

Package Leaflet: Information for the User  
**Gentisone® HC Ear Drops**  
(gentamicin sulfate / hydrocortisone acetate)

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

### 1. What Gentisone HC Ear Drops are and what they are used for

The name of your medicine is Gentisone HC Ear Drops. Gentisone HC Ear Drops contain the active ingredients gentamicin which belongs to a group of medicines called antibiotics and hydrocortisone acetate which is a steroid.

Gentisone HC 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 Gentisone HC Ear Drops

#### Do not use Gentisone HC Ear Drops:

- if you are allergic to gentamicin, hydrocortisone or similar medicine containing an aminoglycoside antibiotic or steroid or 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 Gentisone HC Ear Drops:

- 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 any problems with your kidneys or liver
- if you are using this medicine for a long period of time
- if you have open wounds or damaged skin.

Some medicines may increase the effects of Gentisone HC 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 either 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 Gentisone HC Ear Drops

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

#### 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.

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

#### Driving and using machines

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

**Gentisone HC Ear Drops contain benzalkonium chloride** which may irritate the skin.

### 3. How to use Gentisone HC 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 Gentisone HC 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 Gentisone HC 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 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:**

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 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 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 Gentisone HC Ear Drops

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not freeze or mix with other liquids.
- Do not use Gentisone HC Ear Drops after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Do not use for more than 4 weeks after opening.
- If your medicine shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Gentisone HC Ear Drops contain

The drops contain 0.3% w/v of 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 Gentisone HC Ear Drops look like and contents of the pack

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

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

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

Procured from within the EU by the Product Licence Holder:  
MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way,  
Aldridge, Walsall, WS9 8ER.

Repackaged by MPT Pharma Ltd.

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Braille, large print or audio please  
call 01922 745645 and ask for the  
Regulatory Department.

# Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v Ear Drops (gentamicin sulfate / hydrocortisone acetate)

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- 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.
- Your medicine is called Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v Ear Drops but will be referred to as Gentamicin and Hydrocortisone Ear Drops throughout the remainder of this leaflet.

## 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

The name of your medicine is Gentamicin and Hydrocortisone Ear Drops. 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 Gentamicin and Hydrocortisone Ear Drops:

- if you are allergic to gentamicin, hydrocortisone or similar medicine containing an aminoglycoside antibiotic or steroid or any of the other ingredients of this medicine (listed in section 6)
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### 3. How to use Gentamicin and Hydrocortisone Ear Drops

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## 6. Contents of the pack and other information

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