

Package leaflet: Information for the user

Nasofan™ Aqueous 50 microgram Nasal Spray Suspension fluticasone propionate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Nasofan Nasal Spray is and what it is used for
2. What you need to know before you use Nasofan Nasal Spray
3. How to use Nasofan Nasal Spray
4. Possible side effects
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1. What Nasofan Nasal Spray is and what it is used for

Your medicine is called Nasofan Aqueous 50 microgram Nasal Spray Suspension (described as ‘Nasofan Nasal Spray’ throughout this leaflet) and contains 50 micrograms of the active ingredient, fluticasone propionate, in each spray. Fluticasone propionate is one of a group of medicines known as corticosteroids.

Nasofan Nasal Spray has anti-inflammatory properties. When sprayed into your nose it will reduce swelling and irritation. It is used to prevent and treat seasonal allergic rhinitis (e.g. hay fever) and perennial rhinitis (e.g. blocked or runny nose and sneezing and itching caused by house dust mites or animals such as cats and dogs). It can be used by adults and children aged 4 years and older.

2. What you need to know before you use Nasofan Nasal Spray

Do not use Nasofan Nasal Spray

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

Warnings and precautions

Talk to your doctor or pharmacist before using Nasofan Nasal Spray:

- if you have ever had an operation to your nose.
- if you are suffering or have recently suffered from an infection of the nasal airways.
- if you are suffering or have recently suffered from any type of untreated infection or from tuberculosis or ocular herpes.
- if you have recently been treated with injected steroids, or you have been taking oral steroids for a long time.

Nasofan Nasal Spray will usually control seasonally allergy 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.

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

Children and adolescents

Nasofan Nasal Spray may have potential systemic effects which may include growth retardation in children and adolescents and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Other medicines and Nasofan Nasal Spray

Please tell your doctor if you are taking/using or have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription.

Some medicines can interfere with Nasofan Nasal Spray, in particular tell your doctor or pharmacist if you are taking:

- Any medicines used in the treatment of fungal infections (e.g. ketoconazole)
- Some medicines may increase the effects of Nasofan Nasal Spray and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

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

The medicinal product has no or negligible influence on the ability to drive and use machines.

Nasofan Nasal Spray contains benzalkonium chloride solution

This medicine contains 40 micrograms benzalkonium chloride solution in each delivered dose.

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

In case of such a reaction (persistently congested nose) medicinal products for nasal use without preservative should be used if possible. Unless such products are available another pharmaceutical form should be taken. It may also cause bronchospasm.

3. How to use Nasofan Nasal Spray

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is

Adults (including the elderly) and children aged 12 years and older:

When you first start using Nasofan Nasal Spray you normally take two sprays in each nostril once a day, preferably in the morning. Your doctor may increase this to a **maximum** of two sprays into each nostril twice a day.

Once your symptoms are under control your doctor may reduce your dose to one spray into each nostril once a day. If the use of such a reduced dose signals a worsening in your symptoms, your dose may be increased back to the starting dose.

Children aged 4 to 11 years:

For children aged between 4-11 years old the dose is normally one spray in each nostril once a day, preferably in the morning. Your doctor may increase this to a **maximum** of one spray into each nostril twice a day.

This product is not suitable for children under 4 years old.

Your doctor will prescribe the lowest dose of Nasofan Nasal Spray capable of effectively controlling your symptoms.

It may take a few days for this medicine to work. Do not stop using your medicine unless you are told to by a doctor.

You must not take a larger dose, or use your Nasofan Nasal Spray more often, than is prescribed by your doctor. It is important not to use more of your medicine than your doctor has told you to.

If your eyes remain itchy or watery as a result of hay fever despite using this medicine tell your doctor. He/she may be able to give you another medicine to treat your eye symptoms.

Before you use your nasal spray

Your Nasofan Nasal Spray 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 Nasal Spray 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 until a further five times – the bottle is now primed.

If you have not used your Nasofan Nasal Spray 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

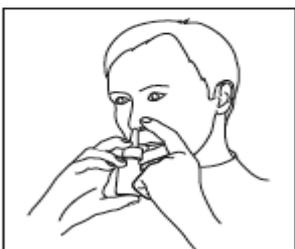
1. Remove the dust cap.
2. Pull the white collar upwards to remove the nozzle.



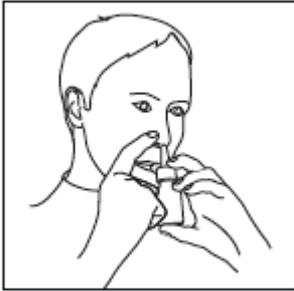
3. Place the nozzle and dust cap in warm water and soak for a few minutes, and then rinse by placing under a running tap.
 4. Shake off the excess water and allow the nozzle and dust cap to dry in a warm (not hot) place.
 5. Re-fit the nozzle.
 6. 'Prime' the bottle as necessary by pumping the spray 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 Nasal Spray than you should

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse.

If you accidentally use more Nasofan Nasal Spray than you were told to use please inform your doctor.

Take this leaflet, and your Nasofan Nasal Spray, to show the doctor.

If you forget to use Nasofan Nasal Spray

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose at the right time, take it as soon as you remember. If it is almost time to take the next dose, wait until then and then carry on as before.

If you stop using Nasofan Nasal Spray

Your nose symptoms may only start to improve after you have been using your medicine for a few days – therefore it is very important that you use your medicine regularly as prescribed, and that you keep using your medicine unless your doctor tells you to stop, even if you feel better.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you are using high doses of Nasofan Nasal Spray 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. Treatment with nasal corticosteroids may affect the production of steroids in the body. The likelihood of such an incidence is increased by use of a high dose over a long period of time. Your doctor will help prevent this happening by prescribing the lowest dose of steroid capable of adequately controlling your symptoms.

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

Very common: may affect more than 1 in 10 people

- epistaxis (nose bleeds).

Common: may affect up to 1 in 10 people

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

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).

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.

Not known: frequency cannot be estimated from available data

- blurred vision.
- sores in the nose.

Additional side effects in children and adolescents

Children may grow more slowly than others, and therefore children receiving treatment with nasal corticosteroids over a long period of time will have their height checked regularly by their doctor. Your doctor will help prevent this happening by prescribing the lowest dose of steroid capable of adequately controlling the symptoms.

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:

Ireland

HPRa Pharmacovigilance.. Website: www.hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nasofan Nasal Spray

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

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nasofan Nasal Spray contains

- The active substance is fluticasone propionate.

Each metered spray contains 50 micrograms of fluticasone propionate.

- The other ingredients are glucose, dispersible cellulose, phenylethyl alcohol, benzalkonium chloride solution (40 micrograms per delivered dose), polysorbate 80, and purified water.

What Nasofan Nasal Spray looks like and contents of the pack

Nasofan Nasal Spray consists of a white, opaque suspension contained within an amber glass multi-dose bottle fitted with an atomising metering pump to create the spray. Each bottle of Nasofan Nasal Spray contains suspension capable of delivering 60, 120, 150, 240 (2 bottles each containing 120 sprays) or 360 (3 bottles each containing 120 sprays) sprays.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder:**

Teva B.V.

Swensweg 5

2031GA Haarlem

The Netherlands.

Manufacturer: Teva Czech Industries s.r.o., Opava, Czech Republic.

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic	Nasofan, nosní sprej
Denmark	Fluticasonpropionat "Teva" 50 mikrogram/dosis, næsespray, suspension
Finland	Nasofan 50 mikrog/annos nenäsumute
Germany	Flutica-TEVA 50 Mikrogramm Nasenspray, Suspension
Hungary	Flutirin orrspray
Ireland	Nasofan Aqueous 50 microgram Nasal Spray Suspension
Malta	Nasofan Aqueous 50 microgram Nasal Spray Suspension
The Netherlands	Fluticasonpropionaat Mylan 50 microgram/dosis, neusspray, suspensie
Norway	Flutikason Teva
Poland	Fanipos, 50 mikrogramów/dawkę donosową aerosol donosa, zawiesina
Portugal	Fluticasona Nasofan 50 microgramas Suspensão para pulverização nasal
Slovak Republic	Nasofan 50 mikrogramová nosová aerodisperzia aer nas
Spain	Fluticasona Teva 50 microgramos suspensión para pulverización nasal
United Kingdom	Nasofan Aqueous 50 microgram Nasal Spray

This leaflet was last revised in September 2020.