

**Patient Information Leaflet**  
**NASONEX® AQUEOUS NASAL SPRAY 0.05%**

Mometasone Furoate 50 mcg/dose

**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 2 and older to treat the symptoms of seasonal or perennial rhinitis.

To help prevent moderate to severe symptoms of seasonal allergic rhinitis, NASONEX may be used 2 to 4 weeks before the beginning of the pollen season.

In adults aged 18 and over, NASONEX is also used to treat nasal polyps.

NASONEX may also be used in adults and children 12 years of age and older for the treatment of symptoms of acute rhinosinusitis (inflammation and blockage of the sinuses behind the nose) without signs or symptoms of bacterial infection.

**What is seasonal and perennial rhinitis?**

Seasonal allergic rhinitis, 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.

**What is acute rhinosinusitis?**

Mild to moderate uncomplicated acute rhinosinusitis without signs and symptoms of bacterial infection is the inflammation and blockage of the sinuses behind the nose. Symptoms can include a stuffy or runny nose, feeling of something running down the back of the throat, and facial pressure or pain. NASONEX relieves these symptoms by reducing the inflammation in the nose.

## **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.

**Take special care with 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.
- 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 (fungal, bacterial or viral).

- if you are taking other corticosteroid medicines, either by mouth or by injection.
- if you have sores in the nose.

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.

If you have been prescribed NASONEX for mild to moderate uncomplicated acute rhinosinusitis, consult your doctor if you develop signs or symptoms of bacterial infection (such as fever, persistent severe facial/tooth pain especially on one side of the face), facial swelling, worsening of symptoms after an initial improvement or thick nasal discharge with a yellow or green colour.

### **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.

If you develop visual disturbances such as blurred vision while on Nasonex, please consult your doctor immediately.

### **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.

- **For treatment of seasonal 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.

### **Children aged 2 to 11 years**

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

Young children should be aided by an adult when using NASONEX.

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 seasonal allergic rhinitis, 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 seasonal allergic rhinitis symptoms from occurring. At the end of the pollen season your seasonal allergic rhinitis symptoms should get better and treatment may then not be needed.

- **For treatment of 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, 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.
- **For treatment of acute rhinosinusitis:**

Adults and children 12 years of age and older: The usual recommended dose is two sprays (50 micrograms/spray) into each nostril twice daily (total daily dose of

400 micrograms). If no improvement in symptoms is seen after 15 days of twice daily administration, you should contact your doctor to discuss other treatments to replace NASONEX. If symptoms get worse during treatment you should contact your doctor.

### Preparing your nasal spray for use

1. Gently shake the bottle before each use.

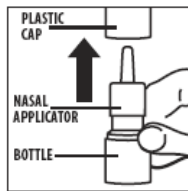


Figure 1



Figure 2



Figure 3

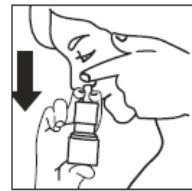


Figure 4

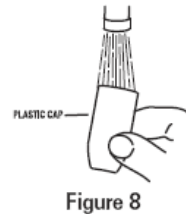
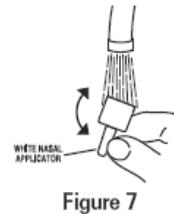
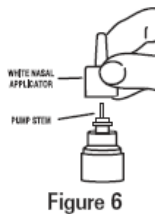
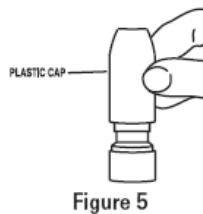
2. Remove the plastic cap (Figure 1).
3. Before you use NASONEX for the first time, prime the pump by pressing downward on the shoulders of the white nasal applicator using your index finger and middle finger while holding the base of the bottle with your thumb (Figure 2). **Do Not** pierce the nasal applicator. Press down and release the pump 10 times or until a fine spray appears. **Do Not** spray into eyes. The pump is now ready to use. The pump may be stored unused for up to 2 weeks without repriming. If unused for more than 2 weeks, reprime by spraying 2 times or until a fine spray appears.
4. Gently blow your nose to clear the nostrils and then use your finger to close off one of your nostrils. Tilt your head forward slightly, keep the bottle upright, carefully insert the nasal applicator into the other nostril (Figure 3). **Do Not** spray directly onto the nasal septum (the wall between the two nostrils).
5. With your thumb supporting the bottom of the bottle, and your index and middle fingers on the shoulder of the applicator, 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 (Figure 4).  
Note: It is important to keep the NASONEX unit in an upright orientation (as seen in Figure 4). Failure to do so may result in an incomplete or non-existent spray.
6. Then breathe out through the mouth.
7. Repeat in the other nostril.
8. Wipe the nasal applicator with a clean tissue and replace the plastic cap.

### Cleaning of Nasal Spray

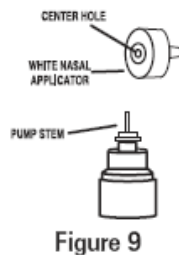
Do not try to unblock the nasal applicator with a sharp object. Please see Patients Instruction for cleaning applicator.

### Patients Instruction for cleaning applicator

1. To clean the nasal applicator, remove the plastic cap (Figure 5).



2. Pull gently upward on the white nasal applicator to remove (Figure 6).
3. Wash the nasal applicator in warm water and rinse both ends of the nasal applicator under warm tap water and dry. (Figure 7). **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.**
4. Rinse the plastic cap under warm water and dry (Figure 8).



5. Put the nasal applicator back together making sure the pump stem is reinserted into the applicator's center hole (Figure 9).
6. Reprime the pump by pressing downward on the shoulders of the white nasal applicator using your index and middle fingers while holding the base of the bottle with your thumb. Press down and release the pump 2 times or until a fine spray appears. **Do Not** spray into eyes. The pump is now ready to use. The pump may be

stored unused for up to 2 weeks without repriming. If unused for more than 2 weeks, reprime by spraying 2 times or until a fine spray appears (Figure 10).

7. Replace the plastic cap (Figure 11).

#### **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. 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 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
- diarrhoea
- nausea
- stomach pain
- chest pain, irregular or fast heartbeat which may occur very rarely
- Blurred vision

#### 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.

If any of these side-effects get 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.
- Store the nasal spray below 30°C. Store away from heat. 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.

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 60 sprays or 140 sprays.

Bottles containing 60 sprays or 140 sprays are supplied in single packs.

This leaflet was last revised in June 2022.

Copyright 2022 Organon groups of companies. All rights reserved.

