

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a physician's prescription only

AVAMYS

Nasal Spray

Each spray releases Fluticasone Furoate 27.5 mcg

The list of additional ingredients is detailed in section 6. Pay attention to the important information about some of the ingredients of the medicine in section 2.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. What is the medicine intended for?

Avamys is intended for the treatment of symptoms of seasonal and perennial allergic rhinitis in patients aged 2 years and older.

Therapeutic group: Corticosteroids

Avamys is used to treat symptoms of allergic rhinitis including: stuffy nose, runny nose, itchy nose, sneezing, and watery, itchy and red eyes.

Avamys contains the active ingredient fluticasone furoate. This medicine belongs to a group of medicines known as corticosteroids, which are frequently called “steroids”. These are not “anabolic steroids” which athletes often abuse.

Avamys reduces the inflammation caused by allergy (rhinitis).

Avamys is not addictive.

2. Before using the medicine

Do not use the medicine if:

You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine as detailed in section 6.

Special warnings regarding use of the medicine

Before beginning treatment with Avamys, tell your physician if:

- you are allergic to foods, dyes, preservatives or other medicines.

During the course of treatment with Avamys, refer to your physician if:

- you experience vision changes.

Children and adolescents

Avamys is not intended for children under two years of age.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist. Especially if you are taking:

- a protease inhibitor antiviral medicine (e.g., ritonavir) or a medicine to treat fungal infections (e.g., ketoconazole).
- steroids given orally, by inhalation or injection.

Pregnancy and breastfeeding

Tell your physician if you are pregnant or plan to become pregnant. It is not known whether Avamys will harm your unborn baby.

If you are breastfeeding, consult your physician. It is not known whether Avamys can pass into your breast milk.

Driving and operating machinery

Exercise caution when driving and operating machinery until you know how Avamys affects you.

It is unlikely that Avamys will affect your ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

The medicine contains 8.25 mcg benzalkonium chloride in each actuation of the spray (27.5 mcg). Benzalkonium chloride may cause irritation or swelling in the nose, especially when used for a long time. Inform your physician or pharmacist if you feel discomfort when using the spray.

3. How should you use the medicine?

Always use the preparation according to the physician's instructions. Check with the physician or the pharmacist if you are uncertain about the preparation dosage and treatment regimen.

- **This medicine is for use in the nose only. Not for swallowing. Do not use Avamys in or near the eyes.**
- The dosage and treatment regimen will be determined by the physician only.
- The usual recommended starting dosage for **adults and adolescents aged 12 years and older** is 2 sprays in each nostril, once a day. Once the symptoms are under control, your physician may tell you that the dose can be reduced to one spray in each nostril once a day.
- The usual recommended starting dosage for **children aged 2 to 11 years** is one spray in each nostril, once a day. If your symptoms are severe, your physician may increase the dosage to 2 sprays in each nostril once a day, until the symptoms are under control. Then, your physician may tell you that the dosage can be reduced to one spray in each nostril once a day.

Do not exceed the recommended dosage.

For information on how to use Avamys, see section 6 – **Step-by-step instructions for using the nasal spray.**

Shake well before use.

Avamys is sprayed into the nose as a fine mist. It is practically tasteless.

Do not use Avamys in the eyes.

Use Avamys once a day, at the same time each day. This will treat your symptoms throughout the day and night.

Your physician will recommend the treatment duration for you. Do not stop Avamys treatment or change the dose without consulting the physician.

The effect of the medicine is usually felt during the first day, although some people will not feel the effect until several days after the first use.

If you accidentally take a higher dosage

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to use Avamys

- If you forgot to take a dose, take it as soon as you remember.
- If it is almost time for your next dose, wait until the next dose. Do not take a double dose to compensate for the forgotten dose.

Tell your physician if, for whatever reason, you have not taken your medicine exactly as he has instructed you.

Otherwise, your physician may think that the medicine is not working properly and will unnecessarily change your treatment.

Adhere to the treatment regimen as recommended by the physician.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

Refer to your physician as soon as possible, if you think you are experiencing side effects or allergic reactions due to use of Avamys, even if the effect is not listed in the section below.

As with any medicine, use of Avamys may cause side effects in some of the users. If they occur, they are likely to have a mild and temporary effect. Nevertheless, some may be severe and will require medical attention. Do not be alarmed by the list of side effects. You may not suffer from any of them.

- **Refer to your physician immediately if you have any of the following symptoms:**
 - ❖ wheezing
 - ❖ swelling of the lips/mouth
 - ❖ breathing difficulties
 - ❖ hay fever (rhinitis)
 - ❖ hives (urticaria – itchy skin lumps)
 - ❖ faintingThese can be symptoms of an allergic reaction.
- **The most common side effects include:**
 - ❖ nose bleeds.

- ❖ nasal ulceration – may cause irritation or discomfort in your nose. You may also get streaks of blood when you blow your nose.
- ❖ headache.
- **Uncommon side effects:**
 - ❖ pain, burning, irritation or dryness in the nose.

In addition, slowed growth has been observed in children. However, the frequency of this effect cannot be estimated from the available data.

If a side effect occurs, if one of the side effects worsens, or if you suffer from side effect not mentioned in the leaflet, consult with the physician.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. How should the medicine be stored?

- Avoid poisoning! This medicine and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- After first opening, the bottle can be used for two months and no later than the expiry date of the product.
- Always keep the nasal spray with the cap on.
- Do not refrigerate or freeze.
- Do not leave in the car, on the windowsill or in the bathroom.
- There are no special storage conditions. It is recommended to store at room temperature.

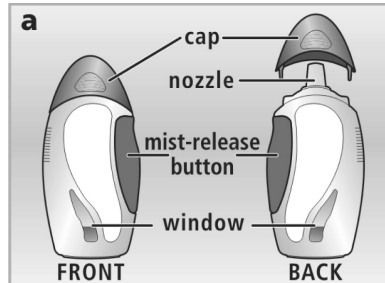
6. Further information

- In addition to the active ingredient, the medicine also contains:
Glucose anhydrous, dispersible cellulose, benzalkonium chloride solution, polysorbate 80, disodium edetate, purified water.
- What the medicine looks like and the contents of the package: Avamys Nasal Spray is a white suspension in a glass amber (dark brown) bottle, fitted with a pump. The bottle is inside a plastic, off-white casing with a light blue cap and side-button. The plastic casing has a window to view the contents of the bottle. The bottle contains 30, 60 or 120 sprays.
Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Operations (UK) Limited, Barnard Castle, UK.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 141-80-31837.

Step-by-step instructions for using the nasal spray

What the nasal spray looks like

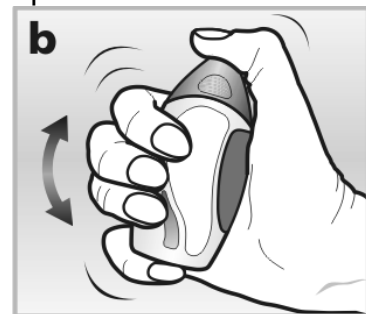
The nasal spray comes in an amber (dark brown) glass bottle inside a plastic casing – see figure a. The spray will contain either 30, 60 or 120 sprays, depending on the pack size that has been prescribed for you.



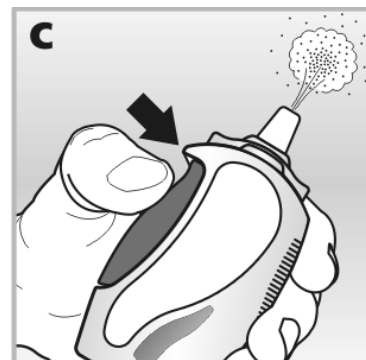
The window in the plastic casing lets you see how much Avamys is left in the bottle. You will be able to see the liquid level in new spray bottles of 30 or 60 sprays, but not in a new bottle of 120 sprays because the liquid level is above the window.

Six important things you need to know about using the nasal spray

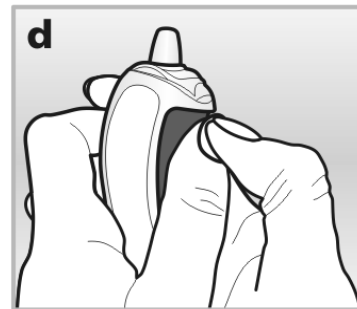
- Avamys comes in an amber glass bottle. If you need to check how much of the preparation is left, **hold the nasal spray upright against a bright light**. You will then be able to see the level through the window.
- When you **first use the nasal spray, you will need to shake it vigorously** with the cap on for about 10 seconds. This is important as Avamys is a thick suspension that becomes liquid when you shake it well – see figure b. It will only spray when it becomes liquid.



- The mist-release button must be **pressed firmly all the way in**, to release the mist through the nozzle – see figure c.



- If you have difficulty pressing the button with your thumb, you can use two hands – see figure d.



- **Always keep the cap on the nasal spray** when you are not using it. The cap protects against dust, maintains internal pressure and prevents the nozzle from getting blocked. When the cap is closed, the mist-release button cannot be pressed accidentally.
- **Never use a pin** or anything sharp to clear the nozzle. It will damage the nasal spray.

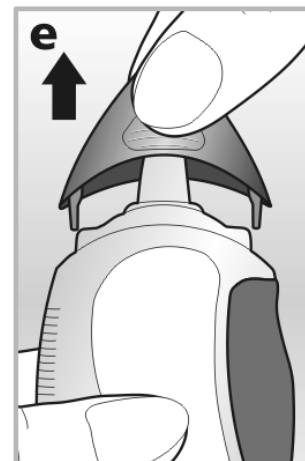
Preparing the nasal spray for use

You must prepare the nasal spray:

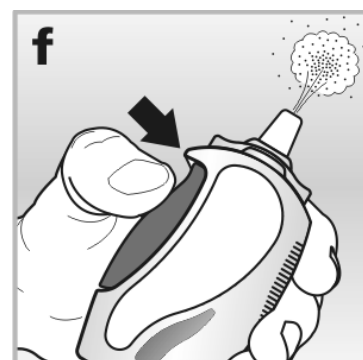
- before you use it for the first time.
- if you have left the cap off for 5 days or if the nasal spray has not been used for 30 days or more.

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

1. **Shake the nasal spray vigorously**, with the cap on, for about 10 seconds.
2. Remove the cap by squeezing firmly on the sides of the cap with your thumb and forefinger – see figure e.



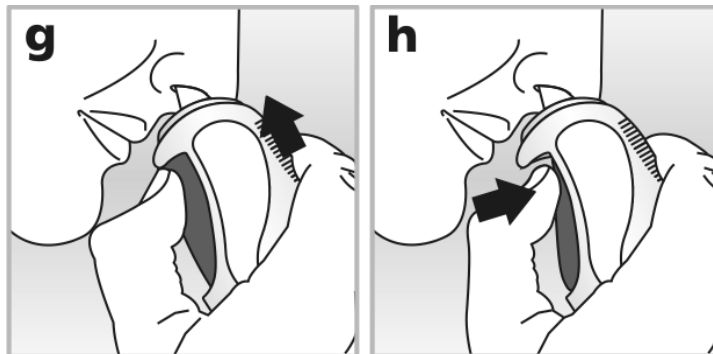
3. Hold the nasal spray upright, and tilt it such that **the nozzle is pointing away from you**.
4. **Press the button firmly** all the way in. **Do this at least 6 times** until a fine mist of spray is released from the nozzle into the air – see figure f.



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, then tilt your head forward a little bit.
4. Place the nozzle in one of your nostrils – see figure **g**. Point the end of the nozzle slightly outwards, away from the centre ridge of your nose. This helps to get the medicine to the correct part of your nose.
5. Press the **button firmly** all the way in, **while you breathe in through your nose** – see figure **h**.



6. Take the nozzle out of your nose and **breathe out through your mouth**.
7. If your dose is 2 sprays in each nostril, repeat steps 4-6.
8. Repeat steps 4-7 to treat the other nostril.
9. **Replace the cap** on the nasal spray.

Cleaning the nasal spray

After each use:

1. Wipe the nozzle and the inside of the cap with a clean, dry tissue – see figures **i** and **j**.



2. Do not use water to clean it.
3. **Never use a pin** or anything sharp on the nozzle.
4. **Always replace the cap** at the end of use.

If the nasal spray does not seem to be working:

- Check whether there is still medicine left. Look at the level of the medicine through the window. If the level is very low, there may not be enough medicine left for the nasal spray to work.
- Check whether the nasal spray has been damaged.

- If you think the nozzle is blocked, **do not use a pin** or anything sharp to clear it.
- Try to reset the spray by following the instructions in the section **“Preparing the nasal spray for use”**.
- If the spray is still not working, or if it releases liquid, take the nasal spray back to the pharmacy to get advice.

Revised in February 2021 according to MoH guidelines.

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