

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

Use for ages 4-18 years is with a physician's prescription only
Over 18 years of age – the medicine is dispensed without a physician's
prescription

Flixonase Nasal Spray

Fluticasone propionate 0.05% w/w

Each metered dose contains 50 mcg fluticasone propionate.

For the list of inactive and allergenic ingredients in the preparation – see section 2 “Important information about some of the ingredients of the medicine” and section 6 “Further information”.

Read the 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 your treatment. Do not pass it on to others. It may harm them even if you think that their medical condition is similar. Use the medicine according to the instructions provided in this leaflet. Consult the pharmacist if you need further information. Refer to a physician if the symptoms worsen or are not improving after 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

Without physician's instructions:

To prevent and treat seasonal allergic rhinitis, including hay fever in adults.

With physician's instructions:

To prevent and treat seasonal allergic rhinitis, including hay fever in children from 4 years of age and above and perennial rhinitis in adults and children from 4 years of age and above.

Therapeutic group: corticosteroids.

The active ingredient is fluticasone propionate, an anti-inflammatory corticosteroid which, when used every day, works in a similar way to natural body chemicals to control inflammation. This spray helps control your body's reactions to allergens ('triggers') in the environment.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (as detailed in section 6).
- You are **under 4 years of age**.

Special warnings regarding the use of the medicine**Before treatment with Flixonase Nasal Spray, tell the physician if:**

- You have an **infection** in your nose or sinuses, if you have a **high temperature** or you have recently had **surgery**, an **injury** or **ulcers** in your nose.
- **Your symptoms do not improve, or if the symptoms are not controlled after 7 days**, talk to your physician or pharmacist.
- Contact the physician if you have blurred vision or other vision disturbances, which can be the result of conditions, such as cataract or glaucoma.
- **Do not use continuously for more than 3 months** unless your physician tells you to.
- The physician has told you to take high dosages of Flixonase Nasal Spray, there may be situations in which the physician will tell you to add treatment with other steroid medicines.

Children and adolescents

The medicine is intended for adults and children over 4 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Especially if you are taking:

- **corticosteroid** medicines (including eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops)
- **ritonavir** or **cobicistat (anti-HIV medicines)**
- ketoconazole (to treat **fungus infections**).

Some medicines may increase the effects of Flixonase Nasal Spray and your physician may wish to monitor you carefully if you are taking these medicines (including some medicines used to treat HIV: ritonavir, cobicistat).

Use of the medicine and food

Flixonase Nasal Spray can be used at any time of the day, with or without food.

Pregnancy and breastfeeding

If you are pregnant, planning to become pregnant or breastfeeding, consult the physician or pharmacist before using the medicine.

Driving and operating machinery

Flixonase Nasal Spray is not likely to affect your ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

Flixonase Nasal Spray contains 0.02 mg **benzalkonium chloride** in each dose unit.

Benzalkonium chloride may cause breathing problems (bronchospasm). Benzalkonium chloride may also cause irritation or swelling in the nose, especially if use is long-term.

3. HOW SHOULD YOU USE THE MEDICINE?

Prevention and treatment of seasonal allergic rhinitis, including hay fever, in children from 4 years of age and above and perennial rhinitis in adults and children from 4 years of age and above are with a physician's prescription **only**.

Check with the physician or pharmacist if you are uncertain about the dosage and the treatment regimen of the medicine.

Always shake well before use. Only use in the nose. Do not swallow.

Flixonase Nasal Spray quickly starts to reduce inflammation and swelling in your nose, although it may take 3 or 4 days to build up to its maximum protective effect. To prevent the onset of symptoms, start to use Flixonase Nasal Spray before exposure to one of your usual 'triggers' (allergens). You should try to use the spray in the morning.

- **Do not use in children under 4 years of age.**
- **For use in the nose only; avoid contact with the eyes.**
- **It will take a few days until the medicine begins to have an effect. Therefore, continue using it, even if you do not feel an immediate improvement.**
- Use the spray daily.

The recommended dosage for adults and children over 12 years of age is generally: two puffs into each nostril daily, preferably in the morning.

Once your symptoms have improved, you may be able to reduce the dose to **one puff into each nostril, once daily.**

If your symptoms are especially bad, you may need to **spray two puffs into each nostril twice daily**, until the symptoms improve.

- **Do not use more than 8 sprays (4 sprays in each nostril) 400 micrograms, in a day.**
- **Use the lowest dose possible to control your symptoms.**
- **If your symptoms do not improve, or are not well controlled, after 7 days, talk to your physician or pharmacist.**

The recommended dosage for children of ages 4 to 11 years is generally:

- The usual starting dosage is one puff into each nostril once daily, preferably in the morning.
- The maximum dosage is 4 puffs (2 puffs into each nostril) per day.

Flixonase Nasal Spray is not for use for more than one month in children.

Do not exceed the recommended dose.

If you have accidentally taken a higher dosage

Tell your physician.

It is important to take your dose as recommended by the physician or the recommended dosage regimen. Use of a smaller or larger dose of the medicine may worsen your symptoms.

If you forget to take the medicine

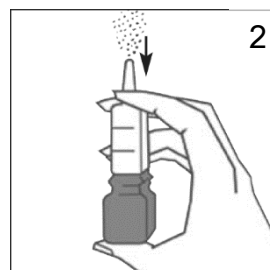
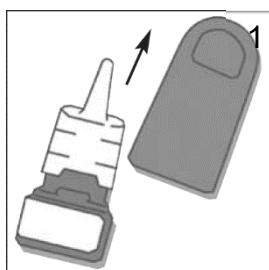
Do not take a double dose; take the next dose at the usual time.

If you stop taking the medicine that was prescribed by the physician

If the medicine was prescribed for you by the physician, do not stop treatment even if you feel better, unless the physician has instructed you to stop. If you stop the treatment, the symptoms may recur.

Before using a new bottle of Flixonase Nasal Spray:

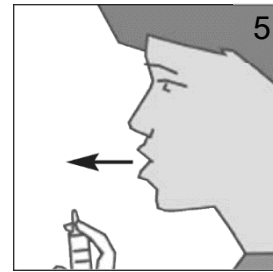
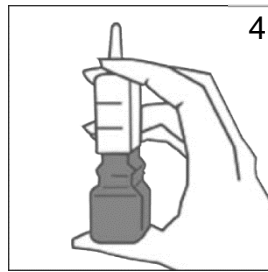
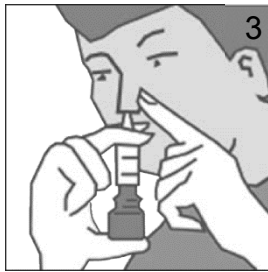
- Flixonase Nasal Spray has a dust cap which protects the nozzle and keeps it clean. Remember to take it off before you use the spray (Picture 1).
- Before you start to use a new bottle of Flixonase Nasal Spray, or if you have not used the spray for a few days, press the pump down several times until you get a fine spray.
- Hold the bottle straight, as shown in the picture, with your forefinger and middle finger supporting either side of the nozzle and your thumb underneath the bottle.
- Keeping your thumb still, press down with your fingers to pump the spray (Picture 2).
- When pressing, make sure you do not point the nozzle at yourself or anyone else.
- If the spray still does not work, try to clean it as described under the 'To clean the spray' section. Do not try to unblock or enlarge the tiny spray hole with a pin or other sharp objects because this will destroy the spray mechanism.



Using Flixonase Nasal Spray:

1. Shake the bottle well and remove the dust cap.
2. Blow your nose gently.

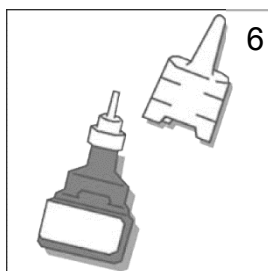
3. Close one nostril, as shown in the picture, and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright. Hold the bottle as shown (Picture 3).
4. Start to breathe in slowly through your nose. While you are breathing in, squirt a spray of fine mist into your nostril by pressing down firmly on the collar with your fingers (Picture 4).
5. Breathe out through your mouth. Repeat step 4 to take a second spray in the same nostril.
6. Remove the nozzle from this nostril and breathe out through your mouth (Picture 5).
7. Repeat steps 3 to 6 for the other nostril.
8. After using the spray, wipe the nozzle carefully with a clean tissue or handkerchief and replace the dust cap.



To clean the spray:

Clean your spray at least once a week or more frequently, if it gets blocked.

1. Take the dust cap and nozzle off (Picture 6).
2. Soak the nozzle and dust cap in warm water for a few minutes and then rinse under running tap water.
3. Shake off the excess water and allow to dry in a warm place – not too hot!
4. Re-fit the nozzle.
5. If necessary, press the pump down several times until you get a fine spray.



- **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, the use of Flixonase Nasal Spray may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Very rare side effects (effects that occur in less than 1 in 10,000 users)
Stop taking the medicine and **seek immediate medical help.**

A small number of people experience allergic reactions to Flixonase Nasal Spray, which can develop into a more serious and even life-threatening problems.

Allergic reactions. These may include developing a rash or skin redness, swelling of the mouth, tongue or face, sudden weakness or dizziness (which may lead to fainting or loss of consciousness), cough, wheezing or difficulty breathing.

Immediately after using the spray

- You may sneeze a bit, but this quickly stops.
- You may rarely experience an unpleasant smell or taste.

Stop taking the medicine and **tell your physician** if you experience:

- Eye problems such as pain or blurred vision.
- Nasal problems such as pain and/or persistent bleeding.

Tell your physician as soon as possible if you experience any of the following side effects:

Very common side effects (effects that occur in more than one user in ten):

- Nose bleeds.

Common side effects (effects that occur in 1-10 users in 100):

- Headache.
- Unpleasant smell or taste.
- Dryness or irritation in the nose or throat.

Very rare side effects (effects that occur in less than one user in 10,000):

- Skin reactions – ranging from redness, rash and itching, to more serious skin reactions, such as dry, cracked and peeling skin.
- Eye problems, such as pain and blurred vision.
- Nasal damage.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Blurred vision.
- Nasal sores.

Additional side effects that have been reported:

- Sneezing after using the spray, but this soon stops.

Very rarely, the proper production of steroids in your body may be affected. This is more likely to occur if you are using high dosages for a long period of time.

Your physician will help you stop the effect by being sure to use the lowest dosage of steroids that controls your symptoms.

In children, this side effect may, in rare cases, cause slowed growth. The physician will regularly monitor the height of children being treated with Flixonase Nasal Spray for an extended period of time.

It is important to follow the dose instructions shown in section 3. Using Flixonase Nasal Spray at higher doses or for longer than 3 consecutive months can cause a number of changes in your body such as catching infections more easily.

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

Reporting side effects

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 to the online form for reporting side effects or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants 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.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains - Dextrose (anhydrous), microcrystalline cellulose and sodium carboxymethylcellulose (Avicel RC591), phenylethyl alcohol, benzalkonium chloride, polysorbate 80, purified water and dilute hydrochloric acid.
- What the medicine looks like and the content of the package - Flixonase Nasal Spray is supplied in a glass bottle with a dedicated pump that contains 120 doses.
- Registration holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer and address: Glaxo Wellcome S.A., Burgos, Spain.
- Revised in November 2023 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 060-33-26912

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