



50 micrograms per dose

Nasal Spray

Fluticasone propionate

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use Flixonase Allergy Relief Nasal Spray carefully to get the best results from it.

- Keep this leaflet you may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.

In this leaflet:

1. What Flixonase Allergy Relief does
2. Check before you use Flixonase Allergy Relief
3. How to use Flixonase Allergy Relief
4. Possible side effects
5. How to store Flixonase Allergy Relief
6. Further information

1. What Flixonase Allergy Relief does

Flixonase Allergy Relief treats and prevents allergic rhinitis caused by airborne allergies including hayfever, house dust mites and animal dander. It helps to relieve the symptoms of allergic rhinitis, such as sneezing, itchy and watery eyes and a runny, itchy or blocked-up nose, for up to 24 hours. The active ingredient is fluticasone propionate, a corticosteroid which, when used every day, has an anti-inflammatory action and works in a similar way to natural body chemicals to control inflammation. This spray helps to control your body's reactions to allergens ('triggers') in the environment.

2. Check before you use Flixonase Allergy Relief

Do not use Flixonase Allergy Relief:

- if you have ever had an allergic reaction to fluticasone propionate or to any of the other ingredients (listed in Section 6).
- if you are under 18 years.
- for more than 6 months unless your doctor tells you to.



Warning and Precautions

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

Take special care and check with your doctor before you take this medicine

- If you have a high temperature, cold or if you have or recently had a nasal or sinus infection.
- If you have recently had surgery, an injury or ulcers in your nose.
- This medicine contains 0.02 mg benzalkonium chloride in each spray.

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

If you are taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription; particularly **corticosteroid medicines** (including eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops); or **ketoconazole** (for fungal infections). Some medicines may increase the effects of Flixonase Allergy Relief and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breastfeeding

Talk to your doctor before using Flixonase Allergy Relief if you are pregnant, trying to become pregnant or are breastfeeding.

3. How to use Flixonase Allergy Relief

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

Make sure you don't get the spray in your eyes.

Flixonase Allergy Relief 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 Allergy Relief before exposure to one of your usual 'triggers'. You should try to use the spray in the morning.

Adults 18 years and over:

Spray two puffs into each nostril once daily.

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 your symptoms improve.



- Do not spray more than 8 sprays (400 micrograms) in a day.
- Do not use in children or adolescents under 18 years of age. Intranasal corticosteroids may cause children to grow more slowly.
- Use the lowest dose possible to control your symptoms.
- If your symptoms have not improved after 7 days, stop using the spray and speak to your doctor.
- If your symptoms have improved after 7 days, but not enough, speak to your doctor or pharmacist for advice.
- Do not use more than the recommended dose.

If you use too many sprays

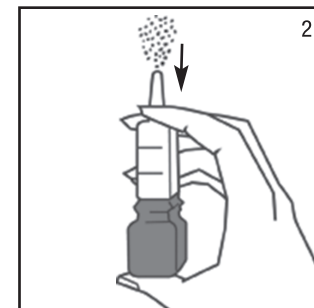
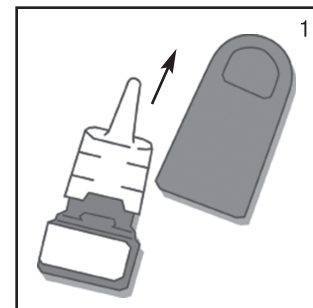
Seek medical advice immediately.

If you forget to use the spray

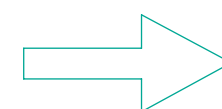
Take your next dose at the usual time. Never take two doses together.

Before using a new bottle of Flixonase Allergy Relief:

- Your Flixonase Allergy Relief 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) and to replace it after use.
- Before you start to use a new bottle of Flixonase Allergy Relief, 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 as shown with your forefinger and middle finger on the collar 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 doing this make sure you do not point the nozzle at yourself or someone else.
- If the spray still doesn't 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.

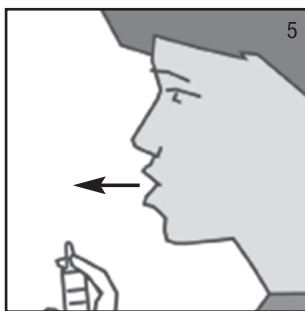
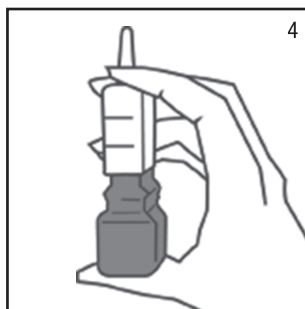


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Using Flixonase Allergy Relief:

1. Shake the bottle well and remove the dust cap.
2. Blow your nose gently.
3. Close one nostril as shown 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.

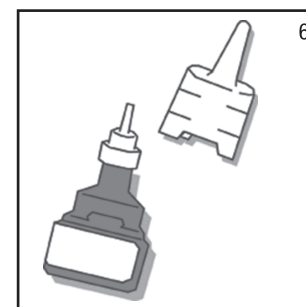


To clean the spray:

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 a running tap.

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.

YOUR NASAL SPRAY SHOULD BE CLEANED AT LEAST ONCE A WEEK OR MORE OFTEN IF IT GETS BLOCKED.



4. Possible side effects

Like all medicines, Flixonase Allergy Relief can have side effects, but not everybody gets them. It won't cause drowsiness, so you can still drive or use machines.

Very rare (affects less than 1 in 10,000 people)

Stop taking this medicine and **seek immediate medical help** if you experience:

- Allergic reactions. These may include developing a rash, swelling of the mouth or face or having difficulty breathing.
- Stop taking** this medicine and **tell your doctor** if you experience:
- Eye problems such as pain.
 - Nasal problems such as pain and/or persistent bleeding.
 - Small holes in the ridge inside the nose that separates the nostrils.
 - Sores in the nose.

Unknown (frequency cannot be estimated from the available data)

- Eye problems such as blurred vision.

Common (affects between 1 in 10 and 1 in 100 people)

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

Very common (affects more than 1 in 10 people)

- Nose bleeds.

Other side effects which have been reported are:

- Sneezing after using the spray but this soon stops.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flixonase Allergy Relief

Keep out of the sight and reach of children.

Do not store above 30°C. Do not refrigerate.

Do not use this medicine after the "Use by end of:" date shown on the label and carton.

Use within three months of first use.

If you are told to stop taking this medicine RETURN ANY UNUSED FLIXONASE TO YOUR PHARMACIST to be destroyed.

6. Further information

Active ingredient Each spray contains

Fluticasone Propionate 50 micrograms.

Other ingredients Microcrystalline cellulose and carmellose sodium, glucose (anhydrous), polysorbate 80, purified water, dilute hydrochloric acid and the preservatives benzalkonium chloride and phenylethyl alcohol.

The bottle contains 60 sprays.

The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare (Ireland) Limited, trading as Allen & Hanbury's, 12 Riverwalk, CityWest Business Campus, Dublin 24, Ireland and all enquiries should be sent to this address.

The manufacturer is Glaxo Wellcome SA, 09400 Aranda de Duero, Burgos, Spain.

This leaflet was last revised in May 2019.

The information in this leaflet only applies to Flixonase Allergy Relief Nasal Spray.

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