

AVAMYS[®] Nasal Spray

Fluticasone furoate

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you use Avamys.

This leaflet answers some common questions about Avamys. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking Avamys against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is Avamys used for?

Avamys is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing, and watery, itchy or red eyes. The effects are usually felt within the first day, although some people will not feel the effects until several days after first taking it.

Avamys contains the medicine fluticasone furoate. This medicine belongs to a group of medicines known as corticosteroids, frequently called 'steroids'. They are not 'anabolic steroids' which

are the steroids sometimes misused by athletes.

Avamys works to decrease inflammation caused by allergy (rhinitis).

Your doctor may have prescribed Avamys for another reason.

Avamys is not addictive.

Before you use Avamys

Do not use if:

You must not use Avamys if:

- you have ever had an allergic reaction to fluticasone furoate or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Tell your doctor if:

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- you are taking an antiviral medicine called a protease inhibitor (e.g. ritonavir) or a type of medicine used to treat fungal infections (e.g. ketoconazole).
- you have severe liver problems.
- you are taking any other medicines, including medicines you buy without a prescription. This includes

inhaled, oral or injected steroids.

- you are breastfeeding, pregnant or trying to become pregnant.

How do I use Avamys?

How much to use

Take Avamys as directed by your doctor or pharmacist. Don't exceed the recommended dose.

Adults and adolescents 12 years and older:

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

Children (2 to 11 years):

- The usual starting dose is 1 spray in each nostril once a day.
- If symptoms are severe your doctor may increase the dose to 2 sprays in each nostril once a day until symptoms are under control. It may then be possible for the dose to be reduced to 1 spray in each nostril once a day.

How to use it

See the instruction leaflet inside the pack for information on how to use Avamys.

Shake well before use.

Avamys is sprayed into the nose as a fine mist. It has virtually no taste.

Avamys is not for use in the eyes.

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

How long to use it for

Your doctor will tell you how long to use Avamys.

Do not stop using Avamys, or change the dose without first checking with your doctor.

Use in children

Avamys is not recommended for use in children below 2 years of age.

What do I do if I use too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (In Australia call 131126. In New Zealand call 0800 POISON or 0800 764 766.) for advice, if you think you or anyone else may have taken too much Avamys, even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Avamys

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

If you forget to use Avamys:

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

If you have not taken your medicine exactly as directed, your doctor may think that it was not

working as it should and change your treatment unnecessarily.

Things you must not do

Do not use Avamys in or near the eyes.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Avamys to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how Avamys affects you.

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

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Avamys, even if the problem is not listed below.

Like other medicines, Avamys can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- nose bleeds
- nasal ulceration – which may cause irritation or discomfort in your nose. You may also get streaks of blood when you blow your nose.
- headache.

Uncommon side effects are:

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

Tell your doctor immediately if you notice any of the following:

- Wheezing, swelling of the lips/mouth, difficulty in breathing, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store Avamys?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Store Avamys below 30°C.

Do not refrigerate or freeze.

Always keep the cap on.

Do not leave in a car, on a window sill or in a bathroom.

Keep Avamys in its pack until it is time to use it.

Return any unused or expired medicine to your pharmacist.

Product description

What Avamys looks like

Avamys Nasal Spray is a white 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-button. The casing has a window for viewing the bottle contents. The bottle contains 120 sprays. Each spray delivers approximately 27.5 micrograms fluticasone furoate.

Ingredients

Avamys contains the active ingredient fluticasone furoate.

Avamys also contains glucose anhydrous, dispersible cellulose, polysorbate 80, benzalkonium chloride, disodium edetate, and purified water.

Supplier

Your Avamys is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia Victoria 3155
Australia

Your Avamys is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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The information provided applies only to: Avamys[®].

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