

**PATIENT PACKAGE INSERT IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Gentatrim Cream/Ointment

The active ingredient and its concentration:

Gentamicin (as sulphate) 0.1%

Inactive ingredients: see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of bacterial skin infections (sores, burns, acne and dermatoses) sensitive to gentamicin.

Therapeutic group: Aminoglycoside antibiotic for topical treatment.

2. BEFORE USING THE MEDICINE

Do not use the preparation if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients in the medicine (see section 6).

Special warnings regarding use of the medicine:

- Sometimes, topical use of antibiotics promotes the growth of other microorganisms, among them fungi. If you notice a fungal infection or if you develop irritation as a result of using Gentatrim, refer to a doctor to replace the treatment with another medicine.
- Do not use in the eyes.
- **Do not use the medicine without consulting the doctor before starting treatment if:**
 - You are pregnant or breastfeeding.
 - You are suffering, or have suffered in the past, from impaired function of the kidney/urinary tract, especially if the treated area is denuded and/or the cream form is being used, since these factors increase the absorption of gentamicin.
 - You are sensitive to any food or medicine, especially to antibiotic agents.

I If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist if it is particularly important to inform the doctor or pharmacist if you are using other external preparations.

Pregnancy and breastfeeding:

Do not commence treatment with the medicine without consulting the doctor if you are pregnant or breastfeeding.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Consult the doctor or pharmacist if you are uncertain about how to use.

- The dosage and treatment regimen will be determined by the doctor only.

Unless instructed otherwise by the doctor:

Clean the affected area before use. With clean hands, massage a small amount of the preparation onto the affected area 3-4 times a day. Wash your hands after use (unless the hands are the area being treated).

- Avoid, as much as possible, further infection of the affected area.

If your condition does not improve within one week, refer to the doctor again so he can tell you how to continue treatment to avoid resistance of the infection to gentamicin.

- The treated area can be covered with a dressing.
- In cases of contagious impetigo, remove the crust before the treatment in order to enable better contact of the medicine with the infection.
- **Do not exceed the recommended dose.**
- Do not swallow! This medicine is intended for external use only. Avoid contact with the eyes.

If you took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose each time you use a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Gentatrim may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue use of the medicine and refer to the doctor immediately if the following effects develop:

Local irritation, inflammation or rash in the treated area.

Side effects of unknown frequency:

Skin sensitivity to light.

If any of the side effects worsen, or if you experience a side effect not mentioned in this leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- The preparation can be used for up to 12 months after first opening, but not beyond the expiry date.
- Store in a cool place, at a temperature below 25°C. Do not freeze.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains inactive ingredients:

Cream:

Purified water, liquid paraffin, cetostearyl alcohol, macrogol cetostearyl ether, chlorocresol, sodium phosphate, phosphoric acid

Ointment:

White soft paraffin, liquid paraffin

- **What does the medicine look like and what are the contents of the pack?** Each pack contains a tube with 15 grams white cream/ointment.

- **Manufacturer and license holder:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

This leaflet was checked and approved by the Ministry of Health in May 2015.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Gentatrim Cream: 045.98.23634.00

Gentatrim Ointment: 047.61.23635.00

Maabarot 4023000

Israel Pharmaceutical Products

Maabarot Ltd.

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