

Patient Information Leaflet

# Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v Ear Drops

Gentamicin and Hydrocortisone acetate

**Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v Ear Drops; it will be called Gentamicin and Hydrocortisone Ear Drops for ease here after.

## What is in this leaflet:

1. What Gentamicin and Hydrocortisone Ear Drops are and what they are used for
2. What you need to know before you use Gentamicin and Hydrocortisone Ear Drops
3. How to use Gentamicin and Hydrocortisone Ear Drops
4. Possible side effects
5. How to store Gentamicin and Hydrocortisone Ear Drops
6. Contents of the pack and other information

### 1. What Gentamicin and Hydrocortisone Ear Drops are and what they are used for

Gentamicin and Hydrocortisone Ear Drops contain the active ingredients gentamicin which belongs to a group of medicines called antibiotics and hydrocortisone acetate which is a steroid.

Gentamicin and Hydrocortisone Ear Drops are used in adults and children to treat eczema and bacterial infections in the external ear, to prevent infections in an injured ear and to treat infected bone cavities (mastoid) behind the ear after an operation.

### 2. What you need to know before you use Gentamicin and Hydrocortisone Ear Drops

#### Do not use this Gentamicin and Hydrocortisone Ear Drops:

- if you are allergic to gentamicin, hydrocortisone or similar medicine containing an aminoglycoside antibiotic or steroid or to any of the other ingredients of this medicine (listed in section 6)

- if you have or suspect you have a burst ear drum, if you are being treated for a problem with your external ear
- if you suffer from myasthenia gravis, a disease causing muscle weakness.

#### Warnings and precautions:

Talk to your doctor or pharmacist before using Gentamicin and Hydrocortisone Ear Drops if you:

- Have any problems with your kidneys or liver
- Are using this medicine for a long period of time
- Have open wounds or damaged skin.

Some medicines may increase the effects of Gentamicin and Hydrocortisone Ear Drops and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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

Contact your doctor if you experience blurred vision or other visual disturbances.

#### Other medicines and Gentamicin and Hydrocortisone Ear Drops

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

#### 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 using this medicine.

Gentamicin and Hydrocortisone Ear Drops are not recommended for use in pregnancy or breast-feeding unless considered appropriate by your doctor.

#### Driving and using machinery

This medicine should not affect your ability to drive or use machines.

#### Gentamicin and Hydrocortisone Ear Drops contain Benzalkonium chloride

Irritant, may cause skin reactions.

### 3. How to use Gentamicin and Hydrocortisone 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.

Shake the bottle before use. The recommended dose is 2-4 drops three to four times a day and at night.

Alternatively, wicks medicated with your medicine may be placed into the external ear or into the bone cavity behind your ear (mastoid).

The drops should not be used continuously for a long time as it may irritate your skin. If your infection is severe, your doctor may also give you antibiotics by injection.

#### **If you swallow your 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 and Hydrocortisone Ear Drops**

If you forget to use your drops, use your next dose as soon as you remember and continue as before. Do not apply 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, pharmacist or nurse.

### 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.**

#### **Other side effects include:**

Not known (frequency cannot be estimated from the available data)

- Super infection (infection occurring after an earlier infection)
- Hearing loss
- Burning sensation
- Stinging sensation
- Itching at the site of administration
- Blurred vision

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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](http://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 and Hydrocortisone Ear Drops

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

Store your medicine in a safe place. Do not store above 25°C and do not freeze or mix with other liquids.

This medicine must not be used after the expiry date printed on the pack. The expiry date refers to the last day of that month.

Do not use for more than 4 weeks after opening.

If your ear drops shows signs of discolouration or deterioration, seek the advice of your pharmacist who will tell you what to do.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

### 6. Contents of the pack and other information

#### **What Gentamicin and Hydrocortisone Ear Drops contain**

The drops contain 0.3% w/v gentamicin (3000 units/ml, as sulfate) and 1% w/v hydrocortisone acetate.

The other ingredients are benzalkonium chloride, povidone (E1201), macrogol 4000, sodium chloride, borax (E285), disodium edetate and water for injections.

#### **What Gentamicin and Hydrocortisone Ear Drops look like and the contents of the pack**

The ear drops are available as a white suspension in 10 ml dropper bottles.

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

Alternative manufacturer: Famar S.A., Agiou Dimitriou 63, Alimos Attiki, 17456, Greece

Product Licence Holder: Purepharm Limited, Unit 3B Bluestone Business Park, Moyraverty West Road, Craigavon, BT65 5HU, UK

**PL 45310/0004.**

**Leaflet date: 28 March 2018**

POM

Blind or partially sighted? To request a copy of this leaflet in an alternative format please call 028 8778 4747