

Package leaflet: Information for the patient

MupiroNasal 20 mg/g nasal ointment Mupirocin

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 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.

What is in this leaflet

1. What MupiroNasal is and what it is used for
2. What you need to know before you use MupiroNasal
3. How to use MupiroNasal
4. Possible side effects
5. How to store MupiroNasal
6. Contents of the pack and other information

1. What MupiroNasal is and what it is used for

The active substance in this medicine is the antibiotic mupirocin. It has a high activity against certain bacteria, which are commonly isolated from the nose and in many cases are resistant to the effects of other antibiotics.

MupiroNasal is a local antibiotic that is used to treat bacterial infections of the nose. It is also used to remove nasal carriage of certain types of bacteria (the so-called Staphylococci), which commonly cause infections in haemodialysis patients.

2. What you need to know before you use MupiroNasal

Do not use MupiroNasal

- if you are allergic to mupirocin or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may present with rash, itching, irritation in the area of the nose.

Warnings and precautions

Talk to your doctor or pharmacist before using MupiroNasal.

The effect of the application of MupiroNasal usually occurs between the 3rd and the 5th day after the initiation of treatment.

Do not use this medicine for longer than the time specified by the physician. Like other antibiotics, prolonged treatment may lead to overgrowth of non-susceptible microorganisms.

Rarely, allergy may develop or severe irritation may occur in the nose. In these cases, and if any other ailment appears, you should immediately discontinue the treatment and contact your doctor.

This medicine is for nasal use only. It is necessary to avoid the contact with eyes or the application in them. If the medicine falls into the eye/eyes, they need to be thoroughly rinsed with lukewarm water.

Other medicines and MupiroNasal

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Upon co-administration of other products intended for nasal use, there is a possibility of diluting the medicine, which may lead to reduction of its activity or loss of stability of the ointment.

MupiroNasal with food, drink and alcohol

There are no restrictions.

Pregnancy, breast-feeding and fertility

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 using this medicine.

If you are pregnant or breast-feeding, you should not use this medicine unless your doctor has ordered the treatment with it.

Driving and using machines

MupiroNasal has no influence on the ability to drive and use machines.

3. How to use MupiroNasal

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

Posology*Adults and children*

A small amount of the ointment (about the size of a match head) is inserted 2 times daily in each nostril for not less than 5 days.

Elderly

No adjustment of the indicated dose is required.

Patients with liver and kidney diseases

No adjustment of the indicated dose is required.

Method of administration

To put the required amount of the ointment, it is appropriate to use an individual cotton swab for each nostril.

After inserting the medicine, close the nostrils by gently pressing with your fingers on both sides and massage carefully.

After insertion of the ointment in the nasal passages, no other medicines should be used, in order to avoid the possibility of diluting the medicine and reducing its activity, as well as the loss of stability of the ointment.

Duration of treatment

To achieve the intended effect, the medicine should be used for not less than 5 days.

Maximum duration - 10 days.

If you use more MupiroNasal than you should

If you have occasionally applied more ointment than you should, you can remove it with a cotton swab. The likelihood to experience any complications of overdose with this medicine is very low.

If you forget to use MupiroNasal

If you forget to apply the required dose, do it as soon as you remember. If it is almost the time for your next dose, skip the missed dose and follow your regular dosing schedule. Do not use a double dose.

If you stop using MupiroNasal

Do not stop the treatment early because it is important to complete the full course of treatment with this medicine, in order to reduce the likelihood of reappearance of the infection or to induce the development of resistant bacteria.

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.

During the treatment with mupirocin, the following side effects are likely to occur:

- **Uncommon side effects** (affect more than 1 in 1,000 and less than 1 in 100 patients): burning, itching, pain or blistering at the administration site.
- **Very rare side effects** (affect less than 1 in 10,000 patients): inflammation of the skin, sometimes with blistering, redness, itching, different skin rashes, burning sensation and irritation of the skin.

During the treatment with mupirocin-containing medicines, severe allergic reactions that cause difficulty in breathing or dizziness, swelling of the face or throat, swelling around the eyes, hives have been reported very rarely.

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:

Bulgarian Drug Agency
8 “Damyan Gruev” Str.
1303 Sofia
Tel.: +359 2 8903417
website: www.bda.bg.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MupiroNasal

Keep this medicine out of the sight and reach of children.

Store below 25°C.

After first opening the tube, store in the original package at a temperature below 25°C.

Do not use this medicine after the expiry date which is stated on the carton after „EXP”. The expiry date refers to the last day of that month.

After first opening the tube, you may use this medicine for 10 days.

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 MupiroNasal contains

- The active substance in 1 g of the ointment is mupirocin of 20 mg.
- The other ingredients (excipients) are bis-diglyceryl polyacyladipate-2; paraffin, white soft.

What MupiroNasal looks like and contents of the pack

MupiroNasal is an ointment with homogenous consistency.

MupiroNasal 20 mg/g ointment of 3 g in an aluminium tube fitted with a cannula and closed with a screw cap.

One tube with a patient leaflet is inserted in a cardboard carton.

Marketing Authorisation Holder

Antibiotic-Razgrad AD
Office 201, 68 “Aprilsko vastanie” Blvd.
7200 Razgrad, Bulgaria

Manufacturer

Balkanpharma-Razgrad AD
68 “Aprilsko vastanie” Blvd.
7200 Razgrad, Bulgaria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Antibiotic-Razgrad AD
Office 201, 68 “Aprilsko vastanie” Blvd.
7200 Razgrad, Bulgaria
Tel.: +359 084 613 427

This leaflet was last revised in 06/2013.