

**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 actuation delivers fluticasone furoate 27.5 mcg**

For the list of the inactive and allergenic ingredients in the medicine, see in section 2 – “Important information about some of the ingredients in the medicine” and section 6 – “Additional information”.

**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 contains the active ingredient fluticasone furoate. This medicine belongs to a group of medicines known as corticosteroids, which are frequently called “steroids”.

Avamys reduces the inflammation caused by allergy (rhinitis).

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

Avamys is not addictive.

#### **2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

You are sensitive (allergic) to fluticasone furoate or to any of the additional ingredients contained in the medicine (listed in section 6).

**Special warnings regarding use of the medicine**

**Before the treatment with Avamys, tell the physician if:**

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

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

- you experience vision changes.

**Refer to a physician straight away or go straight to the emergency room at your nearest hospital if you develop symptoms of an allergic reaction while using Avamys.** For information on symptoms of an allergic reaction you should pay attention to while using Avamys, see section 4 – “Side effects”.

### **Children and adolescents**

Avamys is not intended for children under 2 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. Some medicines may interfere with Avamys and affect how it works. These include:**

- medicines like ketoconazole, used to treat fungal infections, and ritonavir, used to treat HIV infection. If you are taking these medicines, consult the physician or pharmacist who will advise on what you should do.

### **Pregnancy and breastfeeding**

Tell the 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 or plan to breastfeed, consult the physician. It is not known whether Avamys can pass into your breast milk.

### **Driving and using machinery**

Be careful before you drive or use any machines or tools until you know how Avamys affects you.

Avamys is unlikely to affect your ability to drive or use machinery.

### **Important information about some of the ingredients in 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 the 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 (55 mcg fluticasone furoate). Once the symptoms are under control, the physician may tell you that the dosage 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 (27.5 mcg fluticasone furoate). If your symptoms are severe, the physician may increase the dosage to 2 sprays in each nostril once a day, until the symptoms are under control. Then, the physician may tell you that the dosage can be reduced to one spray in each nostril once a day.

**Do not exceed the recommended dose.**

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.

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

**The 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 have taken 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 forgot to use Avamys**

If it is almost time for your next dose, skip the missed dose and take the next dose when you are meant to. Otherwise, take the dose as soon as you remember. Then, continue using the medicine as you normally do.

**Do not take a double dose to compensate for the forgotten dose.**

Do so, otherwise, the 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 a medicine. Wear glasses if you need them.**

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

## **4. SIDE EFFECTS**

As with any medicine, use of Avamys may cause side effects in some of the users. If you do experience any side effects, most of them are minor and temporary. However, some may need medical attention. Do not be alarmed by the list of side effects. You may not suffer from any of them. Read the information that appears below in this section and, if needed, talk to the physician or pharmacist if you have additional questions regarding side effects.

### **Serious side effects**

**Allergic reaction – rare side effect (may occur in up to 1 in 1,000 people): Refer to a physician straight away or go straight to the emergency room at your nearest hospital if you have any of the following symptoms:**

- wheezing
- swelling of the lips/mouth
- breathing difficulties
- hay fever (rhinitis)
- hives (urticaria – itchy skin lumps)

- fainting

These can be symptoms of an allergic reaction.

### **Very common side effects**

These may affect **more than 1 in 10** people:

- nosebleeds.

### **Common side effects**

These may affect **up to 1 in 10** people:

- 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**

These may affect **up to 1 in 100** people:

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

### **Side effects of unknown frequency (side effects whose frequency was not yet determined)**

- slowing of growth in children. This side effect has been observed, however the frequency of this occurring cannot be estimated from the available data.

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

### **Reporting side effects**

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](http://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.
- There are no special storage conditions. It is recommended to store at room temperature.
- If you no longer need to use the medicine or if the expiry date that appears on the package has passed, return the medicine to the pharmacy for safe disposal.

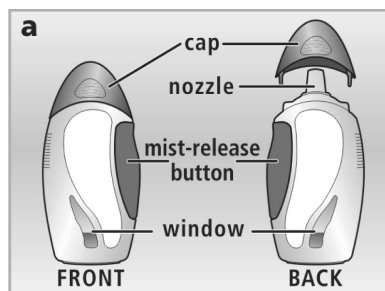
## **6. ADDITIONAL INFORMATION**

- 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 an amber (dark brown) glass 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: GlaxoSmithKline Trading Services Limited, Dublin, Ireland.
- 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

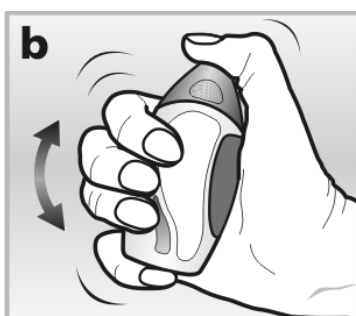
The nasal spray comes in an amber (dark brown) glass bottle inside a plastic casing – see Figure a. The spray will contain either 30, 60 or 120 sprays, depending on the pack size that has been prescribed for you.



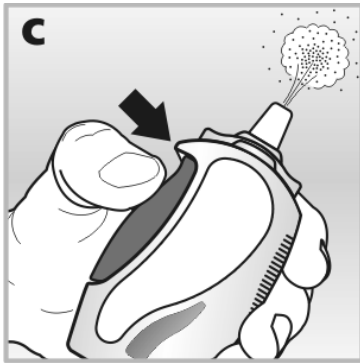
The window in the plastic casing lets you see how much Avamys is left in the bottle. You will be able to see the liquid level for a new 30 or 60 spray bottle, but not in a new 120 spray bottle because the liquid level is above the window.

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

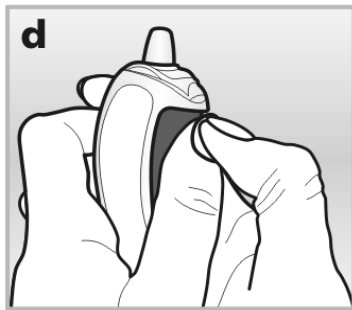
- Avamys comes in an amber glass bottle. If you need to check how much of the preparation is left, **hold the nasal spray upright against a bright light**. You will then be able to see the level through the window.
- When you **first use the nasal spray, you will need to shake it vigorously** with the 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 keeps the dust out, seals in the pressure and stops the nozzle from blocking up. When the cap is in place 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.

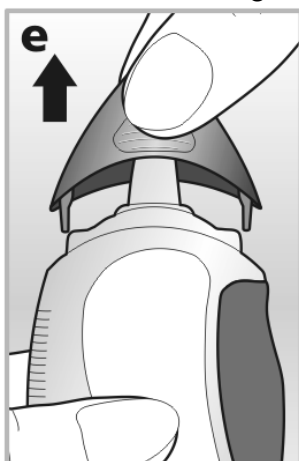
### Preparing the nasal spray for use

#### You must prepare the nasal spray:

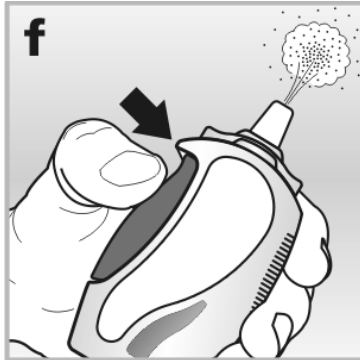
- before you use it for the first time.
- if you have left the cap off for 5 days or if the nasal spray has not been used for 30 days or more.

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.



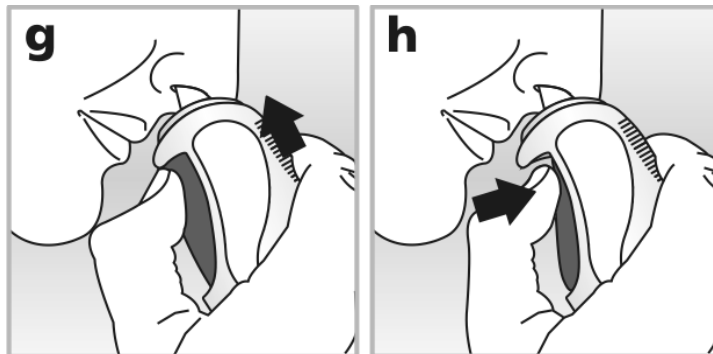
3. Hold the nasal spray upright, then tilt and **point the nozzle away from you**.
4. **Press the button firmly** all the way in. **Do this at least 6 times** until a fine mist of spray is released from the nozzle into the air – see Figure f.



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.

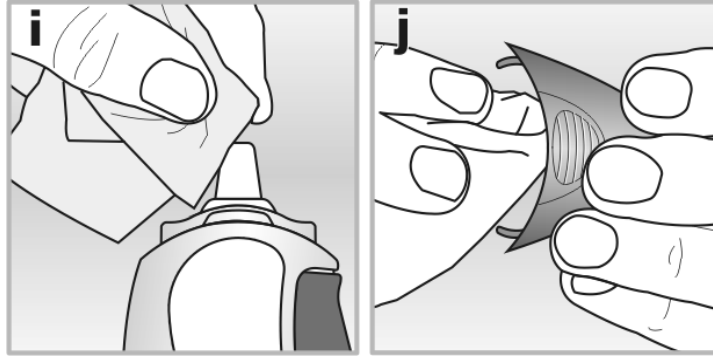


6. Take the nozzle out of your nose and **breathe out through your mouth.**
7. If your dose is 2 sprays in each nostril, repeat steps 4-6.
8. Repeat steps 4-7 to treat the other nostril.
9. **Replace the cap** on the nasal spray.

#### 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 produces a jet of liquid, take the nasal spray back to the pharmacy to get advice.

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