

FLIXONASE® NASULE® DROPS

Fluticasone propionate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before taking Flixonase Nasule Drops.

This leaflet answers some common questions about Flixonase Nasule Drops. 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 risks of you taking Flixonase Nasule Drops against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Flixonase Nasule Drops are used for

Flixonase Nasule Drops contain a steroid called fluticasone propionate, which treats inflamed tissue.

Flixonase Nasule Drops work by shrinking swelling inside your nose. This makes breathing easier. You may not feel the maximum benefit for a few weeks.

Inflamed tissue inside the nose can form grape-like swellings called 'polyps'. They cause nasal blockage and discomfort. Flixonase Nasule Drops are used to relieve the symptoms caused by nasal polyps by shrinking them. Flixonase Nasule Drops have not been studied in patients under 16 years of age.

Your doctor may have prescribed Flixonase Nasule Drops for another reason.

Ask your doctor if you have any questions or if you aren't sure why Flixonase Nasule Drops has been prescribed for you.

Flixonase Nasule Drops are not addictive.

Before you use Flixonase Nasule Drops

When you must not use Flixonase Nasule Drops

- **Do not use Flixonase Nasule Drops if you have ever had an allergic reaction to fluticasone propionate or any of the ingredients listed at the end of this leaflet. Read the side effects section to find out the symptoms of an allergic reaction.**

- **Do not use Flixonase Nasule Drops if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

Your doctor will discuss the risks and benefits of using Flixonase Nasule Drops if you are pregnant or breastfeeding.

- **Do not use Flixonase Nasule Drops after the expiry date (EXP) printed on the pack.** If you use the product after the expiry date has passed, they may not work as well.

- **Do not use Flixonase Nasule Drops if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be using Flixonase Nasule Drops, talk to your doctor.

Before you start to use Flixonase Nasule Drops

You must tell your doctor if:

- You are pregnant or planning to become pregnant
- You are breastfeeding
- You have an infection in your nose or sinuses
- You have had nasal surgery
- You have been treated with steroid injections, or taken steroid tablets
- You are allergic to foods, dyes, or any other medicine
- You are diabetic
- You have a disease or are taking medication that could compromise your immune system
- You have ever had thrush in your mouth.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. For example, medicines like ketoconazole, used to treat fungal infection, and ritonavir used to treat HIV infection, may affect how Flixonase Nasule Drops works. If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

Use in children

Flixonase Nasule Drops are not recommended for use in patients under 16 years of age.

How to use Flixonase Nasule Drops

How much to use

Always use Flixonase Nasule drops exactly as your doctor has told you to. Don't exceed the recommended dose. Check with your doctor or pharmacist if you're not sure.

In patients over 16 years of age, the normal dose is one container (400 micrograms contained in 400 microlitres) once or twice every day, unless your doctor tells you otherwise.

The medicine should be divided equally between both affected nostrils.

Your doctor will advise you what to do if only one nostril is affected.

You may not feel the maximum benefit from your medicine straight away, but it is important that you continue to use the drops regularly.

Your doctor will assess your polyps regularly to decide on the best treatment.

How to use the product

Note: It may be easier if someone else puts the drops in for you.

1. Gently blow each nostril, in turn, to clear.
2. Open the foil pack by tearing off one side.
3. Detach one container and return the remaining containers, in the foil, to the carton.
4. It is important to ensure that the contents of your Nasule are well mixed before use.
5. While holding the container horizontally by the larger tab, flick the other end a few times and shake. Repeat this process several times until the entire contents of the container are completely mixed.

6. Hold the lower tab of the container securely. Twist and remove the top, and discard the drops.

7. To ensure the medicine treats the affected area, ideally you should position yourself as follows (see also the diagrams inside the pack):

(a) Move into one of the following positions: kneeling, sitting, or standing. Bend forward until your head is at knee level

OR

(b) Lie on your back on a bed with your head supported but tilted backwards over the edge. Gently insert the opened nozzle of the container into one nostril. Squeeze the container to deliver 6 drops. This is approximately half the dose.

NOTE: It is not always easy to count the drops. Make sure you hold the container by the dimpled sides. When the container is held just inside the nostril, squeeze until the dimpled sides meet. This delivers about half the dose.

8. Transfer the container to the other nostril and squeeze it to deliver the remaining drops.

9. Keep your head in this position for at least 1 minute. If you are lying down, rest your head to one side. After about half a minute rest your head to the other side, for a similar time.

How long to use the product

Flixonase Nasule Drops help control nasal polyps, but are not a cure. Continue to use Flixonase Nasule Drops regularly for as long as your doctor tells you to.

If you forget to use the product

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the product as soon as you remember, then go back to using the product as you would normally.

Do not use a double dose to make up for the dose that you missed.

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think you or anyone else may have used too much Flixonase Nasule Drops, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are using Flixonase Nasule Drops

Things you must do

Tell your doctor or pharmacist that you are using Flixonase Nasule Drops if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Use Flixonase Nasule Drops only in your nose.

Things you must not do

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

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

Do not use Flixonase Nasule Drops to treat any other complaints unless your doctor says to.

Avoid getting the drops in your eyes. Rinse the eyes with water if you do.

Side-Effects

Check with your doctor as soon as possible if you have any problems while using Flixonase Nasule Drops, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Flixonase Nasule Drops 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:

- sneezing
- irritation or dryness in the nose or throat
- bad taste or smell
- nose bleed
- difficulty in breathing

Rare side effects include:

- allergic reactions
- breakdown of tissue inside the nose (nasal septal perforation)
- cloudy lens in the eye (cataract), increased pressure of the eye that causes problems with vision (glaucoma). These eye problems occurred in people who used Flixonase Nasule Drops for a long time.

If any of these side effects persist, or are troublesome, see your doctor.

Ask your doctor or pharmacist to answer any questions you may have.

If you think you are having an allergic reaction to Flixonase Nasule Drops, TELL YOUR DOCTOR IMMEDIATELY or go to the emergency department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

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.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After using Flixonase Nasule Drops

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Condensation may form on the inside of the foil pack during storage, but it is not a cause for concern.

Store your Flixonase Nasule Drops upright, at below 30°C.

Protect the drops from direct sunlight.

Do not freeze the drops.

Do not store the drops, or any other medicine, in a bathroom or near a sink.

Do not leave the drops in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your product in its pack until it is time to use the drops.

If you take the product out of its packaging it may not keep well.

Disposal

If your doctor tells you to stop using Flixonase Nasule Drops, or the product has passed its expiry date, ask your pharmacist what to do with any product left over.

Product Description

What Flixonase Nasule Drops look like

Flixonase Nasule Drops come in individual polyethylene 'bubbles', in strips of 7 units. Each 'bubble' holds a single dose of 400 micrograms of fluticasone propionate, in a volume of 400 microlitres. The complete strip of 7 is wrapped in foil. Packs contain 4 foil-wrapped strips, each of seven units.

Ingredients

Flixonase Nasule Drops contain the active ingredient fluticasone propionate. The product also contains the following inactive ingredients:

- Polysorbate 20,
- sorbitan monolaurate,
- sodium phosphate - dibasic dihydrate,
- sodium phosphate - dibasic anhydrous,
- sodium chloride,
- water for injection.

Supplier

Your Flixonase Nasule Drops are supplied by:
GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street,
Abbotsford, Victoria 3067
Australia

Further Information

This is not all the information that is available on Flixonase Nasule Drops. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

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. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 30 September 2014.

The information provided applies only to:
Flixonase® Nasule® Drops.

Flixonase and Nasule are registered trade marks of the GSK group of companies.

Flixonase Nasule Drops: AUST R 71294

©1999-2014 GSK group of companies. All rights reserved.

Version 5.0