

Nasofan Allergy 50 microgram Nasal Spray

Fluticasone propionate

Package leaflet: Information for the user

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

This medicine is available without prescription. However, you still need to use Nasofan Allergy 50 microgram Nasal Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 7 days.
- You should not use Nasofan for more than 3 months continuously without consulting a doctor.
- 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.

Nasofan Allergy 50 microgram Nasal Spray will be referred to as 'Nasofan Allergy' throughout this package leaflet.

What is in this leaflet

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

1 What Nasofan Allergy is and what it is used for

Nasofan Allergy is one of a group of medicines known as corticosteroids. It has anti-inflammatory properties. When sprayed into your nose it will reduce swelling and irritation.

Nasofan Allergy is used to treat and prevent:

- seasonal allergic rhinitis e.g. hayfever
- perennial rhinitis (blocked or runny nose, sneezing, and itching caused by dust mites or animals such as cats and dogs).

It provides relief from sneezing, itchy and runny nose, itchy and watery eyes and a blocked nose.

2 What you need to know before you use Nasofan Allergy

DO NOT use Nasofan Allergy:

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

Warnings and precautions

Tell your doctor or pharmacist before you start to use this medicine if you:

- have had a recent injury or ever had an operation on your nose
- have had problems with ulcers in your nose
- are suffering or have recently suffered from a cold or an infection in your nose or sinuses
- are suffering or have recently suffered from any type of untreated infection or from tuberculosis or ocular herpes
- have recently been treated with injected steroids, or you have been taking oral steroids for a long time
- are taking more than 8 sprays (the maximum recommended daily dose) of Nasofan Allergy per day since additional steroid therapy may be required in time of stress.

Nasofan Allergy may decrease your own hormone production, especially if larger doses than recommended are used over a longer period of time. In this case, your doctor may need to give you extra medicine with adrenal hormone for extreme stress, after serious injuries or before surgery.

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

Nasofan Allergy will usually control seasonal allergic rhinitis (hay fever), however if you are exposed to excessive amounts of pollen additional therapy may be helpful for controlling other symptoms such as itching eyes. Please consult your doctor in such an event.

Other medicines and Nasofan Allergy

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including

medicines obtained without a prescription:

- other corticosteroid medicines, such as prednisolone used to treat asthma or rheumatoid arthritis, hydrocortisone cream used to treat eczema or dermatitis, or other similar nasal sprays or eye/nose drops
- any medicines used in the treatment of fungal infections, e.g. ketoconazole
- any antiviral medicines used to treat HIV infections e.g. ritonavir, cobicistat. Some medicines may increase the effects of Nasofan Allergy and your doctor may wish to monitor you carefully if you are taking these medicines.

Important information about some of the ingredients of Nasofan Allergy

- Nasofan Allergy also includes the ingredient benzalkonium chloride, which is an irritant and may cause skin reactions. If Nasofan Allergy is used for long periods, the preservative benzalkonium chloride may cause nasal mucosa swelling (persistently congested nose). In case of such a reaction, medical products for nasal use without preservative should be used if possible. If these are not available, another pharmaceutical form should be used.

Pregnancy, breast-feeding and fertility

- Women of childbearing potential have to use effective contraception during treatment.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

- Nasofan Allergy is not known to affect your ability to drive or operate machinery.

3 How to use Nasofan Allergy

If your doctor has prescribed this medicine, always use Nasofan Allergy exactly as your doctor has told you.

Otherwise, follow the instructions below:

- Nasofan Allergy is a nasal spray and should only be used as directed.
- For full benefit, use the spray regularly. When you start using the spray, you may not get relief of your symptoms straight away. It can take 3 to 4 days before the spray takes full effect.
- Nasofan Allergy should not be used continuously for more than 3 months without consulting a doctor.
- If you are not sure how to use this medicine, talk to your doctor or pharmacist.
- Treatment should be stopped or the advice of a doctor sought if an improvement is not seen within 7 days.

Adults aged 18 and over, and the Elderly

• Treatment of symptoms:

Take two sprays into each nostril once a day, preferably in the morning.

This may be increased to two sprays into each nostril twice a day if your symptoms are particularly bad.

Once your symptoms are under control you may reduce your dose to one spray in each nostril once a day.

If, by reducing the dose, your symptoms worsen you should increase the dose back to the starting dose of two sprays in each nostril once a day (200 mcg).

You should use the lowest dose of Nasofan Allergy that keeps your symptoms under control.

If symptoms persist after 7 days, consult your doctor.

The maximum daily dose should not exceed four sprays into each nostril.

• Prevention of symptoms:

If you want to prevent the onset of your symptoms start to use Nasofan Allergy 2 to 3 days before you would expect your symptoms to develop.

• During times of stress

Additional steroid therapy may be required during times of extreme stress or before a surgical operation. Your doctor will advise you under these circumstances.

Children and Adolescents under 18 years of age

Nasofan Allergy is not recommended for use in children or adolescents under 18 years of age.

Before you use your nasal spray

Your Nasofan Allergy has a dust cap that protects the nozzle and keeps it clean – this must be taken off prior to using the spray and then replaced after use.

When your Nasofan Allergy is new the bottle must be primed as follows:

1. Shake the bottle gently and then remove the dust cap.

2. Hold the bottle upright with your thumb under the bottle and your index finger and middle finger on either side of the nozzle. Ensure that the nozzle is pointing away from you when you do this.
3. Press down with fingers in order to pump the spray.
4. Repeat steps 2 and 3 a further five times – the bottle is now primed. If you have not used your Nasofan Allergy for 7 days, prime until a fine mist is produced.



If after attempting to prime the bottle the spray still does not work and you think it may be blocked you may clean the spray using the following procedure:

Cleaning your nasal spray

1. Remove the dust cap.
2. Pull the white collar upwards to remove the nozzle.
3. Place the nozzle and dust cap in warm water and soak for a few minutes, and then rinse by placing under a running tap.
4. Shake off the excess water and allow the nozzle and dust cap to dry in a warm (not hot) place.
5. Re-fit the nozzle.
6. 'Prime' the bottle as necessary by pumping the spray a few times until a fine mist is produced.

You should clean your nasal spray at least once a week to stop it from getting blocked up. Additional cleaning is required when your spray becomes blocked. You must **never** attempt to unblock or enlarge the spray hole with a pin or other sharp object because this will destroy the spray mechanism.



Using your nasal spray

1. Shake the bottle and remove the dust cap.
2. Gently blow your nose.
3. Close one nostril by pressing your finger against it and place the nozzle of the spray in your other nostril. Tilt your head forward slightly so that the bottle is kept upright.
4. Breathe in slowly through your open nostril and, at the same time, press the collar of the nozzle down firmly with your fingers to squirt a spray of fine mist into your nostril.
5. Breathe out through your mouth. Repeat step 4 to take a second spray into the same nostril.
6. Remove the nozzle from this nostril and breathe out through your mouth.
7. Repeat steps 3 to 6 with your other nostril.



After using your nasal spray

Wipe the nozzle carefully with a clean tissue and put the dust cap back on.

If you use more Nasofan Allergy than you should

It is important that you take your dose as stated on the carton and in the "How to use" section of this leaflet, or as advised by your pharmacist. You should not exceed the recommended dose; using more or less may make your symptoms worse.

If you (or someone else) use more Nasofan Allergy than is recommended, or if you think a child has used Nasofan Allergy, contact your doctor immediately.

Please take this leaflet, any remaining solution, and the container with you to the doctor so that they know which spray was used.

If you forget to use Nasofan Allergy

If you forget to take a dose, take it as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten dose.

If you stop using Nasofan Allergy

Your symptoms may only start to improve after you have been using your medicine for a few days, therefore it is important that you use your medicine regularly for full benefit. If your symptoms do not improve after 7 days, consult your doctor before you stop using this medicine.

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

4 Possible side effects

Like all medicines, Nasofan Allergy can cause side effects, although not everybody gets them.

If you are using high doses of Nasofan Allergy you may require extra steroids in times of extreme stress, or during admission to hospital after a serious accident or injury, or

before a surgical operation. Your doctor may decide to give you extra steroid medication during this period in the form of tablets or injection if you are in hospital.

Some side effects are more serious than others and if you should experience any of the following events you should discontinue taking Nasofan Allergy and consult with your doctor as soon as possible:

Rare (may affect up to 1 in 1,000 people)

- severe allergic reaction giving rise to the sudden onset of a rash, swelling (usually of the tongue, face or lips) or difficulty in breathing
- bronchospasm (the narrowing of the airways in the lungs) with the signs of very wheezy or laboured breathing and coughing)
- sudden drowsiness or dizziness (resulting in fainting or loss of consciousness).

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

- glaucoma (raised pressure in the eye) and cataracts (clouding of the lens in the eye) have been reported following prolonged treatment
- perforation of the nasal septum (the dividing partition in the nose) and ulceration to the nose's mucus membranes - although these usually impact on patients who have had previous surgery to the nose.

Other possible side effects:

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

- epistaxis (nose-bleeds) (if this is severe you should stop using the medicine and contact your doctor).

Common (may affect up to 1 in 10 people)

- dryness and irritation of the nose and throat and sneezing
- unpleasant taste in the mouth or an unpleasant smell in the nose
- headache.

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

- blurred vision
- sores in the nose.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Nasofan Allergy

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

Do not store above 25°C.

Do not use Nasofan Allergy after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month. Discard 3 months after first using the spray. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Nasofan Allergy Nasal Spray contains:

- The active substance is fluticasone propionate. Each metered spray contains 50 micrograms (mcg) of fluticasone propionate.
- The other ingredients are glucose, microcrystalline cellulose, carmellose sodium, phenylethyl alcohol, benzalkonium chloride, polysorbate 80 and purified water.

What Nasofan Allergy Nasal Spray looks like and contents of the pack:

- White opaque suspension in an amber glass bottle fitted with an atomising metered pump to create the spray.
- Each bottle contains sufficient suspension to deliver 60 metered sprays.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom. The company responsible for manufacture: TEVA Czech Industries s.r.o. Ostravská 29, c.p. 305 747 70 Opava-Komárov, Czech Republic.

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