

## Package leaflet: information for the user

### Nasonex 50 micrograms/spray, nasal spray, suspension Mometasone furoate

Read the entire 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.
- Do you have any questions? Then contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may be harmful to others, even if their symptoms are the same as yours.
- Do you experience any side effects mentioned in section 4? Or do you experience a side effect that is not mentioned in this leaflet? Then contact your doctor or pharmacist.

#### Contents of this leaflet

1. What is Nasonex and what is it used for?
2. When should you not use this medicine or be extra careful with it?
3. How do you use this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the package and other information

#### 1. What is Nasonex and what is this medicine used for?

##### What is Nasonex?

Nasonex nasal spray contains mometasone furoate, a medicine that belongs to a group of medicines called corticosteroids. When mometasone furoate is sprayed into the nose, it can reduce the inflammation (swelling and irritation of the nose), sneezing, and itching, and provide relief for a blocked or runny nose.

##### What is Nasonex used for?

###### Hay fever and perennial rhinitis

Nasonex is used in adults and children aged 3 years and older to relieve the symptoms of hay fever (also known as seasonal allergic rhinitis) and perennial rhinitis treat.

Hay fever, which occurs at certain times of the year, is an allergic reaction caused by inhaling pollen from trees, grasses, weeds, and also molds and mold spores. Perennial rhinitis occurs throughout the year and the symptoms can be caused by sensitivity to various substances, such as house dust mites, animal hair (or dander), feathers, and certain nutrients. Nasonex reduces the swelling and irritation in the nose and thus relieves sneezing, itching, and a blocked or runny nose caused by hay fever or perennial rhinitis.

###### Nasal polyps

Nasonex is used in adults aged 18 years and older for the treatment of nasal polyps.

Nasal polyps are small growths that develop on the nasal mucosa and usually occur in both nasal cavities. Nasonex reduces the inflammation of your nose, thereby reducing the size of the polyps

gradually decreases. This can relieve the blocked feeling in your nose, which can affect your breathing. be relieved.

## 2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- You have an untreated infection in your nose. Using Nasonex during an untreated infection in your nose, such as herpes, can make the infection worse. You should wait until the infection is healed before you start using the nasal spray. to use.
- You have recently undergone nasal surgery or had an injury to your nose. You must wait until the lesions have healed before you start using the nasal spray to use.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine

- if you have or have ever had tuberculosis (TB)
- if you have another type of infection
- if you are taking other corticosteroids, either orally or in the form of injections
- if you have cystic fibrosis.

While using Nasonex, tell your doctor: if

- your immune system is not working properly (making it difficult for you to fight off an infection) and you come into contact with someone who has measles or chickenpox . You should each person who has measles or chickenpox . You must each avoid contact with people who have these infections.
- if you have an infection in the nose or throat
- if you use this medicine for several months or longer
- if you have persistent irritation of the nose or throat.

When nasal sprays containing corticosteroids are used in high doses for longer periods, side effects can occur because the drug is absorbed into the body.

If your eyes itch or become irritated, your doctor may advise you to use other treatments in addition to Nasonex.

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

Children

With long-term use of high doses a corticosteroid-based nasal spray can cause certain side effects such as growth retardation in children. cause side effects such as growth retardation in children.

It is recommended to keep the light body length of children who are on long-term treatment with a corticosteroid-based nasal spray regularly and inform their doctor if changes in growth are observed. bring if changes in growth are observed.

Are you using any other medications?

Are you using any other medications besides Nasonex, have you done so recently, or is there a possibility that you will use other medications in the near future? Then tell your possibility that you will use other medicines in the near future? Then tell or pharmacist. This also applies to medications for which you do not need a prescription. If you are using other corticosteroids for allergy, whether

orally or in the form of injections, your doctor may advise you to stop them once you start using Nasonex.using Nasonex. It may sometimes occur that patients, once they have stopped using oral corticosteroids, experience symptomsagain. or injected corticosteroids, experience sideeffects such as joint or muscle pain, weakness, and depression (severe despondency). You may also develop other allergies, such as itchy, watery eyes or patches of red and itchy skin. If you experience any of these side effects, contact your doctor.

Some medicines can increase the effects of Nasonex and it may be that your doctor wants to monitor you carefully if you use these medications (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breastfeeding

There is little or no data available on the use of Nasonex in pregnant women. It is not known whether mometasone furoate passes into breast milk.

Are you pregnant, do you think you are pregnant or are, want to become pregnant or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. Driving and using machines

There is no data available on the effect of Nasonex on driving ability or the ability  
There are no data available on the effect of Nasonex on driving ability or the capacity use machines. Nasonex nasal spray contains benzalkonium chloride

Benzalkonium chloride

can cause irritation or swelling in the nose, especially with long-term use. 3. How to use this medicine?

Always use this medicine exactly as

Always use this medication exactly as doctor has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist. Do not use a higher dose and do not spray more often or for a longer period than or longer than your doctor has told you.

Treatment of hay fever and non-seasonal rhinitis

Use in adults and children over 12 years

The recommended dosage is two sprays in each nostril once a day.

Once your symptoms are under control, your doctor may advise you to reduce the dosage.

If you do not start to feel better, you should contact your doctor; he/she may advise you to increase the dosage; the maximum daily dose is four sprays in each nostril once a day.

Use in children aged 3 to 11 years

The recommended dosage is one spray in each nostril once a day.

In some patients, symptoms begin to decrease within 12 hours after the first dose of Nasonex; however, it may sometimes take up to two days for the treatment to have full effect. Therefore, you should continue using the nasal spray regularly to achieve the full effect of the treatment.

If you or your child suffers greatly from hay fever, your doctor may recommend using Nasonex a few days before the start of the pollen season, as this will help to prevent hay fever symptoms.

Nasal polyps

Use in adults aged 18 years and older

The recommended starting dose is two sprays in each nostril once a day.

- If the symptoms are not sufficiently controlled after 5 to 6 weeks, your doctor may increase your dose to two sprays in each nostril twice a day. Once the symptoms are controlled, your doctor may advise you to reduce the dose. your doctor may advise you to reduce the dose.
- no improvement in symptoms is observed after 5 to 6 weeks with twice daily administration, contact your doctor. no improvement in symptoms is observed after 5 to 6 weeks with a your nasal spray for use

Your Nasonex nasal spray has a cap that protects the spray nozzle and keeps it clean. Remember prepare nasal spray for use

Your Nasonex nasal spray has a cap that protects the spray head and keeps it clean. Remember this to remove before using the spray and replace it after use.

When using the spray for the first time, you need to 'prime' the bottle by pressing the pump to press 10 times until a fine mist is produced:

1. Shake the bottle gently.
2. Place your index and middle fingers on either side of the spray head and your thumb at the bottom of the bottle. Do not pierce the spray mechanism.
3. Point the spray head away from you and then press the pump 10 times with your fingers until a fine mist is produced. fine mist is produced.

you have not used the nasal spray for 14 days or longer, you need to re-prime the bottle by pressing the pump twice until a fine mist is produced. How to use activate by pressing the pump twice until a fine mist is produced.

How to use your nasal spray?

1. Shake the bottle gently and remove the cap (Figure 1).
2. Gently blow your nose.
3. Close one nostril off and insert the spray tip into the other nostril as shown (Figure 2). Tilt your head slightly forward while keeping the bottle upright.
4. Begin to slowly and gently breathe in through your nose and as you inhale, spray a fine mist into your nose by pressing the pump ONCE with your fingers.
5. Exhale through the mouth. Repeat step 4 to spray a second dose into the same nostril, if applicable.
6. Remove the spray tip from this nostril and exhale through the mouth.
7. Repeat steps 3 through 6 for the other nostril (Figure 3).

Dry after using the nasal spray, gently wipe the spray nozzle with a clean handkerchief or a paper tissue and replace the cap.

#### Your cleaning the nasal spray

- It is important to clean the nasal spray regularly because it otherwise may not function correctly .
- Remove the cap and gently detach the spray nozzle.
- Wash the spray nozzle and the cap in warm water and then rinse them under running water off.
- If the spray mechanism becomes blocked, do not attempt to clear it with a pin or other sharp object, as this will damage the spray mechanism, resulting in an incorrect dose of your medication.
- Let the cap and spray nozzle dry in a warm place.
- Reattach the spray nozzle to the bottle and replace the cap.
- The spray must be re-primed with 2 sprays when used for the first time after cleaning.

Have you used too much of this medicine?

Contact your doctor if you accidentally used more than you were prescribed.

If you use steroids for a long period or in large amounts, it can in rare cases affect some of your hormones. In children it can affect growth and development. affect growth and development.

Did you forget to use this medicine to use?

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

If you stop using this medicine

In some patients, symptoms should decrease within 12 hours after the first dose of Nasonex; however, it may sometimes take up to two days for the treatment to have full effect. It is very important that you your nasal spray regularly. Do not stop your treatment, even if you feel better, unless advised by your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like any medicine can this medicine also have side effects, although not everyone gets them. experience.

Acute hypersensitivity reactions (allergic reactions) may occur after using this product. These reactions can be severe. Stop using Nasonex and seek immediate medical help if you experience the following symptoms:

- swollen face, tongue, or throat
- difficulty swallowing
- skin rash with intense itching (hives)
- wheezing breathing or difficulty breathing.

When nasal sprays containing corticosteroids are used in high doses for long periods, can side effects are prevented because the substance is absorbed in the body.

#### Other side effects

Most people do not experience problems after using the nasal spray. However, some people after using Nasonex or another corticosteroid-based nasal spray may notice that they suffer from:

Common side effects (occur in less than 1 in 10 users):

- headache
- sneezing
- nosebleeds (occurred very frequently [in more than 1 in 10 users] in people with nasal polyps who received two sprays of Nasonex in each nostril twice daily)
- sore nose or throat
- nasal ulcers
- respiratory tract infection

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

- increased intraocular pressure (glaucoma) and/or cataract, which cause disturbances in vision cause
- damage to the nasal septum, which separates the nostrils
- changes in taste and smell
- wheezing or difficulty breathing
- blurred vision

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects [www.lareb.nl](http://www.lareb.nl). Due to side effects can report, can 5. How to store this medicine?

Keep out of the sight and reach of children.

- Store below 25 °C. Do not freeze.
- Do not use this medicine

- after the expiry date. It is after the expiration date. It is to find on the bottle and the packaging after EXP. It shows a month and a year. The last day of that month is the expiration date.
- Use the bottle within 2 months after the first opening. Open one bottle at a time.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed in a responsible manner and will not enter the environment.

## 6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is mometasone furoate. Each spray contains 50 micrograms mometasone furoate, as monohydrate.
- The other substances in this medicine are dispersible cellulose, glycerol, sodium citrate, citric acid monohydrate, polysorbate 80, benzalkonium chloride, purified water.
- This medicine contains 0,02 mg benzalkonium chloride per spray.

What does Nasonex look like and how much is in a package?

Nasonex is a nasal spray suspension.

Each bottle contains 60 or 140 sprays.

The bottles with 60 sprays are supplied in packages with 1 bottle.

The bottles with 140 sprays are supplied in packages of 1, 2, or 3 bottles.

Not all mentioned package sizes are marketed. marketed .

Marketing authorization holder market N.V. Organon

Kloosterstraat 6

5349 AB Oss

Netherlands

Tel.: 00800 66550123

E-mail:

Email: [dpoc.benelux@organon.com](mailto:dpoc.benelux@organon.com)

Manufacturer

Organon Heist bv

Industriepark 30

2220 Heist-op-den-Berg

Belgium

Registered under:

Nasonex 50 micrograms/spray, nasal spray, suspension - RVG 21613

This medicine is registered in EEA member states under the following names:

- Belgium, Denmark, Germany, Estonia, Finland, France, Greece, Hungary, Ireland, Iceland, Italy, Croatia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Slovenia, United Kingdom, Sweden: Nasonex
- Bulgaria, Romania, Slovakia, Czech Republic: NASONEX

- Austria: Nasonex aquosum – Nasenspray
- Latvia: Nasonex 50 mikrogrami/dose nasal aerosol, suspension
- Portugal: Nasomet
- Spain: NASONEX 50 micrograms nasal spray suspension

This leaflet was last approved in November 2022.

More information about this medicine is available on the CBG website:  
[www.geneesmiddeleninformatiebank.nl](http://www.geneesmiddeleninformatiebank.nl).

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