

PACKAGE LEAFLET: Information for the patient

GENTAKOL Eye drops solution – 0.3% (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.

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1. What Gentakol is and what it is used for
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1. WHAT GENTAKOL IS AND WHAT IT IS USED FOR

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

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

Gentamicin is inactive against anaerobic bacteria.

Gentakol eye drops solution is used for the treatment of bacterial eye infections caused by gram-negative and gram-positive bacteria such as: infective conjunctivitis, keratitis and blepharitis. It is also used for prophylaxis before and after ocular surgery.

2. BEFORE YOU USE GENTAKOL

Do not use Gentakol:

- if you are hypersensitive (allergic) to aminoglycosides where gentamicin belongs, or to any of the excipients of the medicinal 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 Gentakol

Ask your doctor before using Gentakol.

- If during treatment with Gentakol you are not relieved from symptoms, proceed with a bacteriological examination and a gentamicin resistance test. In such cases, also in case an irritation or hypersensitivity to one of the ingredients of the preparation occurs, the treatment with Gentakol should be stopped and other appropriate therapeutic measurements should be taken.
- Remove contact lenses during the period of treatment of ocular infections and replace them temporarily with glasses.
- Like all antibiotics, avoid long-term treatment because it can lead to proliferation of resistant bacteria.
- Do not continue using Gentakol in case of superinfection, but replace it with an appropriate treatment.
- To prevent the resistance phenomenon, avoid the preventive unjustified use of Gentakol.

Taking other medicines

Tell your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor about the treatment with Gentakol if you are given another drug during treatment.

Clinically significant interactions may occur only after systemic absorption of Gentakol.

Use of other drugs such as: kanamycin, neomycin, streptomycine, ciclosporin, acyclovir, polymyxin B, colistin, vancomycin, cisplatin, cephalosporins, amphotericin and fludarabine increases the risk of nephrotoxicity. Concomitant use of gentamicin with other ototoxic drugs

such as etachrynic acid and perhaps furosemide should be avoided because the risk of aminoglycoside toxicity may be increased as well as concomitant use with curare-type muscle relaxants.

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

In rare cases, patients may complain about burning sensation or stinging sensation in the eye, also having vision disorders. In these cases, driving or using machines is not allowed.

Important information about some of the excipients of Gentakol

This product contains 1 mg benzalkonium chloride / flacon 10 ml. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. HOW TO USE GENTAKOL

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

Gentakol is used locally in the eye in adults and children.

1 or 2 drops should be instilled in the affected eye every 4 hours (up to six times daily) in mild to moderate infections. In severe infections 2 drops every hour should be instilled.

Method of administration

- Wash your hands thoroughly
- Avoid touching the dropper tip
- Look up
- Pull down the lower lid of your eye to form a pocket
- Hold the dropper (tip down), as close to the eye as possible without touching it
- Drop the right quantity of drops in the pocket
- Close your eye for about 2 minutes
- Wipe any excess liquid from your face with a sterile tissue.

Eye drops may cause a burning sensation, but this sensation does not last more than several minutes. Otherwise, talk to your doctor or pharmacist.

If you use more Gentakol

If you use more Gentakol 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 Gentakol

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, Gentakol 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 treatment and disappear spontaneously during treatment.

The most common side effects of Gentakol are those of hypersensitivity which appear with itching, redness, local edema, difficulty in breathing or wheeziness can also happen.

If hypersensitivity reaction occurs, treatment with Gentakol should be discontinued.

In rare cases patients may complain about burning sensation or stinging sensation in the eye, also having vision disorders.

Other side effects may include:

- super-infection (infection occurring after an earlier infection);
- problems with your kidney function.

Talk to your doctor or pharmacist if any of these side effects gets serious or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE GENTAKOL

Store in a cool, dry place, under 25°C!

Protect it from light and humidity.

Do not freeze.

Do not use Gentakol after the expiry date.

Keep out of the sight and reach of children because it may harm them.

6. FURTHER INFORMATION

What Gentakol eye drops solution contains

The **active substance** is gentamicin sulphate.

1 ml eye drops solution contains gentamicin sulphate equivalent to 3 mg gentamicin (0.3 %).

The **excipients** are: benzalkonium chloride, sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate, water for injections.

Contents of the pack

Box with one sterile plastic bottle of 10 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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