

PACKAGE LEAFLET: INFORMATION FOR THE USER

GENTOKULIN

0.3% w/v Eye/Ear Drops

GENTAMICIN SULPHATE

• 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 Gentamicin is and what it is used for
2. Before you use Gentamicin
3. How to use Gentamicin
4. Possible side effects
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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

- 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
- 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. 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 25°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 leaflet was last revised in: 06/2015