

GENTAMICIN
Eye/Ear Drops 0.3% w/v
Gentamicin Sulphate

Please read this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or pharmacist. This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms 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. The medicine will be called Gentamicin in this leaflet.

In this leaflet:

1. What Gentamicin is and what it is used for
2. Before you use Gentamicin
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1. WHAT GENTAMICIN IS AND WHAT IT IS USED FOR

Gentamicin eye/ear Drops are a sterile, preserved, aqueous solution used as eye/ear drops. The active ingredient Gentamicin is an antibiotic used to kill bacteria which cause infection. It is used for the management of eye & ear infection.

2. BEFORE YOU USE GENTAMICIN

Do not use

- if you are allergic to Gentamicin, any of the ingredients, or any other aminoglycoside antibiotics
- if you have a perforated ear drum
- if you suffer from myasthenia gravis and related conditions

Before you use Gentamicin:

Take special care with Gentamicin

Avoid prolonged use

The drops must not be used in the ear if the ear drum is damaged in any way. Your doctor will check the condition of the ear drum before prescribing the drops. In severe infections treatment with a systemic antibiotic may be necessary in addition to Gentamicin Eye / Ear Drops

Ear damage may occur especially in susceptible individuals such as those with kidney or liver problems and in the elderly.

Caution is advised when the drops are used with other aminoglycoside antibiotics given by injection.

Do not use the eye drops with contact lenses.

Important information about some of the ingredients of Gentamicin Eye/Ear Drops

The drops contain benzalkonium chloride as preservative. This preservative is known to cause eye irritation and discolour soft contact lenses. Avoid contact with soft contact lenses. Remove contact lenses before using the eye drops and wait at least 15 minutes before reinserting.

Taking or using other medicines:

Check with your doctor before using the eye/ear drops if you are taking or using any other medicines. In particular:

- cephalosporins, amphotericin, cisplatin or cyclosporin which may increase the risk of kidney damage
- diuretic medicines such as ethacrynic acid or frusemide which may increase the risk of ear damage
- curare-type muscle relaxants

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicines.

Gentamicin should not be used during pregnancy and breast-feeding unless considered essential by your doctor.

Driving and using machines

No effects on ability to drive and use machines have been reported. However, do not drive or operate machines if you experience blurred vision after using as eye drops. Wait until your vision clears before driving or operating machines.

3. HOW TO USE GENTAMICIN

Always use Gentamicin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dose: Eye: Instill 1-2 drops into the affected eye every four hours as required.

Ear: The area should be cleaned and 2-4 drops instilled 3-4 times daily.

Children: No dosage adjustment required in children.

Instructions for use (Please also refer to pictograms at the end of the leaflet)

- First wash your hands
- Avoid touching the eye (or any other surface) with the tip of the bottle
- If you wear soft contact lenses, they should be removed before using the eye drops and wait at least 15 minutes before reinserting
- These drops are supplied as a sealed bottle with a spiked cap. When using the bottle for the first time, screw the cap down tightly in order to pierce the tip of the bottle
- Tilt your head back and look at the ceiling
- Pull the lower eyelid gently downwards
- Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye
- Keep the affected eye closed and press your fingertip against the inside corner of the closed eye, and hold for 1 minute
- Repeat for the other eye if necessary
- Replace and tighten the cap immediately after use.

As ear drops: The area should be cleaned, tilt head sideways and dispense drops with gentle pressure

Ocular solutions if handled wrongly, can become contaminated by common bacteria and cause eye infections. If you do develop any other eye condition whilst using this product, see your doctor immediately.

If you use more Gentamicin than you should : In adults an overdose due to the use of the eye / ear drops is unlikely, however, if you use too many drops or if the eye / ear drops are accidentally swallowed, you should contact your doctor.

If you forget to use Gentamicin Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal scheduled dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines Gentamicin can cause side effects although not everybody gets them. Side effects which you may experience include

- ear damage such as difficulty in keeping your balance or hearing loss
- kidney problems such as passing less water than usual or signs of blood in urine

- local sensitivity in the eye, transient eye irritation, blurred vision,
- burning or stinging sensation, itching
- local sensitivity in the ear, burning or stinging sensation, itching, skin inflammation
- if irritation or sensitivity occurs, tell your doctor at once. The treatment should be stopped.
- if any other side effect gets serious or if you notice any side effect 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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE GENTAMICIN

Do not store above 25⁰ C. Protect from light

Discard after 28 days of opening.

Keep all medicines out of the sight and reach of children.

The product should not be used after the expiry date. (This is printed on both the bottle label and on the carton the bottle is packed in).

6. FURTHER INFORMATION

What Gentamicin contains

Active ingredient is Gentamicin sulphate 0.3% w/v. Also contains 0.02% v/v benzalkonium chloride solution (as preservative), sodium chloride, disodium edetate, sodium metabisulphite, borax, sodium hydroxide solution, hydrochloric acid and purified water

What Gentamicin looks like and contents of the pack

Each bottle contains 10 ml of the clear, colourless to pale straw coloured eye/ear drop solution.

Marketing Authorisation Holder and Manufacturer

FDC International Ltd, Unit 6, Fulcrum 1, Solent Way, Whiteley, Fareham, Hampshire, PO15 7FE

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Hard to see or read the leaflet? Call + 44(0) 1489 565222 for help.

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MODE OF USE



Tighten the cap
on the nozzle.



The spike in
the cap will
pierce the tip
of the bottle.



Tilt head backwards.
Dispense drops with
gentle pressure. Do not
touch dropper tip to
the surface of the eye.