

PACKAGE LEAFLET

Package leaflet: Information for the patient

Fluttasino 400 micrograms, nasal drops, suspension

fluticasone propionate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What X is and what it is used for
2. What you need to know before you use X
3. How to use X
4. Possible side effects
5. How to store X
6. Contents of the pack and other information

1. What X is and what it is used for

This medicine contains fluticasone propionate. This belongs to a group of medicines called steroids (also called ‘corticosteroids’).

- steroids work by reducing inflammation
- they reduce swelling and irritation in your nose
- this helps to relieve itching, sneezing and your blocked or runny nose.

(Invented name) nasal drops are used to treat:

- small growths inside the nose (polyps)
- symptoms associated with nasal obstruction.

(Invented name) nasal drops are provided in small plastic containers.

2. What you need to know before you use X

Do not use X

- if you are **allergic** to fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk with your doctor or pharmacist before using your medicine:

- if you have an infection in your nose.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using (Invented name) nasal drops.

(Invented name) nasal drops may lower the normal production of steroid hormones in your body, particularly if doses higher than those recommended are used for a long time. In this situation people may need to take extra steroids in times of extreme stress, following serious injury or before a surgical operation.

It is important therefore that you are taking the lowest dose of (Invented name) to control your symptoms. Your doctor will check you for signs of any problems.

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and X

Tell your doctor or pharmacist if you are taking, have recently taken any prescribed medicines, including medicines or herbal products obtained without a prescription.

Particularly if:

- you are taking a type of antiviral medicine known as a protease inhibitor (such as ritonavir)
- you are taking a medicine used to treat fungal infections (such as ketoconazole)
- you have had steroids for a long time, either as an injection or by your mouth.

Some medicines may increase the effect of (Invented name) nasal drops and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

Do not use this medicine if you are pregnant, or planning to become pregnant, or if you are breast-feeding, unless your doctor or pharmacist tells you to.

Driving and using machines

This medicine is not likely to affect you being able to drive or use any tools or machines.

3. How to use X

Always use this medicine exactly as your doctor has told you. Don't exceed the recommended dose.

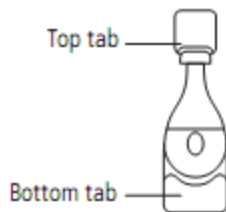
Check with your doctor or pharmacist if you are not sure.

- Do not use in children or young people under 16 years old.
- Only use in your nose, contact with the eyes should be avoided.
- It may take a few weeks for this medicine to work. So keep using it, even though you may not feel better straight away.
- You should use (Invented name) nasal drops every day.

How much to use- adults (over 16 years of age)

- The usual starting dose is one single-use plastic container (400 micrograms) divided equally between each nostril, once or twice a day.
- As your symptoms improve, your doctor may ask you to use a lower dose.
- If your symptoms do not improve after 4 to 6 weeks your doctor may change your medicine.

What the plastic container looks like



Using your (Invented name) nasal drops

1. Open the foil pack by tearing off one side. Do not open the pack until the drops are needed.
2. Take out the strip of plastic containers from the foil and pull off one container



3. Put the remaining containers back into the foil pack and put the pack back in the box.
4. Flick and shake the plastic container for 30 seconds. The contents of the container **must be well mixed** before use.
5. Then shake downwards to make sure the liquid is not in the neck of the container.
6. Hold the bottom tab of the container firmly. Twist and remove the top tab to open it.



How to put the drops in

Before you put the drops in, you must choose one of the positions shown in these pictures. Although they may not be easy, the positions will make sure the drops get to where they are needed.

1. Gently blow your nose to clear it.
2. While standing up, bend right over.



3. If you can't do this, kneel down and then bend right over.



4. Put the opened container into one nostril and gently squeeze.
5. Keep squeezing until the sides of the container touch each other. This will mean that about half the dose has been given (about 6 drops).
6. Repeat this step to use the rest in your other nostril.
7. Stay with your head down for at least one minute after putting the drops in.

If these positions are difficult you can lie on a bed with your head tilted over the edge. After you have put the drops in, rest your head sideways on the bed for at least one minute.



Be careful not to get the drops in your eyes or on broken skin. If you do, rinse your eyes or skin with water immediately.

If you use more (Invented name) nasal drops than you should

Tell your doctor if you use more than you were told to.

If you forget to use (Invented name) nasal drops

If you miss a dose, just use the next dose when it is due. Do not use a double dose to make up for a forgotten dose.

If you stop using (Invented name) nasal drops

Do not stop treatment even if you feel better, unless your doctor tells you to stop. If you do stop, the symptoms may come back.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Allergic reactions: get a doctor's help straight away

A small number of people get allergic reactions to (Invented name) nasal drops, which can develop into a more serious, even life-threatening problem if not treated. Symptoms include;

- becoming very wheezy, coughing or having difficulty with breathing
- suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness)
- swelling around the face, mouth or tongue
- skin rashes or redness.

In many cases, these symptoms will be signs of less serious side effects. But you must be aware that they are potentially serious — so, if you notice any of these symptoms: **See a doctor as soon as possible.**

Allergic reactions to (Invented name) nasal drops are very rare (these affect less than 1 in 10,000 people).

Other side effects include:

Very common (may affect more than 1 in 10 people)

- Nose bleeds.

Common (may affect up to 1 in 10 people)

- A dry or irritated nose or throat.

Very rare (may affect up to 1 in 10,000 people)

- Cloudy lens (cataract), increased pressure in the eye that can cause problems with vision (glaucoma). These eye problems occurred in people who used (Invented name) for a long time.
- Small holes (perforations) in the ridge inside the nose that separates the nostrils.

Not known (frequency cannot be estimated from the available data)

- Blurred vision.
- Sores in the nose.

In addition, the production of steroids in your body may be affected. This is more likely to happen if you use high doses for a long time. Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national](#)

reporting system listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store X

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

After first opening the foil pouch, use the single-dose containers within 28 days. Keep the single-dose containers in the foil pouch in order to avoid evaporation. Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will help protect the environment.

6. Contents of the pack and other information

What X contains

- The active substance is fluticasone propionate.
- The other ingredients are polysorbate 20, sorbitan laurate, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, salt (sodium chloride), sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injections.

What X looks like and contents of the pack

Each container contains 400 micrograms of fluticasone propionate, giving a strength of 1 milligram per millilitre. Each carton contains 6 strips of 5 single-dose containers (30 single-dose containers per carton).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last revised in 2025-04-16.