

PACKAGE LEAFLET: Information for the patient

GENTA

Cream – 0.1%

(Gentamicin sulphate)

Read all of this leaflet carefully before you start using this medicine.

- 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 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.

In this leaflet:

1. What Genta is and what it is used for?
2. Before you use Genta
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4. Possible side effects
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1. WHAT GENTA IS AND WHAT IT IS USED FOR?

Genta is a pharmaceutical product which contains the active substance gentamicin sulphate.

Gentamicin is an aminoglycoside antibiotic, more active against aerobic gram-negative bacteria, particularly *Escherichia coli*, *Proteus*, *Klebsiella*, *Serratia*, *Enterobacter* and *Citrobacter*.

Gentamicin is inactive against anaerobic bacteria, fungi and viruses.

Genta cream is used in skin infections caused by bacteria sensitive to gentamicin such as: pyoderma with different spreading and gravity, folliculitis, furunculosis, microbial eczema. It is also used in secondary skin infections such as: dermatitis, eczema, ulcers, traumatic lesions, burns and infected wounds. Other skin infections that can be treated with Genta cream are acne

and psoriasis pustulosa, integroid form.

2. BEFORE YOU USE GENTA

Do not use Genta cream:

- if you are hypersensitive (allergic) to aminoglycosides where gentamicin belongs, to propylene glycol, methyl hydroxybenzoate, propyl hydroxybenzoate, or to any of the excipients of the product, because allergic reactions may occur, including anaphylaxis. Allergic reactions caused by aminoglycosides are not common, but when they occur, they are often cross-sensitive reactions within the chemical group.

Take special care with Genta

Ask your doctor before using Genta cream.

- The possibility of absorption of the antibiotic should be considered if gentamicin is applied topically to large skin areas. This may consist in a small risk of ototoxicity, especially in elderly and in patients with renal impairment.
- If irritation, sensitization or superinfection develops, treatment should be discontinued and appropriate therapy instituted.
- It should be used with extreme caution in children younger than one year old as safety and efficacy in these children have not been established.
- Genta cream is for external use only.
- The simultaneous and/or sequential use of other drugs causing kidney toxicity (nephrotoxicity) and/or brain toxicity (neurotoxicity) by systemic (oral or injection) or topical (local application on skin or mucous) administration should be avoided.

Taking other medicines

Tell your doctor or pharmacist if you are taking / using, have recently taken / used other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor about the treatment with Genta cream if you are given another drug during treatment. Clinically significant interactions may occur only after systemic absorption of Genta cream. Use of other drugs such as: kanamycin, neomycin, streptomycine, ciclosporin, acyclovir, polymyxin B, colistin, vancomycin, cisplatin, and fludarabine increases the risk of

nephrotoxicity. Concomitant use of gentamicin with other ototoxic drugs such as etacrynic acid and perhaps furosemide should be avoided because the risk of aminoglycoside toxicity may be increased.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using this drug.

Safety of use of this drug in pregnancy and breastfeeding has not been established. Anyway, the use of this drug should be avoided during pregnancy and breastfeeding.

Driving and using machines

There are no data regarding the impairment of the ability to drive and to use machines.

Important information about some of the excipients of Genta cream

Genta contains methyl hydroxybenzoate and propyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

It also contains propylene glycol which may cause skin irritation.

3. HOW TO USE GENTA?

Always use Genta - cream as prescribed by your doctor. If you are not sure, contact your doctor or pharmacist. If you feel that the effects of Genta cream are too weak or too strong, talk to your doctor or pharmacist.

Before using the cream, the affected area should be washed and completely dried. Before application, it may be required to remove the crusts from the skin, in order to facilitate the contact and action of gentamicin with the responsible pathogenic bacteria.

The cream is used 3-4 times a day till improvement is achieved. Then, it can be applied 2-3 times a day. It is good to cover the area after application with a sterile gauze dressing, but this is not indispensable.

If you use more Genta than you should

If you use more Genta cream than you should, or if the children take it accidentally, please

contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to use Genta

If you forget to use one dose, use the next dose in its usual time. Do not use a double dose to make up 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, Genta cream can cause side effects, although not everybody gets them.

Most of the side effects are dose - related and disappear when the dose is reduced or the treatment is stopped. Some of the side effects appear in the beginning of the treatment and disappear spontaneously during the treatment.

If the cream is applied continuously or repeatedly, there is a risk of occurrence of sensitization reactions.

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.

5. HOW TO STORE GENTA?

Store in a cool, dry place, not above 25°C!

Protect it from light and humidity.

Do not use Genta cream after the expiry date.

Keep out of the sight and reach of children!

6. FURTHER INFORMATION

What Genta cream contains

The **active substance** is gentamicin sulphate.

1 g cream contains gentamicin sulphate equivalent to 1 mg gentamicin (0.1%).

The **excipients** are: white soft paraffin, light liquid paraffin, methyl hydroxybenzoate, propyl hydroxybenzoate, propylene glycol, PEG stearate glycol stearate, purified water.

Content of the pack

Box with one tube that contains 15 g cream.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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