

PACKAGE LEAFLET: INFORMATION FOR THE USER

GARAMYCIN

1 mg/g ointment

GENTAMYCINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Garamycin is and what it is used for
2. Before you take Garamycin
3. How to take Garamycin
4. Possible side effects
5. How to store Garamycin
6. Further information

1. WHAT GARAMYCIN IS AND WHAT IT IS USED FOR

Garamycin is aminoglycoside antibiotic.

The ointment is suitable for the treatment of skin infections, infected venous ulcers, infected burns or frostbite affecting smaller surfaces of the skin.

2. BEFORE YOU TAKE GARAMYCIN

Do not take Garamycin:

- If you are allergic (hypersensitive) to gentamycin, any of the ingredients of Garamycin or any of the aminoglycoside antibiotic.

Be careful with Garamycin

- If you notice severe redness of diseased area or you feel that a condition got worse, stop using the ointment.
- If after one week there is no improvement, consult a doctor.

- When the large areas of skin are affected, we do not recommend the use of Garamycin, particularly in premature babies, infants, young children and elderly patients with impaired hearing or renal function.

The prolonged use on large surfaces of affected skin can enable the medicine to enter the blood in such quantities which may damage your hearing.

Taking other medicines with Garamycin

Tell your doctor or pharmacist if you are taking or have recently taken, or there is a possibility that you are taking any other medicines, including those that you bought without a prescription.

Avoid simultaneous use of other local products.

Pregnancy and breastfeeding

Consult a doctor or pharmacist before taking any medicine.

The safety of administration of Garamycin during pregnancy and lactation is not established. It should be used only in cases of emergency, when the expected benefit to the mother justifies the risk to the child. It is not recommended if large surface of the skin is affected.

Driving and using machines

Since the medicine usually enters the blood at a negligible amount, we do not expect it to have effect on the ability to drive and use machines.

Important information about some of the ingredients of Garamycin

Garamycin contains parahydroxybenzoates E218 and E216, which may cause allergic reactions (also delayed reactions).

3. HOW TO TAKE GARAMYCIN

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.

Use the ointment 3 to 4 times a day.

Remove the crust and apply the ointment on infected area. The surface can be covered with gauze.

Your doctor will tell you for how long to use the ointment.

If you take more Garamycin than it should

The problems rarely occur, unless you applied the ointment on a very large area of damaged skin for a long time (several weeks).

If you forget to use Garamycin

Do not use a double dose if you missed a previous one.

If you have stopped using Garamycin

Apply the medicine to the affected area according to the doctor's prescription; otherwise your condition may worsen.

If you have any further questions on the use of Garamycin talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines and medicine Garamycin has side effects, although not everybody gets them.

Side effects are listed according to the following categories of frequency:

Very common: occurs in more than 1 in 10 patients

Common: occurs in 1 to 10 in 100 patients

Uncommon: occurs in 1 to 10 in 1000 patients

Rare: occurs in 1 to 10 to 10000 patients

Very rare: occurs in less than 1 in 10000 patients

Unknown frequency: cannot be estimated on the basis of the available data.

Very rare: hypersensitivity to light (rash), mild stimulation of the skin (erythema and itching), overgrowth of non-susceptible organisms, for example fungi; in this case, we need to end the treatment.

If you notice any side effects, it is necessary to inform your doctor or pharmacist.

5. HOW TO STORE GARAMYCIN

Keep the medicine out of reach and sight of children.

Store at the temperature below 25°C.

Shelf life is 5 years.

Garamycin medicine must not be used after the expiry date that is specified on the packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What does the medicine Garamycin contain?

The active substance is gentamycine. One gram of ointment contains 1 mg (1000 IU) of gentamycine in the form 1.66 mg gentamycine sulphate.

- the other substances are methyl parahydroxybenzoate (E218), propyl (other ingredients), liquid paraffin and white Vaseline.

What Garamycin looks like and contents of the pack

Ointment is white to light yellow in color.

There are boxes with 15 g of ointment in a tube.

Regime of dispensing

The medicine is issued to the doctor's prescription

Manufacturer

KRKA, tovarna zdravil, d.d.

Šmarješka cesta 6, Novo Mesto, the Republic of Slovenia

Manufacturer of the medicinal product

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