

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

The medicine is dispensed without a physician's prescription

Flixonase Nasal Spray

Fluticasone propionate 0.05% w/w

Each metered spray contains 50 mcg fluticasone propionate.

The 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.

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 of the disease worsen or do not improve after 7 days.

1. What is the medicine intended for?

Prevention and treatment of seasonal allergic rhinitis, including hay fever and perennial rhinitis in adults and children from 4 years of age and above.

Therapeutic group: corticosteroids

The active ingredient is fluticasone propionate, a corticosteroid with anti-inflammatory activity. This spray helps control your body's reactions to allergens in the environment.

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 (as detailed in section 6)
- You are **under 4 years of age**.

Special warnings regarding use of this medicine

Before using Flixonase Nasal Spray, tell the physician if:

- You have an **infection** in your nose or sinuses, if you have **high fever** or if you recently underwent **surgery**, suffered an **injury** or had **ulcers** in your nose.
- If the symptoms do not improve, or are not under control, after 7 days**, consult your physician or pharmacist.
- Contact the physician if you experience blurred vision or other visual disturbances, which can be the result of conditions such as cataract or glaucoma.
- Do not use the spray for more than 3 consecutive months** unless the physician has instructed you to do so.

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 or nutritional supplements, tell the physician or pharmacist, particularly if you are taking:

- Corticosteroids** (including creams for eczema, inhalers for asthma, tablets, injections, nasal sprays and eye drops or nose drops)
- Ritonavir **or** cobicistat (medicines to treat HIV)
- Ketoconazole (**to treat fungal infections**).

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

Pregnancy and breastfeeding

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

Important information about some of the ingredients in this medicine

Flixonase Nasal Spray contains **benzalkonium chloride** which may cause breathing problems (bronchospasm).

3. How should you use the medicine?

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

Always shake well before use. For intranasal use only. Do not swallow.

Flixonase Nasal Spray quickly begins to reduce inflammation and swelling in your nose, although it may require 3 to 4 days to achieve its maximal protective activity. To prevent onset of symptoms, start using Flixonase Nasal Spray before being exposed to one of your common allergens. Try to use the spray in the morning hours.

The usual dosage for adults and children over the age of 12, is generally: two actuations into each nostril, once a day.

When the symptoms improve, you can reduce the dosage to **one actuation in each nostril, once a day**.

If the symptoms are particularly severe, you may need to **spray two actuations in each nostril, twice a day**, until the symptoms improve.

- Do not use more than 8 actuations (4 times in each nostril) (400 mcg) per day.**
- Use the lowest possible dosage to control your symptoms.**
- If your symptoms do not improve or are not well controlled after 7 days**, consult your physician or pharmacist.

The usual dosage for children ages 4 to 11, is generally:

- The usual starting dosage is one actuation per day in each nostril, preferably in the morning.
- The maximal dosage is 4 actuations (2 actuations in each nostril) per day.

Flixonase Nasal Spray is not for use in children for a period longer than 1 month.

Do not exceed the recommended dose

If you accidentally took a higher dosage

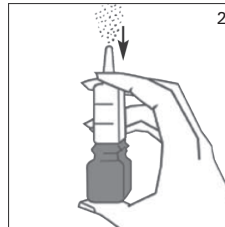
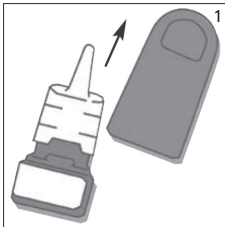
Inform your physician.

If you forgot to take the medicine

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

Before using a new Flixonase Nasal Spray bottle:

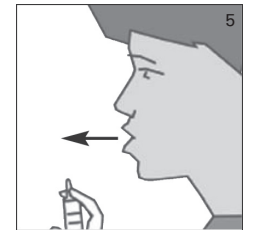
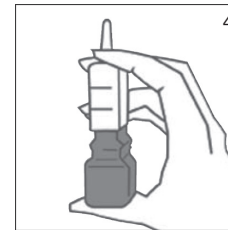
- Flixonase Nasal Spray has a cap which protects the nozzle and keeps it clean. Remember to take the cap off before using the spray (Figure 1).
- Before starting to use a new bottle of Flixonase Nasal Spray or if you did not use the spray for a few days, press the pump down a few times until a fine mist is obtained.
- Hold the bottle as shown in the picture, with the forefinger and middle finger supporting from either side of the nozzle and the thumb under the bottle.
- Without moving the thumb, press down with your fingers to pump the spray (Figure 2).
- While pressing, make sure that the spray nozzle is not facing you or any other person.
- If the spray still does not work, try to clean it as described in the "Cleaning the spray" section. Do not use a pin or sharp object to try to open a blockage or to enlarge the hole in the spray nozzle, since this will ruin the spraying mechanism.



Using Flixonase Nasal Spray:

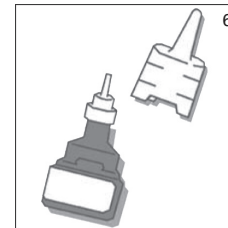
- Shake the bottle well and take off the cap.
- Blow your nose gently.

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



Cleaning the spray:

- Take off the cap and the nozzle (Figure 6).
- Soak the nozzle and cap in warm water for a few minutes and then rinse under running tap water.
- Shake the excess water off and let it dry.
- Put the nozzle back on.
- If necessary, press the pump a few times until a fine mist is obtained.



- Do not take medicines in the dark! Check the label and the dose each time you take the 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 Nasal Spray 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.

Very rare side effects (occur in less than 1 in every 10,000 people)

Stop taking the medicine and refer for medical treatment immediately if you experience:

- Allergic reactions. These can include onset of a rash or skin redness, swelling of the mouth, tongue or face, sudden weakness or dizziness, cough or breathing difficulties, dry, cracked and peeling skin.

Stop taking the medicine and report to a physician if you experience:

- Eye problems, such as pain.
- Nose problems, such as pain and/or prolonged bleeding.

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

- Nose bleeds.

Common side effects (occur in 1 in every 10 people to 1 in every 100 people):

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

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

- Eye problems such as blurred vision.
- Sores in the nose.

Additional side effects which have been reported:

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

It is important to follow the dosage instructions specified in section 3. Use of Flixonase Nasal Spray at high dosages or for more than 3 consecutive months can cause several changes in your body, such as increased tendency of infections.

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 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.

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 contents of the package -
Flixonase Nasal Spray is provided in a glass bottle with a fitted pump that contains 120 doses.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer and address: Glaxo Wellcome S.A., Burgos, Spain.
- 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 July 2017 and updated in April 2018, in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 060-33-26912

Trade marks are owned by or licensed to the GSK group of companies.

©2018 GSK group of companies or its licensor.