

Gentisone[®] HC Ear Drops

(gentamicin sulphate and hydrocortisone acetate)

Patient Information 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, pharmacist or nurse. 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 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 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
- 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 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, 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.

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 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 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 Website: 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.**
- Store your medicine in a safe place below 25°C and do not freeze or mix with other liquids.
- Do not use for more than 4 weeks after opening.
- Do not use this medicine after the expiry date which is stated on the label and the outer carton after EXP. The expiry date refers to the last day of that month.
- Return any unused medicine 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.
- If your medicine becomes discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6) Contents of the pack and other information

What Gentisone HC Ear Drops contain:

The active substances are gentamicin sulphate 0.3% w/v gentamicin base and 1.0% w/v hydrocortisone acetate.

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

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

Gentisone HC Ear Drops are available as a white, odourless suspension in 10ml dropper bottles.

PL 46420/0305 Gentisone HC Ear Drops

POM

Who makes and repackages your medicine?

Your medicine is 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.

Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 20.09.2021

Gentisone is a registered trademark of Amdipharm Mercury International Limited, Jersey.

Blind or partially sighted?

Is this leaflet hard to see or read?

Call 020 8839 3000 to obtain the leaflet in a format suitable for you.

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

(gentamicin sulphate and hydrocortisone acetate)

Your medicine is known by the above name but will be referred to as Gentamicin and Hydrocortisone Ear Drops throughout this leaflet.

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- 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
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1) What Gentamicin and Hydrocortisone Ear Drops are and what they are used for

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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

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