

Package leaflet: Information for the patient
Gentamicin 0.3% w/v Eye/Ear Drops
gentamicin

Read all of this leaflet carefully before you start using 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. See section 4.

What is in this leaflet

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2. What you need to know before you use Gentamicin 0.3% w/v Eye/Ear Drops
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1. What Gentamicin 0.3% w/v Eye/Ear Drops are and what they are used for

The name of your medicine is Gentamicin 0.3% w/v Eye/Ear Drops. Gentamicin 0.3% w/v Eye/Ear Drops contain the active ingredient gentamicin which belongs to a group of medicines called antibiotics.

Gentamicin 0.3% w/v Eye/Ear Drops are used in adults and children to treat bacterial infections in the eye or ear and to prevent infections in an injured eye or ear.

2. What you need to know before you use Gentamicin 0.3% w/v Eye/Ear Drops

Do not use Gentamicin 0.3% w/v Eye/Ear Drops:

- if you are allergic to gentamicin, any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to a similar medicine containing an aminoglycoside antibiotic
- if you have or suspect you have a burst ear drum, if you are being treated for a problem with your ear
- if you suffer from myasthenia gravis, a disease causing muscle weakness.

Warnings and precautions

Talk to your doctor or pharmacist before using Gentamicin 0.3% w/v Eye/Ear Drops:

- if you have any problems with your kidneys, liver or hearing
- if you know (or think you have) a mitochondrial disease (mutations in the parts of your cells which help make energy); certain mitochondrial diseases may increase your risk of hearing loss with this product.
- if you have open wounds or damaged skin
- if you are using this medicine for a long period of time.

Contact lenses should be removed when treating an eye infection with these drops.

If any of these apply to you, or if you are not sure, tell your doctor.

Other medicines and Gentamicin 0.3% w/v Eye/Ear Drops

Tell your doctor or pharmacist if you are using, or have recently used, or might use any other medicines.

This is especially important if you are taking:

- Ethacrynic acid (used in the treatment of high blood pressure and swelling) and furosemide (used in the treatment of congestive heart failure and swelling)
- Antibiotics such as cephalosporins
- Ciclosporin (used to stop the body rejecting bone marrow or organ transplants)
- Amphotericin (used to treat fungal infections)
- Cisplatin (used in anti-cancer therapy)
- Muscle relaxants

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Gentamicin 0.3% w/v Eye/Ear Drops are not recommended for use in pregnancy or breast-feeding unless considered appropriate by your doctor.

Driving and using machines

Gentamicin 0.3% w/v Eye/Ear Drops may cause temporary blurred vision when used in the eyes. If you are affected, do not drive or use machinery until the blurring has cleared.

Gentamicin 0.3% w/v Eye/Ear Drops contain Benzalkonium Chloride

This medicine contains 0.2mg of benzalkonium chloride in each 1 ml, which is equivalent to 0.2mg/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 Gentamicin 0.3% w/v Eye/Ear Drops

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Eyes:

The recommended dose is 1-2 drops into the infected eye up to 6 times a day. For more severe infections your doctor may tell you to use the drops more often than this. Contact lenses should be removed when treating an eye infection with these drops.

Ears:

You should clean the area and then use 2-3 drops, three to four times a day and at night. Your doctor may tell you to use the drops more often than this.

The drops should not be used continuously for a long time as it may irritate your skin and the drops may stop working.

If your infection is severe, your doctor may also give you antibiotics by injection.

If you swallow your Gentamicin 0.3% w/v Eye/Ear Drops

If you, or someone else, accidentally swallows some of this medicine, contact your doctor, pharmacist or nearest hospital emergency department **immediately**.

If you forget to use Gentamicin 0.3% w/v Eye/Ear Drops

If you forget to use your drops, use your next dose as soon as you remember and continue as before.

Do not take a double dose to make up for 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, this medicine can cause side effects, although not everybody gets them.

If you notice following side effects, stop using these drops and tell your doctor immediately:

- hearing loss when used in your ears
- symptoms like dizziness or vertigo (vestibular disorder)
- irritation, burning, stinging, and itching of the skin (at the application site)
- blurred vision
- super infection (infection occurring after an earlier infection)
- skin inflammation (dermatitis)
- problems with your kidney function.

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gentamicin 0.3% w/v Eye/Ear Drops

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the carton and label after EXP.

The expiry date refers to the last day of that month.

Store your medicine in a safe place below 25°C and do not freeze.

Do not use for more than 4 weeks after opening.

Return any unused drops to the pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Gentamicin 0.3% w/v Eye/Ear Drops contain

The active substance is gentamicin sulfate 0.3% w/v gentamicin base.

The other ingredients are benzalkonium chloride BP, borax Ph.Eur, Sodium chloride Ph.Eur, water for injection Ph.Eur.

What Gentamicin 0.3% w/v Eye/Ear Drops look like and contents of the pack

The eye/ear drops are available in 10ml dropper bottles.

Marketing Authorisation Holder

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