

Rhinex Relief 50 micrograms/actuation nasal spray, suspension

mometasone furoate

For use in adults only

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

1. What Rhinex Relief is and what it is used for
2. What you need to know before you use Rhinex Relief
3. How to use Rhinex Relief
4. Possible side effects
5. How to store Rhinex Relief
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1 What Rhinex Relief is and what it is used for

What is Rhinex Relief?

Rhinex Relief contains the active substance 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).

What is Rhinex Relief used for?

Rhinex Relief is used to treat the symptoms of hay fever (also called seasonal allergic rhinitis) in adults, after a seasonal allergic rhinitis has been initially diagnosed by a doctor.

Hay fever, 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. Rhinex Relief reduces the swelling and irritation in your nose and thereby relieving sneezing, itching and a blocked-up or runny nose caused by hay fever.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2 What you need to know before you use Rhinex Relief

Do not use Rhinex Relief

- 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 Rhinex Relief during an untreated infection in your nose, such as herpes, can worsen the infection. You have to 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 must not use the nasal spray until your nose has healed.

Warnings and precautions

Talk to your doctor or pharmacist before using Rhinex Relief

- 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 Rhinex Relief, talk to your doctor or pharmacist

- 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.

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

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

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

Children and adolescents

Rhinex Relief should not be used in children and adolescents below the age of 18.

Other medicines and Rhinex Relief

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription. Some medicines may increase the effects of Rhinex Relief and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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 Rhinex Relief. 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 Rhinex Relief 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 Rhinex Relief on the ability to drive or use machinery.

Rhinex Relief contains benzalkonium chloride

Rhinex Relief contains benzalkonium chloride, which may cause irritation or swelling inside the nose, especially if used for a long time.

3 How to use Rhinex Relief

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

- Once your symptoms are under control, you can decrease the daily dose to one spray into each nostril. If your symptoms worsen, increase the dose to two sprays in each nostril once daily.

In some patients Rhinex Relief 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 suffer badly from hay fever, the treatment may need to start some days before the pollen season starts. At the end of the pollen season your hay fever symptoms should get better and treatment may then not be needed.

You must seek medical advice if there is no/insufficient improvement of your symptoms after a maximum of 14 days. Rhinex Relief should not be used for longer than 3 months continuously without medical advice.

Preparing your nasal spray for use

Your Rhinex Relief 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.

Shake the bottle before each use. Do not pierce the nasal applicator (nozzle hole) with pin or other sharp object.

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. Shake the bottle well.
2. Remove the plastic cap.
3. 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.
4. 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).

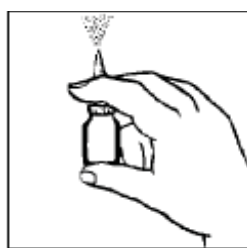


Figure 1

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.

How to use your nasal spray

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



Figure 2

2. Gently blow your nose to clear the nostrils.
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).

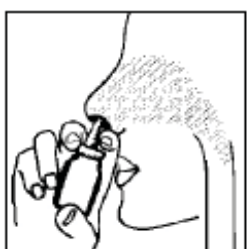


Figure 3

- Breathe out through your mouth. Repeat step 4 to inhale a second spray in the same nostril if applicable.
- Remove the nozzle from this nostril and breathe out through the mouth.
- 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 Rhinex Relief than you should

Always use a dose exactly as described in this leaflet or as your doctor has told you. If you use more or less your symptoms can worsen.

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.

If you forget to use Rhinex Relief

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 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 medicinal product. These reactions may be severe. You should stop taking Rhinex Relief 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 medicine being absorbed in the body.

Other side effects

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

- headache
- sneezing
- nose bleeds
- sore nose
- 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
- blurred vision
- 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 or pharmacist. 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 Rhinex Relief

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 or carton box after EXP. The expiry date refers to the last day of that month.

Do not freeze.

Prior to administration of the first dose users are advised to shake the bottle well and to actuate the pump 10 times (until a uniform spray is obtained). If the pump is not used for 14 days or longer, the pump should be reprimed with 2 actuations until a uniform spray is observed, before next use.

Once opened, bottle should be used within two months. Open only one bottle at a time. Do not unscrew the nasal spray pump system.

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 Rhinex Relief contains

- The active substance is mometasone furoate. Each actuation of the pump delivers a metered amount of 50 micrograms of mometasone furoate (as mometasone furoate monohydrate). The total weight of one actuation is 100 mg.

- The other ingredients are microcrystalline cellulose, carmellose sodium, glycerol, citric acid monohydrate, sodium citrate dihydrate, polysorbate 80, benzalkonium chloride, water for injection.

What Rhinex Relief looks like and contents of the pack

Rhinex Relief is a white, homogenous nasal spray, suspension packed in a white bottle fitted with a spray pump with a blue protective cap.

1 bottle containing 10 g nasal spray, suspension, corresponding to 60 actuations

1 bottle containing 17 g nasal spray, suspension, corresponding to 120 actuations

1 bottle containing 18 g nasal spray, suspension, corresponding to 140 actuations

2 bottles containing 18 g nasal spray, suspension, corresponding to 140 actuations each

3 bottles containing 18 g nasal spray, suspension, corresponding to 140 actuations each

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

Manufacturer

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

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

Bulgaria:	MomaNose 50 micrograms/ actuation, nasal spray, suspension
Croatia:	Momanose 50 mikrograma sprej za nos, suspenzija
Czech Republic:	Momanose
Denmark:	Mommox
Estonia:	Nasomentin
Germany:	Mometasonfuroat – 1 A Pharma Heuschnupfenspray 50 Mikrogramm/Sprühstoß Nasenspray, Suspension
Hungary:	Momopax 50 mikrogramm/adag szuszpenziós orrspray Rhinex Relief
Ireland:	50 micrograms/actuation nasal spray, suspension
Italy:	Mometasone Sandoz BV
Latvia:	Nasometin 50 mikrogrami/ izsmidzinājuma deguna aresols, suspensija
Lithuania:	Nasometin 50 mikrogramų/dozėje nosies purškalas (suspensija)
Poland:	Mometasone Sandoz
Romania:	Rinamet 50 micrograme/ doză, spray nazal, suspensie
Slovakia:	Nasometin 0,05 mg/ dávka
Slovenia:	Mommox RINO 50 mikrogramov/vpih pršilo za nos, suspenzija

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