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 taking 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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 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, any of the other ingredients of Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension or similar medicine containing an aminoglycoside antibiotic or steroid
- have or suspect you have a burst ear drum, if you are being treated for a problem with your external ear
- suffer from myasthenia gravis, a disease causing muscle weakness.

Warnings and precautions

Talk to your doctor or pharmacist 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.
- 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

Please tell your doctor if you are taking or have recently taken, or might take any other medicines including those 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 taking 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 and 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
told. Check with your doctor or pharmacist if you are not
sure.

Shake the bottle, and use 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.

4. Possible side effects
Like all medicines, Gentisone HC 0.3% w/v & 1.0% w/v Ear
Drops Suspension 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:
• 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.

Reporting of side effects
If you get any side effects, talk to your doctor or 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; E-mail: 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.
Store your medicine in a safe place below 25°C and do not
freeze or mix with other liquids.

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.

Do not use for more than 4 weeks after opening.
Return any unused drops to the pharmacist.

Like all medicines, Gentisone HC 0.3% w/v & 1.0% w/v Ear
Drops Suspension can cause side effects, although not
everybody gets them.

6. Contents of the pack and other information
What Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops
Suspension contains
Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops Suspension
contains the active ingredient gentamicin sulphate 0.3% w/v
gentamicin base and 1.0% w/v hydrocortisone acetate.
The other ingredients are: benzalkonium chloride, povidone
(E1201), macroag 4000, sodium chloride, borax (E285),
disodium edetate and purified water.

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 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

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