

## **Package leaflet: information for the user**

### **Gentisone®HC 0.3% w/v & 1.0% w/v Ear Drops Suspension Gentamicin and 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, 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 0.3% w/v & 1.0% w/v Ear Drops Suspension is and what it is used for
2. What you need to know before you use Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension
3. How to use Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension
4. Possible side effects
5. How to store Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension
6. Contents of the pack and other information

#### **1. What Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension is and what it is used for**

The name of your medicine is Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension. This medicine contains the active ingredients gentamicin which belongs to a group of medicines called antibiotics and hydrocortisone acetate which is a steroid.

Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension is 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 0.3% w/v & 1.0% w/v Ear Drops Suspension**

##### **Do not use this medicine:**

- 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, pharmacist or nurse before using Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension 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 in infants, as there is a theoretical risk that adrenal suppression (reduced steroid production) may occur if sufficient Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension is absorbed. Symptoms might include not taking food, vomiting, diarrhoea and general weakness.

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

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

**Other medicines and Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension**

Tell your doctor 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 0.3% w/v & 1.0% w/v Ear Drops Suspension is 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 0.3% w/v & 1.0% w/v Ear Drops Suspension contains benzalkonium chloride**

Irritant. May cause skin reactions.

**3. How to use Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension**

Always use this medicine exactly as your doctor or pharmacist has told. 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 Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension 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 0.3% w/v & 1.0% w/v Ear Drops Suspension**

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 take Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension**

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 reported at the following frequency include:

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

- hearing loss;
- problem with your kidney function;
- skin reactions (irritation, burning, itching, stinging, redness);
- super infection (a new, added infection);
- tinnitus (ringing in your ears);
- dizziness;
- 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 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 Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension**

**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 label and carton after EXP. The expiry date refers to the last day of that month.

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.

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 Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension contains**

- The active substances are gentamicin sulfate 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 water for injections.

### **What Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension looks like and the contents of the pack**

Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension is a white to pale yellow suspension. This is 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.

### **Alternative manufacturer responsible for release:**

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

**This leaflet was last revised in February 2024.**

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