

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a physician's prescription only

Flixonase Nasule Drops

Each container contains: fluticasone propionate, 400 mcg (1 mg/ml).

A list of the additional ingredients is detailed in section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Flixonase Nasule Drops are used to treat:

- Small growths inside the nose (polyps).
- Symptoms associated with nasal obstruction.

Therapeutic group: Steroids.

Flixonase Nasule Drops contain a medicine called fluticasone propionate. This medicine belongs to a group of medicines called steroids (also called 'corticosteroids').

- Steroids act by reducing inflammation
- They reduce swelling and irritation in your nose
- They help to relieve itching, sneezing and a blocked or runny nose.

Flixonase Nasule Drops are provided in small plastic containers (Nasules).

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

You are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the medicine (detailed in section 6).

Special warnings regarding use of this medicine

Before beginning treatment with Flixonase Nasule Drops, tell the physician if:

- you have an infection in your nose.

If you are not sure if the above applies to you, consult with your physician or pharmacist before using Flixonase Nasule Drops.

Flixonase Nasule Drops may lower the natural production of steroid hormones in your body, particularly if dosages higher than those recommended are used for a long time. In this situation, you may need to take extra steroids in cases of stress, such as serious injury or before a surgical operation.

It is therefore important that you take the lowest dosage of Flixonase Nasule Drops to control your symptoms. Your physician will check you for signs of any problems.

Contact the physician if you experience blurred vision or other visual disturbances.

Children and adolescents

The medicine is intended for adults and adolescents over 16 years of age.

If you are taking, or have recently taken, other medicines including non–prescription medicines or nutritional supplements, tell the physician or pharmacist, particularly if you are taking:

- An antiviral medicine known as a protease inhibitor (such as ritonavir)
- A medicine used to treat fungal infections (such as ketoconazole)
- You have taken steroids for a long time, either by injection or orally.

Some medicines might increase the effect of Flixonase Nasule Drops, and therefore, if you are taking these medicines (including some of the medicines used to treat HIV: ritonavir, cobicistat), your physician may want to monitor your condition.

Pregnancy and breastfeeding

Do not use Flixonase Nasule Drops if you are pregnant, planning to become pregnant or if you are breastfeeding, unless instructed by your physician or pharmacist.

Driving and operating machinery

Flixonase Nasule Drops are not likely to affect your ability to drive or operate tools or machinery.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the physician's instructions.

Check with the physician or the pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the physician only.

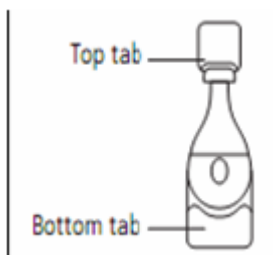
- Do not use in children or adolescents under the age of 16.
- For nasal application only; contact with the eyes should be avoided.
- It may take a few weeks for this medicine to act. So keep using it, even though you may not feel an immediate improvement.
- You should use Flixonase Nasule Drops every day.

The usual dosage for adults (16 years and over) is:

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

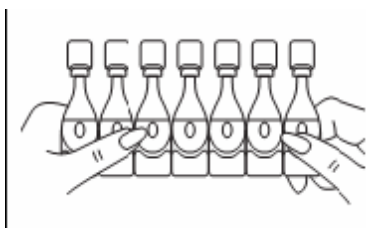
Do not exceed the recommended dose.

What the plastic container looks like



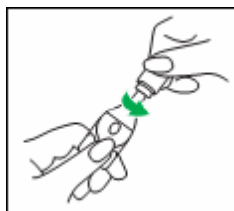
Using Flixonase Nasule Drops

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



3. Put the remaining containers back into the aluminum foil wrapper and put it back in the box.
4. Flick and shake the plastic container several times. The contents of the container **must be well mixed** before use.

5. Then shake the container 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 instill the drops

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

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



3. If you cannot do this, kneel down and then bend forward.



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

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



Be careful not to get the drops in your eyes or on broken skin.

If such contact occurs, rinse your eyes or skin with water immediately.

If you accidentally took a higher dosage

Inform your physician if you used a higher dosage than you were told to.

If you forgot to take the medicine

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult the physician.

Adhere to the treatment regimen recommended by the physician.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the physician or pharmacist.

If you stop taking the medicine the symptoms may return.

- Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Flixonase Nasule Drops may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Allergic reactions: Refer immediately to the physician

A small number of people get allergic reactions to Flixonase Nasule Drops, which can develop into more serious, even life-threatening problems if not treated. The symptoms include:

- wheezing, cough, or breathing difficulties
- suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness)
- swelling around the face, mouth or tongue
- skin rash 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 physician as soon as possible.**

Allergic reactions to Flixonase Nasule Drops are very rare (these occur in less than 1 in 10,000 people).

Additional side effects

Very common side effects (occur in more than 1 in 10 people):

- Nosebleed.

Common side effects (occur in up to 1 in 10 people):

- A dry or irritated nose or throat.

Very rare side effects (occur in 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 have used Flixonase Nasule Drops for a long time.
- Small holes (perforations) in the ridge inside the nose that separates the nostrils.

Side effects of unknown frequency (effects whose frequency cannot be determined based on the existing information)

- Blurred vision
- Sores in the nose

In addition, the natural production of steroids in your body may be affected from use of Flixonase Nasule Drops. This is more likely to happen if you use high dosages for a long time. Your physician will help stop this from happening by making sure you use the lowest dosage of steroids needed to control your symptoms.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Side effects can be reported to the Ministry of Health by clicking on the link “Report side effects of drug treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 30° C.
- Protect from light.
- Do not freeze.
- Store Flixonase Nasule Drops in the aluminum foil wrapper and in the carton in an upright position.
- Can be used for 28 days after first opening the aluminum foil wrapper.

6. FURTHER INFORMATION

- In addition to the active ingredient the medicine also contains -
Sodium dihydrogen phosphate dihydrate, Sodium chloride, Dibasic sodium phosphate anhydrous, Polysorbate 20, Sorbitan laurate, Water for injections.
- What the medicine looks like and the contents of the package -
Each container contains 400 micrograms fluticasone propionate, at a concentration of 1 milligram per milliliter. Each carton contains 4 strips of 7 Nasule containers each (28 Nasule containers per carton).
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Australia PTY Ltd., Boronia, Australia.
- The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in October 2014, and was updated in April 2018, in accordance with Ministry of Health guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
115-01-29642

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