

Package leaflet: Information for the user

MONADIA 50mcg/actuation Nasal spray, suspension Mometasone Furoate

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. 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 MONADIA is and what it is used for
2. What you need to know before you use MONADIA
3. How to use MONADIA
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1. What MONADIA is and what it is used for

What is MONADIA?

MONADIA Nasal Spray contains mometasone furoate, one of a group of medicines called corticosteroids. When mometasone furoate is sprayed into the nose, it can help to relieve inflammation (swelling and irritation of the nose), sneezing, itching and a blocked or runny nose.

What is MONADIA used for?

Hayfever

MONADIA is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) in adults and children aged 3 and older.

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. MONADIA reduces the swelling and irritation in your nose and thereby relieves sneezing, itching and a blocked or runny nose caused by hay fever.

2. What you need to know before you use MONADIA

Do not use MONADIA

- if you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of this medicine (listed in section 6).
- if you have an untreated infection in your nose. Use of MONADIA while you have an untreated infection in your nose, such as herpes, can worsen the infection. 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 not use the nasal spray until your nose has healed.

Warnings and precautions

Talk to your doctor or pharmacist before using MONADIA if you:

- have or have ever had tuberculosis.
- have any other infection.
- are taking other corticosteroid medicines, either by mouth or by injection.

- have cystic fibrosis.

While you are using MONADIA, talk to your doctor if:

- your immune system is not functioning well (if you have difficulty in fighting infection) and you come into contact with anyone with measles or chickenpox. You should avoid coming into contact with anyone who has these infections.
- you have an infection of the nose or throat.
- you have been using the medicine for several months or longer.
- you have persistent irritation to the nose or throat.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

If your eyes are itching or irritated, your doctor may recommend that you use other treatments with MONADIA.

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

Children

When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side-effects, such as slowed growth rate in children.

It is recommended that the height of children receiving long-term treatment with nasal corticosteroids is regularly monitored and if any unusual changes are noted, their doctors should be notified.

MONADIA should not be used in children below 3 years of age because the safety and efficacy of MONADIA in children under 3 years of age have not been established.

Other medicines and MONADIA

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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 MONADIA. 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. 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, you should contact your doctor.

Some medicines may increase the effects of MONADIA 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

There is little or no information on the use of MONADIA in pregnant women. It is not known if mometasone furoate passes into breast milk.

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

There is no known information on the effect of MONADIA on the ability to drive or use machinery.

MONADIA contains benzalkonium chloride

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

3. How to use MONADIA

Always use MONADIA 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 recommended.

Use in adults and children over 12 years old

The usual dose is two sprays into each nostril once a day.

- Once your symptoms are under control, your doctor may advise you to decrease the dose.
- If you do not start to feel any better, you should see your doctor and he or she may tell you to increase the dose; the maximum daily dose is four sprays into each nostril once a day.

Use in children aged 3 to 11 years

The usual dose is one spray into each nostril once a day.

In some patients MONADIA begins to relieve symptoms 12 hours after the first dose; however the full benefit of treatment may not be felt in the first two days. Therefore, you should continue regular use to achieve the full benefit of treatment.

If you or your child suffer badly from hayfever, your doctor may tell you to start using MONADIA some days before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring.

Preparing your nasal spray for use

Your MONADIA 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.

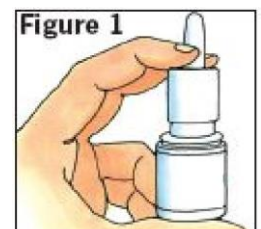
If you are using the spray for the first time you need to ‘prime’ the bottle by pumping the spray 10 times until a fine mist is produced:

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 10 times until a fine mist is produced.

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.

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 while 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 if applicable.
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 to get the wrong dose of medicine.**
- Allow the dust cap and nozzle to dry in a warm place.
- Push the nozzle back onto the bottle and replace the dust cap.
- The spray will need to be primed again with 2 sprays when first used after cleaning.



If you use more MONADIA than you should

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

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 MONADIA

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 MONADIA

In some patients MONADIA should begin to relieve symptoms 12 hours after the first dose; however, the 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, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Immediate hypersensitivity (allergic) reactions may occur after use of this product. These reactions may be severe. You should **stop using MONADIA and get immediate medical help if you experience symptoms such as:**

- swollen face, tongue or throat
- trouble swallowing
- hives
- wheezing or trouble breathing

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

Other side effects

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

Common side effects (may affect up to 1 in 10 people):

- headache
- sneezing
- nosebleeds, sore nose or throat
- ulcers in the nose
- respiratory tract infection

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

- increase in pressure in the eye (glaucoma) and/or cataracts causing visual disturbances
- damage to the septum (partition in the nose which separating the nostrils)
- changes in sense of taste and smell
- difficulty breathing and/or wheezing
- blurred vision

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 **the national reporting system listed in [Appendix V](#)**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MONADIA

- Keep this medicine out of the sight and reach of children.
- Do not store the bottle above 25°C. Do not freeze.
- Do not use this medicine 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.
- The bottle should be used within 2 months of first opening. Only open one bottle at a time.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any tissues used for wiping and/or blowing the nose after treatment with Monadia should be disposed of in the household waste to prevent unused product reaching the aquatic environment. These measures will help protect the environment.

6. Contents of the pack and other information

What MONADIA 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.
- This medicine contains 0.02 mg of benzalkonium chloride per spray.

What MONADIA looks like and contents of the pack

MONADIA is a nasal spray suspension.

Each bottle contains 60 sprays or 140 sprays.

Bottles containing 60 sprays are supplied in single packs.

Bottles containing 140 sprays are supplied in single packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Diapharm GmbH & Co. KG
Am Mittelhafen 56
48155 Münster
Germany

Manufacturer

Organon Heist bv,
Heist-op-den Berg, Belgium

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

Germany: SONEDIA

Ireland: MONADIA

This leaflet was last approved in