

102656/LF/1

Package leaflet: information for the patient

## Gentacin® 0.3% w/v Eye/Ear Drops, Solution

### Gentamicin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

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

#### 1. WHAT GENTACIN 0.3% W/V EYE/EAR DROPS SOLUTION IS AND WHAT IT IS USED FOR

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

Gentacin 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 GENTACIN 0.3% W/V EYE/EAR DROPS SOLUTION

##### Do not use this medicine if you:

- are **allergic** to gentamicin, any of the other ingredients of Gentacin 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 Gentacin 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 Gentacin 0.3% w/v Eye/Ear Drops Solution

Please tell your doctor if you are taking, or have recently taken, or might take any other medicines including those obtained without a prescription.

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. Gentacin 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

Gentacin 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.

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

GNE 75028

AMDIPHARM



AMDIPHARM

PRODUCT NAME: Gentacin Eye/Ear 0.3% drops  
1 x 10 ml  
PIP CODE: 102656/LF/1  
COMPONENT: Leaflet  
SIZE: 140 x 170 mm  
MARKET: Ireland  
COMMODITY NO.: GNE 75028  
PRODUCT SITE: Patheon  
SCALE: 100%  
COLOURS: 281C & Cutter  
DATE: 23/09/2014  
FONT SIZE: 8 pt  
VERSION NO: 1  
AMENDED BY: AMCo  
PROJECT: Amdipharm

#### REGULATORY AUTHORITY APPROVAL CONFIRMATION

Confirmation that this artwork has been approved by the appropriate market authority (if applicable, e.g. MHRA, IMB, etc and that Amdipharm have license approval to distribute this component for sale in the relevant market.

Accept Artwork .....

Reject Artwork .....

Signature .....

Name .....

Date .....

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- for ocular use: May cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour soft contact lenses;
- for ear use: Irritant. May cause skin reactions.

### 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 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 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, Genticin 0.3% w/v Eye/Ear Drops

Solution 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:

- 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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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 Genticin 0.3% w/v Eye/Ear Drops Solution contains

The eye/ear drops contain the active ingredient gentamicin sulphate 0.3% w/v gentamicin base.

The other ingredients are benzalkonium chloride, borax (E285), sodium chloride, purified water.

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

Genticin 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:

Amdipharm UK Limited  
Capital House, 85 King William Street, London EC4N 7BL, UK

#### Date of Preparation of leaflet: September 2014.

*Genticin is a registered trademark of Amdipharm Mercury International Limited*

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