complete list of ingredients in AVAMYS Nasal Spray.

**What should I tell my healthcare provider before taking AVAMYS Nasal Spray?**

**Tell your healthcare provider about all of your medical conditions, including if you:**

- have had recent nasal sores, nasal surgery, or nasal injury.
- have liver problems.
- have eye or vision problems, such as cataracts or glaucoma (increased pressure in your eye).
- have tuberculosis or any untreated fungal, bacterial, viral infections, or eye infections caused by herpes.
- are exposed to chickenpox or measles.
- are feeling unwell or have any symptoms that you do not understand.
- are pregnant or plan to become pregnant. It is not known if AVAMYS Nasal Spray will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if AVAMYS Nasal Spray can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take AVAMYS Nasal Spray.

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal products. AVAMYS Nasal Spray and other medicines may affect each other, causing side effects. **Be certain to tell your healthcare provider if you are taking a medicine that contains ritonavir (commonly used to treat HIV infection or AIDS).**

**How should I use AVAMYS Nasal Spray?**

- This medicine is for use in the nose only. Do not spray it in your eyes or mouth.
- An adult should help a young child use this medicine.
- This medicine has been prescribed for you by your healthcare provider. Do not give this medicine to anyone else.
- Use AVAMYS Nasal Spray exactly as your healthcare provider tells you to. Do not take more of your medicine or take it more often than your healthcare provider 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 healthcare provider or pharmacist.
- **For people aged 12 years and older**, the usual starting dosage is **2 sprays in each nostril, 1 time a day**. After you begin to feel better, your healthcare provider may tell you that 1 spray in each nostril 1 time a day may be enough for you.
- **For children aged 2 to 11 years**, the usual starting dosage is **1 spray in each nostril, 1 time a day**. Your healthcare provider may tell you to take 2 sprays in each nostril 1 time a day. After you begin to feel better, your healthcare provider may change the dosage to 1 spray in each nostril 1 time a day. An adult should help a young child use this medicine.

- Do not use AVAMYS Nasal Spray after 120 sprays (plus the initial priming sprays) have been used or after the expiration date, whichever comes first. The bottle may not be completely empty. The expiration date is printed as “EXP” on the product label and box. Before you throw away AVAMYS Nasal Spray, talk to your healthcare provider to see if you need a refill of your prescription. If your healthcare provider tells you to continue using AVAMYS Nasal Spray, throw away the empty or expired bottle and use a new bottle of AVAMYS Nasal Spray. Follow the **Instructions for Use** below.
- Do not take extra doses or stop taking AVAMYS Nasal Spray without telling your healthcare provider.
- AVAMYS Nasal Spray may begin to work within 24 hours after you take your first dose. It may take several days before it has its greatest effect. If your symptoms do not improve or get worse, call your healthcare provider.
- You will get the best results if you keep using AVAMYS Nasal Spray regularly each day without missing a 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 the possible side effects of AVAMYS Nasal Spray?**

**AVAMYS Nasal Spray may cause serious side effects, including:**

- **thrush (candidiasis), a fungal infection in your mouth and throat.** Tell your healthcare provider if you have any redness or white colored patches in your mouth or throat.
- **hole in the cartilage in the nose (nasal septal perforation).** Symptoms of nasal septal perforation may include:
  - crusting in the nose
  - nosebleeds
  - runny nose
  - whistling sound when you breathe
- **slow wound healing.** You should not use AVAMYS Nasal Spray until your nose has healed if you have a sore in your nose, have had surgery on your nose, or if your nose has been injured.
- **eye problems such as glaucoma and cataracts.** If you have a history of glaucoma or cataracts or have a family history of these eye problems, you should have regular eye exams while you use AVAMYS Nasal Spray.
- **serious allergic reactions.** Serious allergic reactions can happen with AVAMYS Nasal Spray. **Stop using AVAMYS Nasal Spray and call your healthcare provider right away if you have any of the following signs of a serious allergic reaction:**
  - shortness of breath or trouble breathing
  - skin rash, redness, or swelling
  - severe itching
  - swelling of the lips, tongue, or face
- **immune system problems that may increase your risk of infections.** You are more likely to get infections if you take medicines that may weaken your body’s ability to fight infections. Avoid contact with people who have contagious diseases such as chicken pox or measles while you use AVAMYS Nasal Spray. Symptoms of an infection may include:

- fever
- pain
- aches
- chills
- feeling tired
- nausea
- vomiting
- **adrenal insufficiency.** Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. Symptoms of adrenal insufficiency may include:
  - tiredness
  - weakness
  - dizziness
  - nausea
  - vomiting
- **slowed or delayed growth in children.** A child’s growth should be checked regularly while using AVAMYS Nasal Spray.

**The most common side effects of AVAMYS Nasal Spray include:**

- **adults and adolescents 12 years of age and older**
  - headaches
  - nose bleeds
  - sore throat
  - nose sores
  - back pain
- **children 2 to 12 years of age**
  - headaches
  - sore throat
  - nose bleeds
  - fever
  - cough

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of AVAMYS Nasal Spray. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects.

**What should I know about allergic rhinitis?**

“Rhinitis” means inflammation of the lining of the nose. It is sometimes called “hay fever.” Allergic rhinitis can be caused by allergies to pollen, animal dander, house dust mite, and mold spores. If you have allergic rhinitis, your nose becomes stuffy, runny, and itchy. You may also sneeze a lot. You may also have red, itchy, watery eyes; itchy throat; or blocked, itchy ears.

**What are the ingredients in AVAMYS Nasal Spray?**

Active ingredient: fluticasone furoate  
Inactive ingredients: 0.015% w/w benzalkonium chloride, dextrose anhydrous, edetate disodium, microcrystalline cellulose, carboxymethylcellulose sodium, polysorbate 80, and purified water

**Instructions for Use**

Read this leaflet carefully before you start to use AVAMYS Nasal Spray. If you have any questions, ask your healthcare provider or pharmacist.

**The parts of the AVAMYS Nasal Spray**

AVAMYS Nasal Spray comes in a brown glass bottle inside a nasal device. It contains 120 sprays plus the first priming sprays. Be careful not to drop it. If you accidentally drop the device, check it for damage. If the device is damaged, return it to your pharmacist.

The **Cap** has a tab that keeps the **Mist-Release Button** from being pressed accidentally. It also helps keep the nozzle clean. Do not throw the cap away. Always keep the cap on the device when you are not using it.

The **Nozzle** is small and short, so it will fit inside your nose. The medicine comes out of 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, you can keep the nozzle in the right place in your nose while you press the button.

The **Window** lets you see if there is medicine left in the bottle when you hold it in front of a bright light. (You may not be able to see the medicine in a full bottle because the liquid level is above the window.)

**How to prime your AVAMYS Nasal Spray**

Priming helps to make sure you always get the same full dose of medicine. You need to prime AVAMYS Nasal Spray:

- before you use a new bottle for the first time.
- if you have not used your AVAMYS Nasal Spray for 30 days or longer.
- if the cap has been left off the bottle for 5 days or longer.
- if the device does not seem to be working right.

**To prime AVAMYS Nasal Spray:**



Figure 1

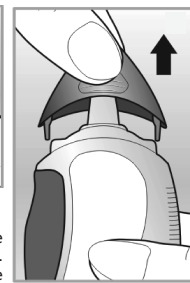


Figure 2

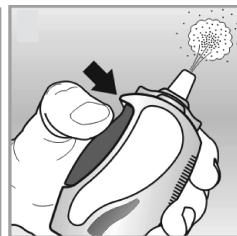


Figure 3

1. With the cap on, shake the device well (Figure 1). This is important to make the medicine a liquid that will spray.
2. Take the cap off by squeezing the finger grips and pulling it straight off (Figure 2).
3. Hold the device with the nozzle pointing up and away from you. Place your thumb or fingers on the button. Press the button all the way in 6 times or until a fine mist sprays from the nozzle (Figure 3). Your AVAMYS Nasal Spray is now ready to use.

**How to use your AVAMYS Nasal Spray**

Follow the instructions below. If you have any questions, ask your healthcare provider or pharmacist.

Before taking a dose of AVAMYS Nasal Spray, gently blow your nose to clear your nostrils. Shake the bottle well. Then do these 3 simple steps: **Place, Press, Repeat.**



Figure 4



Figure 5



Figure 6

**1. PLACE**

Tilt your head forward a little bit. Hold the device upright. **PLACE** the nozzle in one of your nostrils (Figure 4). Point the end of the nozzle toward the side of your nose, away from the center of your nose (septum). This helps get the medicine to the right part of your nose.

**2. PRESS**

**PRESS** the button all the way in 1 time to spray the medicine in your nose while you are breathing in (Figure 5). **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 (Figure 6).

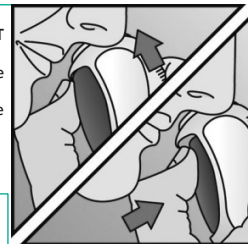
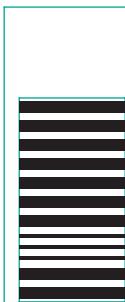


Figure 7



**How to clean your AVAMYS Nasal Spray**



Figure 8

Figure 9

**After each use:** wipe the nozzle with a clean, dry tissue (Figure 8). **Never try to clean the nozzle with a pin or anything sharp because this will damage the nozzle.** Do not use water to clean the nozzle.

**Once a week:** clean the inside of the cap with a clean, dry tissue (Figure 9). This will help keep the nozzle from getting blocked.

**How to store your AVAMYS Nasal Spray**

- Keep your AVAMYS Nasal Spray and all medicines out of the reach of children.
- Store below 30°C. Do not refrigerate or freeze.
- Store with the cap on.
- Store in an upright position.

Manufactured by:  
Glaxo Operations UK Limited\*  
Barnard Castle, UK  
Market Authorization Holder  
GlaxoSmithKline LLC  
Research Triangle Park, NC 27709  
USA

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Revision date: May 2015

**THIS IS A MEDICAMENT**  
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.  
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.  
- Do not by yourself interrupt the period of treatment prescribed.  
- Do not repeat the same prescription without consulting your doctor.  
- Keep all medicaments out of reach of children.  
Council of Arab Health Ministers,  
Union of Arab Pharmacists.