

## **Package leaflet: Information for the patient**

### **MupiroDermal 20 mg/g 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. See section 4.

#### **What is in this leaflet**

1. What MupiroDermal 20 mg/g ointment is and what it is used for
2. What you need to know before you use MupiroDermal 20 mg/g ointment
3. How to use MupiroDermal 20 mg/g ointment
4. Possible side effects
5. How to store MupiroDermal 20 mg/g ointment
6. Contents of the pack and other information

#### **1. What MupiroDermal 20 mg/g ointment is and what it is used for**

The active substance in this medicine is the antibiotic mupirocin.

MupiroDermal 20 mg/g ointment is a topical antibiotic used to treat bacterial infections of the skin. It is also used to prevent bacterial contamination in small skin wounds and bruises.

#### **2. What you need to know before you use MupiroDermal 20 mg/g ointment**

##### **Do not use MupiroDermal 20 mg/g ointment**

- if you are allergic to mupirocin or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using MupiroDermal 20 mg/g ointment.

MupiroDermal 20 mg/g ointment may cause skin irritation and allergic reactions (see section 4).

MupiroDermal 20 mg/g ointment is not suitable for:

- eye infections;
- application inside the nose;
- application to the skin near cannulae (tubes used to inject drugs and fluids into your body).

Keep MupiroDermal 20 mg/g ointment away from your eyes. If the medicine accidentally gets into your eyes, rinse thoroughly with water.

##### **Other medicines and MupiroDermal 20 mg/g ointment**

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

### **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 taking this medicine.

If it is needed to treat the affected nipple in lactating women, the nipple should be thoroughly washed before lactation.

### **Driving and using machines**

MupiroDermal 20 mg/g ointment does not affect the ability to drive or use machines.

## **3. How to use MupiroDermal 20 mg/g ointment**

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

### Dosage

Adults, children and the elderly (over 65 years)

2 to 3 times a day for up to 10 days, depending on the response.

### Method of administration

- Wash your hands before and after applying MupiroDermal 20 mg/g ointment.
- With a piece of clean cotton or a gauze pad, apply a small amount of ointment to cover the affected area.
- After administration of the medicine, you can cover the treated area with a sterile dressing or gauze, unless your doctor tells you otherwise.
- Do not mix MupiroDermal 20 mg/g ointment with other lotions, creams or ointments to avoid the possibility of dilution of the medicine and reduced activity as well as impaired stability of the ointment.

### **If you use more MupiroDermal 20 mg/g ointment than you should**

If you accidentally applied more than the required amount of ointment, you can remove it with a cotton swab. The likelihood of any complication from overdose with this medicine is very low.

### **If you forget to use MupiroDermal 20 mg/g ointment**

If you forget to apply the required dose, do so as soon as you remember and apply the next dose at the usual time.

### **If you stop using MupiroDermal 20 mg/g ointment**

Do not stop treatment prematurely because it is important to complete the full course of treatment with this medicine to reduce the likelihood of infection returning or causing 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.

### **Conditions to watch out for**

#### **Severe allergic reactions**

They are very rare in people using mupirocin ointment. Signs include:

- convex and itchy rash;
- swelling of the face, mouth, tongue, difficulty breathing;
- collapse or loss of consciousness.

When they occur, stop the medication and consult a doctor immediately.

If you develop a severe skin reaction or allergy, stop the application, wipe off the medicine and see your doctor as soon as possible.

In rare cases, medicines such as MupiroDermal 20 mg/g ointment can cause inflammation of the colon, leading to diarrhoea, usually with blood and mucus, stomach pain, fever (pseudomranosous colitis). Tell your doctor as soon as possible if you experience any of these symptoms.

Common side effects (may affect one in 10 patients): burning at the site of administration.

Uncommon side effects (may affect up to one in every 100 patients): itching, redness, tingling and/or dryness at the site of application.

Very rare side effects (may affect one in every 10,000 patients): severe allergic reactions (anaphylaxis, generalized rash, urticaria and angioedema).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **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 Street  
1303 Sofia  
Tel.: +35 928903417  
Website: [www.bda.bg](http://www.bda.bg).

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

## **5. How to store MupiroDermal 20 mg/g ointment**

Keep this medicine out of the sight and reach of children.  
Store below 25 °C.

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

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 MupiroDermal 20 mg/g ointment contains**

- The active substance in 1 g ointment is mupirocin 20 mg.
- The other ingredients (excipients) are: macrogol 3350, macrogol 400

### **What MupiroDermal 20 mg/g ointment looks like and contents of the pack**

MupiroDermal 20 mg/g is a homogenous white to off-white ointment.

MupiroDermal 20 mg/g ointment 15 g in aluminium tubes with a plastic screw cap.  
One tube with a package leaflet, packed in a cardboard box.

**Marketing Authorisation Holder and Manufacturer**

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