

NASONEX[®] Aqueous Nasal Spray

0.05%

Mometasone Furoate Monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NASONEX. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NASONEX is used for

NASONEX contains the active ingredient mometasone furoate. This belongs to a family of medicines called corticosteroids, which are used to help reduce inflammation.

Allergic Rhinitis (hayfever):

NASONEX is sprayed into the nose to help relieve symptoms that may occur with hayfever or other year - round allergies, including stuffiness (congestion) in the nose, discharge, itching and sneezing. Your doctor may also prescribe this medicine to help prevent these symptoms two to four weeks before the beginning of the pollen season.

Nasal Polyps:

Swollen tissue in the nose can cause grape-like swellings called 'polyps'. Polyps can cause nasal stuffiness, discomfort and loss of smell.

NASONEX can be used for the treatment of nasal polyps in patients over 18 years of age.

Acute Rhinosinusitis:

Rhinosinusitis is the swelling of the sinuses resulting in stuffiness of the nose, large quantities of mucus from the nose, cough, face pain and/or fever. These symptoms usually last for less than 4 weeks. NASONEX is used to treat the symptoms of rhinosinusitis in adults and children 12 years of age and

older, who do not have the signs or symptoms of a severe bacterial infection.

Your doctor may have prescribed it for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that this medicine is addictive.

This medicine is available only with a doctor's prescription.

Before you use NASONEX

When you must not use it

Do not use the medicine if:

1. You have an allergy to:

- any medicine containing mometasone furoate
- any of the ingredients listed at the

end of this leaflet.

2. You have a tendency to bleed or recurrent nose bleeding

3. You have severe nose infection, especially fungal infection.

4. You have had recent nose injury or nose surgery; check with your doctor, because you may be told to wait until healing has occurred before using this medicine.

Do not use it after the expiry date (EXP) printed on the pack or if the packaging is torn or shows sign of tampering.

If you are not sure whether you should start taking this medicine, contact your doctor.

Before you start to use it

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- a history of tuberculosis, or active tuberculosis
- infection of the nose, sinus, mouth, throat, lungs or eye
- sores in the nose
- recent injury or surgery to your nose
- open sores in your nose

Tell your doctor or pharmacist if you are taking other corticosteroid medicines, either by mouth, as eye drops, as an asthma inhaler or by injection.

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant

Your doctor will discuss the possible risks and benefits of using this medicine during pregnancy.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Breastfeeding is not recommended during treatment with this medicine.

If you have not told your doctor about any of the above, tell them before you use this medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and NASONEX may interfere with each other. These include:

- Certain antifungals such as ketoconazole and itraconazole
- Some antibiotics such as clarithromycin
- Some medicines used to treat HIV infection such as ritonavir and cobicistat - containing products.

How to use NASONEX

Follow all directions given to you by your doctor or pharmacist carefully and do not use more than the recommended dose.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help

How much to use

Hayfever and allergies in adults (including the elderly) and children 12 years of age and older:

Two sprays into each nostril once daily.

Children 3 to 11 years of age:

One spray into each nostril once daily.

Each actuation of the spray pump delivers the equivalent of 50 microgram of mometasone furoate. The volume of the containers are sufficient to deliver the labelled 65 sprays, or 140 sprays.

When your symptoms have been controlled, your doctor may recommend one spray into each nostril once daily to keep your symptoms under control.

Your doctor may change this dosage, depending on your response to this medicine.

Nasal Polyps in patients (including the elderly) 18 years of age and older:

Two sprays into each nostril once daily. If your symptoms are not controlled, your doctor may increase your dose to two sprays into each nostril twice daily.

When your symptoms have been controlled, your doctor may reduce your dose.

Acute rhinosinusitis in adults and children 12 years of age and older:

Two sprays in each nostril two times a day.

If symptoms worsen during treatment, see your doctor immediately.

About your nasal spray

Your 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.

Do not pierce the nasal applicator.

If you are using the spray for the first time, prime the pump by pumping the spray 10 times until a fine mist is produced. If you have not used the pump for 14 days or more reprime by pumping 2 times.

It is important to clean the nozzle 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 the nozzle to dry. Push the nozzle back onto the bottle and replace the dust cap. The pump will need to be reprimed when first used after cleaning.

How to use it

1. Shake the bottle gently and remove the dust cap.
2. Gently blow your nose.
3. Close one nostril and put the nozzle into the other nostril.
4. Tilt your head forward slightly, keeping the bottle upright.
5. 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.
6. Breathe out through your mouth. Repeat step 5 to inhale a second spray in the same nostril.
7. Remove the nozzle from this nostril and breathe out through the mouth.
8. Repeat steps 3 to 7 for the other nostril. After using the spray, wipe the nozzle carefully with a clean tissue and replace the dust cap.

When to use it

As instructed by your doctor. Do not use more frequently than instructed.

How long to use it

Your doctor will determine the length of treatment.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to use your medicines as you would normally.

Do not use a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre on 13 11 26 if you think you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

While you are using NASONEX

Things you must do

If you become pregnant while you are using this medicine tell your doctor.

Tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

See your doctor immediately if you notice the symptoms of severe bacterial infection.

These symptoms may include fever, persistent face/tooth pain on one side of the face, swelling around the eye area, or worsening of symptoms after an initial improvement.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

This medicine generally does not cause any problems with your ability to drive a car or operate machinery.

If you have a lower resistance to infection, avoid coming into contact with anyone who has measles or chickenpox especially while you are using cortisone-type medicines. Tell your doctor if you do.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine.

The doctor will decide whether any change in your treatment is needed.

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age, you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Most people do not have any problems after using the nasal spray. However, a few people may find that they suffer from one or more of the following:

- headache
- sneezing
- nosebleeds or blood-tinged mucus
- sore throat or burning or irritation inside the nose after using this medicine. These symptoms are consistent with the use of corticosteroid nasal sprays.
- visual disturbances or blurred vision
- cataracts have been reported with the use of corticosteroid nasal sprays

If you develop a rash, wheezing or breathlessness, stop using the nasal spray, as you may be allergic to it and contact your doctor immediately.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Long-term use of corticosteroid sprays may be associated with other side effects. Your doctor will monitor your health if you are using NASONEX for extended periods of time.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using NASONEX

Storage

Keep the nasal spray in a cool dry place where the temperature stays below 25°C. Do not freeze. Store it away from heat.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach.

Disposal

If your doctor tells you to stop using this medicine or it has passed the expiry date, ask your pharmacist what to do with any that is left over.

Further information

Drug testing for sport events:

This product is a corticosteroid for intranasal administration; it is not a restricted drug for sports.

Corticosteroid may be detected in blood and in the urine during drug testing; thus prior written permission for its use may be required by some sport agencies.

Product description

What it looks like

The nasal spray is a white to off- white suspension contained in a plastic bottle with a metered-dose, manual spray pump for intranasal administration.

Ingredients

Active ingredient:

Mometasone furoate monohydrate

Inactive ingredients:

Dispersible cellulose, glycerol, citric acid monohydrate (or anhydrous citric acid), sodium citrate, polysorbate 80 and purified water

Preservatives:

Benzalkonium chloride

Sponsor

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park NSW 2113 AUSTRALIA

Australian Registration Number

2 x 140 metered dose bottles per pack

140 metered doses per pack

65 metered doses per pack (Junior Pack)

NASONEX: AUST R 77112

Date of Preparation

21 November 2018

S-CCDS-MK0887-NS-082017