

PACKAGE LEAFLET: INFORMATION FOR THE USER

NASONEX 50 MICROGRAMS/ACTUATION NASAL SPRAY SUSPENSION

Mometasone Furoate

Please read this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Nasonex is and what it is used for
2. Before you use Nasonex
3. How to use Nasonex
4. Possible side effects
5. How to store Nasonex
6. Further information

1. WHAT NASONEX IS AND WHAT IT IS USED FOR

What is Nasonex?

Nasonex Nasal Spray contains mometasone furoate, one of a group of medicines called corticosteroids. Mometasone furoate should not be confused with “anabolic” steroids misused by some athletes and taken as tablets or injections. When tiny amounts of mometasone furoate are sprayed into the nose, it can help to relieve inflammation, sneezing, itching and a blocked up or runny nose.

What is Nasonex used for?

Nasonex is used in adults and children aged 6 and older to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial rhinitis.
In adults aged 18 and over, Nasonex is also used to treat nasal polyps.

What is hayfever and perennial rhinitis?

Hayfever, which occurs at certain times of the year, is an allergic reaction caused by breathing in pollen from trees, grasses, weeds and also moulds and fungal spores. Perennial rhinitis occurs throughout the year and symptoms can be caused by a sensitivity to a variety of things including house dust mite, animal hair (or dander), feathers and certain foods. These allergies cause a runny nose and sneezing and make the lining of the nose swell, causing a stuffy blocked-up feeling. Nasonex reduces the swelling and irritation in your nose and so relieves sneezing, itching and a blocked-up or runny nose.

What are nasal polyps?

Nasal polyps are small growths on the lining of the nose and usually affect both nostrils. The main symptom is a blocked feeling in the nose which may affect breathing through the nose. Watering from the nose, a feeling of something running down the back of the throat and loss of

taste and smell may also occur. Nasonex reduces the inflammation in the nose, causing the polyps to gradually shrink.

2. BEFORE YOU USE NASONEX

Do not use Nasonex

- if you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of Nasonex.
- if you have an infection in your nose. You should wait until the infection is resolved before you start using the nasal spray.
- if you have recently had an operation on your nose or you have injured your nose. You should wait until it has healed before you start using the nasal spray.

Take special care with Nasonex

- if you have or have ever had tuberculosis
- if you have herpes simplex (virus) infection of the eye
- if you have any other type of infection
- if you are taking other corticosteroid medicines, either by mouth or by injection.
- if you have cystic fibrosis

While using Nasonex, avoid coming into contact with anyone who has measles or chickenpox. You should tell your doctor if you do come into contact with anyone who is suffering from these infections.

Using other medicines

If you are taking other corticosteroid medicines for allergy, either by mouth or injection, your doctor may advise you to stop taking them once you begin using Nasonex. A few people may find that once they discontinue oral or injected corticosteroids they suffer from some undesirable effects, such as joint or muscular pain, weakness and depression. If these occur you should inform your doctor who will advise about continuing use of your nasal spray. You may also seem to develop other allergies, such as itchy, watering eyes or patches of red and itchy skin. If you develop any of these effects and you are worried, you should see your doctor.

Pregnancy and breast-feeding

You should not use Nasonex if you are pregnant unless your doctor has told you to. Tell your doctor if you are pregnant before you start using this medicine. You should not breast feed when you are using this medicine unless your doctor has told you to.

3. HOW TO USE NASONEX

Always use Nasonex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Do not use a larger dose or use the spray more often or for longer than your doctor tells you to.

- **Hayfever and perennial rhinitis**

Adults and children over 12 years old

The usual dose is two sprays into each nostril once a day for adults (including the elderly) and children over the age of 12 years.

- Once your symptoms are under control, your doctor may advise you to only spray once into each nostril once a day.
- If you do not start to feel any better, you should see your doctor and he may tell you to increase the dose to the maximum daily dose of four sprays into each nostril once a day. Once your symptoms are controlled your doctor may advise you to reduce the dose to two sprays into each nostril once daily.

Children aged 6 to 11 years

The usual dose is one spray into each nostril once daily.

Long term use of nasal steroids at high doses may cause slowing of growth in children. Your doctor may check your child's height at intervals during treatment and reduce the dose if any effects are seen.

If you suffer badly from hayfever, your doctor may tell you to start using Nasonex two to four weeks before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring. Your doctor may recommend that you use other treatments with Nasonex, particularly if your eyes are itching or irritated. At the end of the pollen season your hayfever symptoms should get better and treatment may then not be needed.

- **Nasal Polyps**

The usual starting dose for adults aged 18 and over is two sprays into each nostril once daily.

- If symptoms are not controlled after 5 to 6 weeks, the dose may be increased to two sprays in each nostril twice daily. Once symptoms are under control, your doctor should ask you to reduce your dose to the lowest amount where symptoms are still controlled.
- If no improvement in symptoms is seen after 5 to 6 weeks of twice daily administration, you should contact your doctor to discuss other treatments to replace Nasonex.

Preparing your nasal spray for use

Your Nasonex Nasal Spray has a dust cap which protects the nozzle and keeps it clean. Remember to take this off before using the spray and to replace it after use.

If you are using the spray for the first time you need to 'prime' the bottle by pumping the spray 10 times until a fine mist is produced:

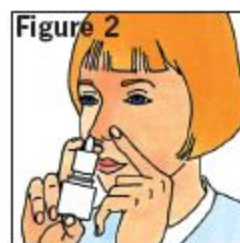
1. Gently shake the bottle
2. Put your forefinger and middle finger either side of the nozzle and your thumb underneath the bottle. **Do Not** pierce the nasal applicator.
3. Point the nozzle away from you and then press down with your fingers to pump the spray.

If you have not used the spray for 14 days or more, you need to “re-prime” the bottle by pumping the spray 2 times until a fine mist is produced.

At normal dose of two sprays into each nostril once daily for the treatment of hayfever and perennial rhinitis and nasal polyps, this product should provide enough doses for 35 days.

How to use your nasal spray

1. Shake the bottle gently and remove the dust cap. (Figure 1)
2. Gently blow your nose.
3. Close one nostril and put the nozzle into the other nostril as shown. (Figure 2) Tilt your head forward slightly, keeping the bottle upright.
4. Start to breathe in gently or slowly through your nose and whilst you are breathing in squirt a spray of fine mist into your nose by pressing down ONCE with your fingers.
5. Breathe out through your mouth. Repeat step 4 to inhale a second spray in the same nostril.
6. Remove the nozzle from this nostril and breathe out through the mouth.
7. Repeat steps 3 to 6 for the other nostril (Figure 3).



After using the spray, wipe the nozzle carefully with a clean handkerchief or tissue and replace the dust cap.

Cleaning your nasal spray

It is important to clean your nasal spray regularly, otherwise it may not work properly. Remove the dust cap and gently pull off the nozzle. Wash the nozzle and dust cap in warm water and then rinse under a running tap. **Do not try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine.** Allow to dry in a warm place. Push the nozzle back onto the bottle and replace the dust cap. The spray will need to be re-primed with 2 sprays when first used after cleaning.

If you use more Nasonex than you should

Tell your doctor if you accidentally use more than you were told.

If you use steroids for a long time or in large amounts they may, rarely, affect some of your hormones. In children this may affect growth and development.

If you forget to use Nasonex

If you forget to use your nasal spray at the right time, use it as soon as you remember, then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop using Nasonex

In some patients Nasonex should begin to relieve symptoms 12 hours after the first dose; however full benefit of treatment may not be seen for up to two days. It is very important that you use your nasal spray regularly. Do not stop your treatment even if you feel better unless told to do so by your doctor.

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

4. POSSIBLE SIDE EFFECTS

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

Rarely, immediate hypersensitivity (allergic) reactions may occur after use of this product. Very rarely, these reactions may be severe. If you have any wheezing or have trouble breathing, get immediate medical help.

In very rare cases, treatment with corticosteroid nasal sprays like Nasonex has led to an increase in pressure in the eye (glaucoma), causing visual disturbances and damage to the partition in the nose which separates the nostrils. Contact your doctor if you notice any of these side effects.

Other side effects

Most people do not have any problems after using the nasal spray. However, a few people after using Nasonex or other corticosteroid nasal sprays may find that they suffer from:

- headache
- sneezing
- nose bleeds
- sore nose or throat
- alterations in taste or smell which may occur very rarely.

Children

When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side effects, such as growth reduction in children. It is recommended that the height of children receiving long-term treatment with nasal corticosteroids is regularly monitored and if any changes are noted, their doctor should be notified.

Nasonex contains benzalkonium chloride which may cause nasal irritation.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE NASONEX

- Keep out of the reach and sight of children.
- Do not store the nasal spray above 25°C. Do not freeze it.
- Do not use Nasonex after the expiry date, which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.
- Each bottle should be used within 2 months of first opening. Only open one bottle at a time.

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. FURTHER INFORMATION

What Nasonex contains

- The active substance is mometasone furoate. Each spray contains 50 micrograms of mometasone furoate, as the monohydrate.
- The other ingredients are dispersible cellulose, glycerol, sodium citrate, citric acid monohydrate, polysorbate 80, benzalkonium chloride, purified water.

What Nasonex looks like and contents of the pack

Nasonex is a nasal spray suspension.

Each bottle contains 140 sprays.

Bottles containing 140 sprays are supplied in packs of 1, 2 or 3 nasal sprays. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation in the UK and Malta is Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU.

The Marketing Authorisation Holder in Ireland is Merck Sharp & Dohme Ireland (Human Health) Limited, Pelham House, South County Business Park, Leopardstown, Dublin 18, Ireland.

The manufacturer is:

Schering-Plough Labo NV,
Heist-op-den Berg, Belgium.

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

Austria	Nasonex aquosum – Nasenspray
Belgium	Nasonex 50 microgrammes par pulvérisation, suspension pour pulvérisation nasale
Denmark	Nasonex, næsespray, suspension
Finland	Nasonex 50 mikrog/annos nenäsumute, suspension
Germany	Nasonex 50µg/Sprühstoß Nasenspray, Suspension
Greece	NASONEX 50 μικρογραμμάρια/ψεκασμό Ρινικό εκνέφωμα, Εναιώρημα
Italy	Nasonex 50 microgrammi/erogazione spray nasale, sospensione
Luxembourg	Nasonex Spray 50 MCG/1 Dose
Netherlands	Nasonex, neusspray, suspensie 50 microgram/verstuiving
Portugal	Nasomet 50 microgramas/pulverização, suspensão para pulverização nasal.
Spain	Nasonex 50 microgramos suspensión para pulverización nasal
UK and Ireland	Nasonex 50 micrograms/actuation Nasal Spray, suspension

This leaflet was last approved in March 2011