

Package leaflet: Information for the user
Gentisone® HC 0.3% w/v & 1.0% w/v Ear Drops, suspension
gentamicin sulphate and hydrocortisone acetate

The name of your medicine is Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops, suspension but will be referred to as Gentisone HC Ear Drops throughout this leaflet.

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, 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 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 this 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 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 machinery

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 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 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 infections (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 website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in 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 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.

Do not store above 25°C. Do not freeze or mix with other liquids.

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 Gentisone HC Ear Drops contains

The ear drops contain the active ingredients gentamicin sulphate = 0.3% w/v gentamicin base (3,000 units per ml), and 1.0% w/v hydrocortisone acetate.

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

What Gentisone HC Ear Drops look like and the contents of the pack

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

Manufactured by Amdipharm UK Limited, Capital House, 85 King William Street, London, EC4N 7BL, UK or Famar S.A., Agiou Dimitriou 63, Alimos Attiki, 17456, Greece and procured from within the EU and repackaged in the UK by the Parallel Import Product Licence holder: CD Pharma Ltd, 4 Cairn Court, East Kilbride, G74 4NB.

Gentisone HC 0.3% w/v & 1.0% w/v, Ear Drops, suspension

PLGB: 20492/0564

POM

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Call 1355 204 448 to obtain a leaflet in a format suitable for you.

Date of Preparation: 21st November 2024

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Package leaflet: Information for the user

Gentamicin 0.3% w/v and Hydrocortisone 1.0% w/v Ear drops

gentamicin sulphate and hydrocortisone acetate

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1. WHAT GENTAMICIN EAR DROPS ARE AND WHAT THEY ARE USED FOR

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Gentamicin 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 EAR DROPS

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