

Package leaflet: Information for the user

Mometasone 50 micrograms/actuation Nasal Spray, Suspension

Mometasone Furoate

ROWEX®

Read all of this leaflet carefully before you start taking 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 only. 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 Mometasone is and what it is used for
2. What you need to know before you use Mometasone
3. How to use Mometasone
4. Possible side effects
5. How to store Mometasone
6. Contents of the pack and other information

1 What Mometasone is and what it is used for

What is Mometasone?

Mometasone 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 up or runny nose.

What is Mometasone used for?

Hay fever and perennial rhinitis

Mometasone is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial 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. 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. Mometasone reduces the swelling and irritation in your nose and thereby relieving sneezing, itching and a blocked-up or runny nose caused by hay fever or perennial rhinitis.

Nasal polyps

Mometasone is used to treat nasal polyps in adults aged 18 and over.

Nasal polyps are small growths on the lining of the nose and usually affect both nostrils. Mometasone reduces the inflammation in the nose, causing the polyps to gradually shrink, thereby relieving a blocked feeling in the nose which may affect breathing through the nose.

2 What you need to know before you use Mometasone

Do not use Mometasone

- if you are allergic 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 Mometasone during 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 Mometasone

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

While you are using Mometasone, 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.
- if you have an infection of the nose or throat.
- if you are using the medicine for several months or longer.
- if 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 **Mometasone**.

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 changes are noted, their doctor should be notified.

Other medicines and Mometasone

Tell your doctor or pharmacist if you are

taking, have recently taken or might take any 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 Mometasone. 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.

Pregnancy and breast-feeding

There is little or no information on the use of Mometasone in pregnant women. It is not known if mometasone furoate is found in 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 Mometasone on the ability to drive or use machinery.

Mometasone contains benzalkonium chloride

Mometasone contains benzalkonium chloride, which may cause nasal irritation.

3 How to use Mometasone

Always use this medicine exactly as your doctor has told you. 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.

Treatment of hayfever and perennial rhinitis

Use in adults and children over 12 years old

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

In some patients Mometasone begins to relieve symptoms 12 hours after the first dose; however full benefit of treatment may not be seen for up to two days. If you or your child suffer badly from hayfever, the treatment may need to start some days before the pollen season starts. At end of the pollen season your hayfever symptoms should get better and treatment may then not be needed.

Nasal Polyps

Use in adults over 18 years old

The recommended starting dose 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 may advise you to decrease your dose.
- If no improvement in symptoms is seen after 5 to 6 weeks of twice daily administration, you should contact your doctor.

Preparing your nasal spray for use

Your Mometasone 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 (Figure 1). **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 (Figure 1).

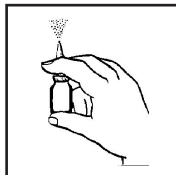


Figure 1

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.

continued on the next page >>

How to use your nasal spray

1. Shake the bottle gently and remove the dust cap (Figure 2).

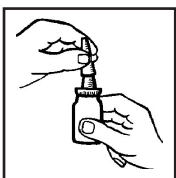


Figure 2

2. Gently blow your nose.
3. Close one nostril and put the nozzle into the other nostril. 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 (Figure 3).

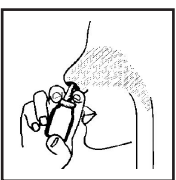


Figure 3

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.

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 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 Mometasone 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 Mometasone

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 Mometasone

In some patients Mometasone 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 medicine, ask your doctor or pharmacist.

4 Possible side effects

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

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

- swollen face, tongue or pharynx
- 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 Mometasone or other corticosteroid nasal sprays, may find that they suffer from:

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

- headache
- sneezing
- nose bleeds [occurred very commonly (may affect more than 1 in 10 people) in people with nasal polyps receiving Mometasone two sprays in each nostril twice a day]
- 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 partition in the nose which separates the nostrils

- changes in taste and smell
- difficulty in breathing and/or wheezing

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Mometasone

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month
- After first opening of the bottle it can be used for 2 months
- Do not freeze
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Mometasone contains

- The active substance is mometasone furoate. Each actuation of the pump delivers a metered dose of 50 micrograms of mometasone furoate (as mometasone furoate monohydrate). The other ingredients are microcrystalline cellulose and carmellose sodium, glycerol, citric acid monohydrate, sodium citrate dihydrate, polysorbate 80, benzalkonium chloride, water for injection.

What Mometasone looks like and contents of the pack

Mometasone is a white nasal spray, suspension packed in white plastic bottle fitted with a spray pump.
1 bottle containing 10.0 g nasal spray suspension, corresponding to 60 delivered doses
1 bottle containing 17.0 g nasal spray suspension, corresponding to 120 delivered doses
1 bottle containing 18.0 g nasal spray suspension, corresponding to 140 delivered doses

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia
Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia
S.C. Sandoz, S.R.L., Str. Livezeni nr. 7A, RO-540472 Targu-Mures, Romania
Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, 39179 Barleben, Germany

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

Austria: Mometason Hexal 50
Mikrogramm/Sprühstoß - Nasenspray
Germany: MomentaHEXAL
Ireland: Mometasone 50 micrograms/actuation Nasal Spray, Suspension
Netherlands: Mometasonfuroaat Sandoz 50 microgram/dosis, neusspray, suspensie

This leaflet was last revised in: 05/2015.

I.M. L/387a 05-15
Article no.