

Package leaflet: information for the patient

Genticin® 0.3% w/v Eye/Ear Drops, Solution 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:

1. What Genticin 0.3% w/v Eye/Ear Drops Solution is and what it is used for
2. What you need to know before you use Genticin 0.3% w/v Eye/Ear Drops Solution
3. How to use Genticin 0.3% w/v Eye/Ear Drops Solution
4. Possible side effects
5. How to store Genticin 0.3% w/v Eye/Ear Drops Solution
6. Contents of the pack and other information

1. What Genticin 0.3% w/v Eye/Ear Drops Solution is and what it is used for

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

Genticin 0.3% w/v Eye/Ear Drops Solution is 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 Genticin 0.3% w/v Eye/Ear Drops Solution

Do not use Genticin 0.3% w/v Eye/Ear Drops Solution if you:

- are allergic to gentamicin, any of the other ingredients of Genticin 0.3% w/v Eye/Ear Drops Solution (listed in section 6), or to a similar medicine containing an aminoglycoside antibiotic;
- have or suspect you have a burst ear drum, if you are being treated for a problem with your ear;
- suffer from myasthenia gravis, a disease causing muscle weakness.

Warnings and precautions

Talk to your doctor or pharmacist before using Genticin 0.3% w/v Eye/Ear Drops Solution if you:

- have any problems with your kidneys or liver and especially if you are elderly;
- are applying into the middle ear, as topical application of aminoglycoside antibiotics into the middle ear may lead to deafness due to ear toxicity;
- have an open wounds or damaged skin, as topical application to these areas may cause deafness;
- are using this medicine for a long period of time as it may lead to skin sensitization and organism resistance;

- are using other aminoglycoside antibiotics such as erythromycin, as cross sensitivity may occur;
- are using this medicine in severe infections, as topical use of gentamicin should be supplemented with appropriate systemic antibiotic treatment-;
- are using contact lenses, as it should be removed during the period of treatment of ocular infections.

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

Other medicines and Genticin 0.3% w/v Eye/Ear Drops Solution

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);
- 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 breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Genticin 0.3% w/v Eye/Ear Drops Solution is not recommended for use in pregnancy or breast-feeding unless considered appropriate by your doctor.

Driving and using machines

Genticin 0.3% w/v Eye/Ear Drops Solution 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.

Genticin 0.3% w/v Eye/Ear Drops Solution contains benzalkonium chloride

Genticin 0.3% w/v Eye/ear drops contains 6.44µg of benzalkonium chloride (50% w/v) in each drop 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.

For use in ear: Benzalkonium chloride may irritate the skin.

3. How to use Genticin 0.3% w/v Eye/Ear Drops Solution

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

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 Genticin 0.3% w/v Eye/Ear Drops Solution

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 Genticin 0.3% w/v Eye/Ear Drops Solution

apply the next dose as soon as you remember and continue as before.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice:

- itching or skin rashes;
- swelling of the face, lips or throat;
- difficulty in breathing or wheeziness.

Stop using these drops and tell your doctor immediately. These may be signs of an allergic reaction.

Side effects may include:

Not known: frequency cannot be estimated from the available data

- problem with your kidney function;
- hearing loss when used in your ears;
- blurred vision;
- irritation, burning, stinging, and itching of the skin (at the application site). If this occurs, stop treatment and talk to your doctor;
- super infection (a new, added infection);
- dizziness;
- tinnitus (ringing in your ears);
- this product contains the preservative benzalkonium chloride which may cause eye irritation or skin reactions and is known to discolour soft contact lenses.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

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

Keep this medicine out of the sight and reach of children.

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

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Gentacin 0.3% w/v Eye/Ear Drops Solution contains

The eye/ear drops contain the active ingredient gentamicin sulfate 0.3% w/v gentamicin base. The other ingredients are benzalkonium chloride, borax (E285), sodium chloride, water for injections.

What Gentacin 0.3% w/v Eye/Ear Drops Solution looks like and the contents of the pack

Gentacin 0.3% w/v Eye/Ear Drops Solution is a clear colourless solution. The eye/ear drops are available in 10ml dropper bottles.

Marketing Authorisation Holder:

Amdipharm Limited,
Temple Chambers,
3 Burlington Road,
Dublin 4,
Ireland.

Manufacturer responsible for release:

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Manufacturer and Batch Release Site:

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