

Avamys® 27.5 micrograms per spray

nasal spray suspension
Fluticasone furoate

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Never pass it on to others. It may harm them, even if their symptoms seem the same as yours.
- **If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.**

In this leaflet:

1. What Avamys is and what it is used for
2. Before you use Avamys
3. How to use Avamys
4. Possible side effects
5. How to store Avamys
6. Further information

1. What Avamys is and what it is used for

Avamys nasal spray is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing and watery, itchy or red eyes, in adults and children aged 6 years and over.

Allergy symptoms can occur at specific times of the year and be caused by allergy to pollen from grass or trees (hayfever), or they can occur all year round and be caused by allergy to animals, house-dust mites or moulds. Avamys belongs to a group of medicines called glucocorticoids. Avamys works to decrease inflammation caused by allergy (*rhinitis*).

2. Before you use Avamys

Do not use Avamys:

If you are allergic (hypersensitive) to fluticasone furoate or any of the other ingredients of Avamys.

Take special care with Avamys:

If you have any liver problems, tell your doctor or pharmacist. Your doctor may adjust your dose of Avamys.

Taking nasal glucocorticoids (such as Avamys):

- may when taken for a long time cause children to grow more slowly. The doctor will check your child's height regularly, and make sure he or she is taking the lowest possible effective dose.
- may cause eye conditions such as glaucoma (increase in pressure in the eye) or cataracts (clouding of the lens of the eye). Tell your doctor if you had these conditions in the past, or if you notice any change in your vision while you are taking Avamys.

Taking other medicines

Tell your doctor if you are taking, or have recently taken, any other medicines, including those bought without a prescription. 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

Your doctor will assess whether you should take Avamys with these medicines.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

Do not use Avamys if you are pregnant, or planning to become pregnant, unless your doctor or pharmacist tells you to.

Do not use Avamys if you are breast feeding unless your doctor or pharmacist tells you to.

Driving and using machines

Avamys is unlikely to affect your ability to drive and use machines.

Important information about some of the ingredients of Avamys

Avamys contains benzalkonium chloride. In some patients this can cause irritation in the inside of the nose. Tell your doctor or pharmacist if you feel discomfort when using the spray.

3. How to use Avamys

Always use Avamys exactly as your doctor has told you. You should check with your doctor if you are not sure.

When to use it and how much to use
Avamys is sprayed into the nose as a fine mist. It has virtually no taste.

Avamys is not for use in the eyes.

When to use Avamys

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

How long Avamys takes to work

Some people will not feel the full effects until several days after first using Avamys. However, it is usually effective within 8 to 24 hours of use.

Adults and children 12 years and over

- The usual starting dose is 2 sprays in each nostril once every day.
- Once symptoms are controlled you may be able to decrease your dose to 1 spray in each nostril, once every day.



Children under 12 years

- In children aged 6 to 11 the usual starting dose is 1 spray in each nostril once every day.
- If symptoms are very bad your doctor may increase the dose to 2 sprays in each nostril once every day until the symptoms are under control. It may then be possible for the dose to be reduced to 1 spray in each nostril once every day.
- Do not use in children under 6 years old.

If you use more Avamys than you should

Talk to your doctor or pharmacist.

If you forget to use Avamys

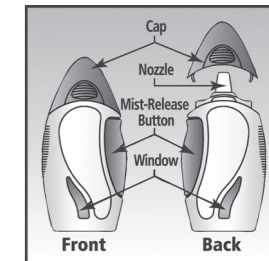
- If you miss a dose, take it when you remember.
- If it is nearly the time for your next dose, wait until then. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

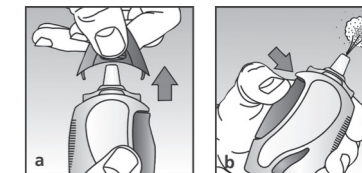
How to test the nasal spray before use

- The nasal spray**
- Your medicine comes in a glass bottle inside a plastic casing.
 - The glass bottle contains either 30, 60 or 120 sprays.
 - A window on the side of the casing allows you to see how much medicine is left. A bottle containing 30 sprays will not appear full when you first receive it.
 - The medicine sprays out of the nozzle when the button on the side is firmly pressed.

- The nozzle is protected by a removable cap.



Testing the nasal spray



The first time you use the nasal spray, you must test that it is working properly. If you have left the cap off or have not used your spray for nearly a month, follow steps 1-4 below.

- 1 With the cap on, shake the nasal spray.
- 2 Remove the cap by gently squeezing the sides of the cap with your thumb and forefinger and pull it straight off – see picture a.
- 3 Holding the nasal spray upright, point the nozzle away from you and firmly press the button on the side at least 6 times to release a fine spray into the air – see picture b.
- 4 The nasal spray is now ready for use.

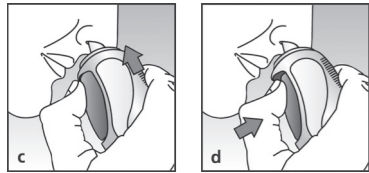


3. How to use Avamys (continued)

If you drop the spray, check for damage and test it again (steps 1-4 above). If the spray is damaged, if it produces anything other than a fine mist (such as a jet of liquid), or if you feel any discomfort using the spray:

→ Return it to your pharmacist.

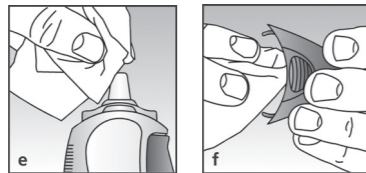
Using your nasal spray



Blow your nose to clear your nostrils. Shake the spray gently before each use.

- 1 Tilt your head forward a little bit.
- 2 Hold the nasal spray upright and carefully place the nozzle in one of your nostrils – see picture c.
- 3 Point the end of the nozzle toward the outside of your nose, away from the centre ridge of your nose. This helps to get the medicine to the right part of your nose.
- 4 As you breathe in through your nose, firmly press the button once to spray the medicine into your nose – see picture d. Be careful not to get any spray into your eyes. If you do, rinse your eyes with water.
- 5 Take the nozzle out and breathe out through your mouth.
- 6 Repeat steps 1 to 5 for your other nostril.
- 7 If your doctor has told you to use 2 sprays per nostril, repeat all the 6 steps above.

Cleaning your nasal spray



- 1 After each use, wipe the nozzle and the inside of the cap – see pictures e and f. Don't use water to do this, wipe with a clean, dry tissue.

If the spray becomes blocked, do not try and unblock the nozzle with a pin or sharp object as this will damage the spray mechanism:

→ Return it to your pharmacist.

- 2 Always replace the cap once you have finished to keep out dust.

If you use more Avamys than you should

Talk to your doctor or pharmacist.

If you forget to use Avamys

- If you miss a dose take it when you remember.
- If it is nearly the time for your next dose, wait until then. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Avamys can cause side effects, although not everybody gets them. Possible side effects are listed below:

Very common side effects

(These can affect more than 1 person in 10)

- Nosebleeds (generally minor), particularly if you use Avamys for more than 6 weeks continuously.

Common side effects

(These can affect less than 1 person in 10 and more than 1 person in 100)

- Irritation or discomfort in the inside of the nose – you may also get streaks of blood when you blow your nose. This may be due to nasal ulceration.

Nasal corticosteroids can affect the normal production of hormones in your body, particularly if you use high doses for a long time. In children this side effect can cause them to grow more slowly than others.

If you get side effects

If any of the side effects gets serious or troublesome, or if you notice any side effects not listed in this leaflet:

→ Tell your doctor or pharmacist.

5. How to store Avamys

Keep out of the reach and sight of children.

Do not use Avamys after the expiry date which is stated on the label and carton. The expiry date refers to the last day of the month. Avamys nasal spray should be used within 2 months after first opening.

Do not refrigerate or freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Avamys contains

The active substance is fluticasone furoate. Each spray delivers 27.5 micrograms of fluticasone furoate. The other ingredients are glucose anhydrous, dispersible cellulose, polysorbate 80, benzalkonium chloride, disodium edetate, purified water.

What Avamys looks like and contents of the pack

The medicine is a white nasal spray suspension contained in an amber glass bottle, fitted with a pump. The bottle is in an off-white plastic casing with a light blue cap and side-actuated lever. The casing has a window for viewing the bottle contents. Avamys is available in pack sizes 30, 60 and 120 sprays.

Marketing authorisation holder

Marketing authorisation:
Glaxo Group Ltd
Greenford, Middlesex, UB6 0NN
United Kingdom

Manufacturer:

Glaxo Operations UK, Ltd,
(trading as Glaxo Wellcome Operations)
Harmire Road
Barnard Castle
County Durham
DL12 8DT
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
GlaxoSmithKline s.a./n.v.
Tél/Tel: + 32 (0)2 656 21 11

България
ГлаксосмитКлайн ЕООД
Тел.: + 359 2 953 10 34

Česká republika
GlaxoSmithKline s.r.o.
Tel: + 420 222 001 111
gsk.czmail@gsk.com

Danmark
GlaxoSmithKline Pharma A/S
Tlf: + 45 36 35 91 00
dk-info@gsk.com

Deutschland
GlaxoSmithKline GmbH & Co. KG
Tel.: + 49 (0)89 36044 8701
produkt.info@gsk.com

Eesti
GlaxoSmithKline Eesti OÜ
Tel: + 372 6676 900
estonia@gsk.com

Ελλάδα
GlaxoSmithKline A.E.B.E.
Τηλ: + 30 210 68 82 100

España
GlaxoSmithKline, S.A.
Tel.: + 34 902 202 700
es-ci@gsk.com

France
Laboratoire GlaxoSmithKline
Tél.: + 33 (0)1 39 17 84 44
diam@gsk.com

Ireland
GlaxoSmithKline (Ireland) Limited
Tel: + 353 (0)1 4955000

Ísland
GlaxoSmithKline ehf.
Sími: + 354 530 3700

Italia
GlaxoSmithKline S.p.A.
Tel: + 39 (0)45 9218 111

Κύπρος
GlaxoSmithKline Cyprus Ltd
Τηλ: + 357 22 89 95 01

Latvija
GlaxoSmithKline Latvia SIA
Tel: + 371 67312687
lv-epasts@gsk.com

Lietuva
GlaxoSmithKline Lietuva UAB
Tel: + 370 5 264 90 00
info.lt@gsk.com

Luxembourg/Luxemburg
GlaxoSmithKline s.a./n.v.
Belgique/Belgien
Tél/Tel: + 32 (0)2 656 21 11

Magyarország
GlaxoSmithKline Kft.
Tel.: + 36 1 225 5300

Malta
GlaxoSmithKline Malta
Tel: + 356 21 238131

Nederland
GlaxoSmithKline BV
Tel: + 31 (0)30 6938100
nlinfo@gsk.com

Norge
GlaxoSmithKline AS
Tlf: + 47 22 70 20 00
firmapost@gsk.no

Österreich
GlaxoSmithKline Pharma GmbH
Tel: + 43 (0)1 97075 0
at.info@gsk.com

Polska
GSK Commercial Sp. z o.o.
Tel.: + 48 (0)22 576 9000

Portugal
GlaxoSmithKline – Produtos Farmacêuticos, Lda.
Tel: + 351 21 412 95 00
FI.PT@gsk.com

România
GlaxoSmithKline (GSK) S.R.L.
Tel: + 4021 3028 208

Slovenija
GlaxoSmithKline d.o.o.
Tel: + 386 (0)1 280 25 00
medical.x.si@gsk.com

Slovenská republika
GlaxoSmithKline Slovakia s. r. o.
Tel: + 421 (0)2 48 26 11 11
repcia.sk@gsk.com

Suomi/Finland
GlaxoSmithKline Oy
Puh/Tel: + 358 (0)10 30 30 30
Finland.tuoteinfo@gsk.com

Sverige
GlaxoSmithKline AB
Tel: + 46 (0)8 638 93 00
info.produkt@gsk.com

United Kingdom
GlaxoSmithKline UK
Tel: + 44 (0)800 221441
customercontactuk@gsk.com

Detailed information on this medicine is available on the European Medicines Agency (EMA) website:
<http://www.emea.europa.eu/>

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