

Flixonase Nasule Drops

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Flixonase Nasule Drops?

Flixonase Nasule Drops contains the active ingredient Fluticasone propionate. Flixonase Nasule Drops are used to treat inflamed tissue in the nose.

For more information, see Section [1. Why am I using Flixonase Nasule Drops?](#) in the full CMI.

2. What should I know before I use Flixonase Nasule Drops?

Do not use if you have ever had an allergic reaction to Flixonase Nasule Drops or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Flixonase Nasule Drops?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Flixonase Nasule Drops and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Flixonase Nasule Drops?

- In patients over 16 years of age, the normal dose is one container (400 micrograms contained in 400 microlitres).
- More instructions can be found in Section [4. How do I use Flixonase Nasule Drops?](#) in the full CMI.

5. What should I know while using Flixonase Nasule Drops?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using Flixonase Nasule Drops.
- Tell your doctor if you become pregnant or are trying to become pregnant.

	<ul style="list-style-type: none"> • Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed. • Tell your doctor if you experience a change in your vision.
Things you should not do	<ul style="list-style-type: none"> • 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.
Driving or using machines	<ul style="list-style-type: none"> • Flixonase Nasule Drops is unlikely to affect your ability to drive.
Looking after your medicine	<ul style="list-style-type: none"> • Store your Flixonase Nasule Drops upright, below 30°C. • Protect the drops from direct sunlight. Keep

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

- Do not freeze.

For more information, see Section [5. What should I know while using Flixonase Nasule Drops?](#) in the full CMI

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Flixonase Nasule Drops can cause allergic reactions which may be severe. **If you develop symptoms of an allergic reaction, call your doctor straight away or go straight to the Emergency Department at your nearest hospital.** For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Flixonase Nasule Drops

Active ingredient: *Fluticasone propionate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Flixonase Nasule Drops. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Flixonase Nasule Drops.**

Where to find information in this leaflet:

- [1. Why am I using Flixonase Nasule Drops?](#)
- [2. What should I know before I use Flixonase Nasule Drops?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Flixonase Nasule Drops?](#)
- [5. What should I know while using Flixonase Nasule Drops?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Flixonase Nasule Drops?

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.

2. What should I know before I use Flixonase Nasule Drops?

Warnings

Do not use Flixonase Nasule Drops if:

- you are allergic to fluticasone propionate, or any of the ingredients listed at the end of this leaflet
- Always check the ingredients to make sure you can use this medicine
- you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should
- the expiry date (EXP) printed on the pack has passed

- the packaging is torn or shows signs of tampering

Check with your doctor if you:

- have any other medical conditions
- have an infection in your nose or sinuses
- have had nasal surgery
- have been treated with steroid injections or taken steroid tablets
- are allergic to foods, dyes, or any other medicine
- take any medicines for any other condition
- are diabetic
- have a disease or are taking medication that could compromise your immune system
- have ever had thrush in your mouth

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with Flixonase Nasule Drops and affect how it works.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Flixonase Nasal Drops.

4. How do I use Flixonase Nasule Drops?

How much to use

- In patients over 16 years of age, the normal dose is one container (400 micrograms contained in 400 microlitres).
- Follow the instructions provided and use Flixonase Nasule Drops until your doctor tells you to stop. Don't exceed the recommended dose.

When to use Flixonase Nasule Drops

- Flixonase Nasule Drops should be used once or twice every day unless your doctor tells you otherwise.

How to use Flixonase Nasule Drops

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.

To use Flixonase Nasule Drops, follow the steps below.

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 Flixonase Nasule Drops

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 Flixonase Nasule Drops

If it is almost time for your next dose, skip the dose you missed and take 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 take a double dose to make up for the dose you missed.

If you use too much Flixonase Nasule Drops

If you think that you have used too much Flixonase Nasule Drops, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Flixonase Nasule Drops?

Things you should 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.
- Tell your doctor if you experience a change in your vision.
- Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- Use Flixonase Nasule Drops only in your nose.

Call your doctor straight away if you:

- think you may be having an allergic reaction

Remind any doctor, dentist or pharmacist you visit that you are using Flixonase Nasule Drops.

Things you should 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.
- Do not stop using this medicine suddenly.

Driving or using machines

Flixonase Nasule Drops is unlikely to affect your ability to drive.

Looking after your medicine

- **Store your Flixonase Nasule Drops upright, 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.

Keep it 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• sneezing• irritation or dryness in the nose or throat• bad taste or smell• nose bleed• difficulty in breathing	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<p data-bbox="204 432 316 477">Eyes</p> <ul data-bbox="204 510 746 1019" style="list-style-type: none">● 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. <p data-bbox="204 1048 316 1093">Nose</p> <ul data-bbox="204 1126 718 1355" style="list-style-type: none">● breakdown of tissue inside the nose (nasal septal perforation)● sores in the nose <p data-bbox="204 1384 614 1429">Allergic Reaction:</p> <ul data-bbox="204 1462 686 1915" style="list-style-type: none">● wheezing● swelling of the lips/ mouth● difficulty in breathing● hay fever● lumpy rash ("hives")● fainting	<p data-bbox="817 432 1375 817">Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Flixonase Nasule Drops contains

Active ingredient (main ingredient)	fluticasone propionate
Other ingredients (inactive ingredients)	Polysorbate 20, sorbitan monolaurate, dibasic sodium phosphate, monobasic sodium

	phosphate, water for injection
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What Flixonase Nasule Drops looks 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.

(AUST R 71294)

Who distributes Flixonase Nasule Drops

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria 3067

Australia

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