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PACKAGE LEAFLET: INFORMATION FOR THE USER

Chloramphenicol 5% w/v Ear Drops

Chloramphenicol

Read all of this leaflet carefully before you are given 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.
- 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.

This medicine will be referred to as Chloramphenicol ear drops in the rest of this leaflet.

What is in this leaflet

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

1. What Chloramphenicol Ear Drops are and what they are used for

Chloramphenicol belongs to a group of medicines called antibiotics. An antibiotic is a medicine which is used for the treatment of a variety of infections caused by bacteria. Chloramphenicol Ear Drops are used in the treatment of a wide range of bacterial infections of the outer ear.

2. What you need to know before you use Chloramphenicol Ear Drops**Do not use Chloramphenicol Ear Drops if:**

- you are allergic to Chloramphenicol, or any of the ingredients of this medicine (listed in section 6).
- you have a hole in your ear drum.
- you or someone in your family ever had a blood disorder or bone marrow disease including anemia (decrease in the number of red blood cells) when using chloramphenicol in the past.
- you have a family history of "dyscrasias", a condition which can cause tiredness, bruising and an increased risk of infections.

Warnings and Precautions**Talk to your doctor, pharmacist or nurse before using Chloramphenicol Ear Drops if:**

- If you use chloramphenicol ear drops for a long time, your doctor may do some blood tests to check for any problems.

Other medicines and Chloramphenicol Ear Drops

Tell your doctor, pharmacist or nurse if

you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking any of the following:

- medicines for cancer such as methotrexate
- medicines for the immune system such as azathioprine
- the dietary supplement chymotrypsin

Pregnancy, breast-feeding and fertility

Chloramphenicol should not be used during pregnancy and breast-feeding unless considered essential by your doctor, as the effects are unknown. If you are a 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.

Driving and using machines

It is unlikely that after using Chloramphenicol Ear Drops your ability to drive and use machines will be affected. However, if you feel unwell you must speak to your doctor before driving or operating machinery.

Chloramphenicol Ear Drops contain propylene glycol.

This medicine contains 0.95g of propylene glycol in 1ml which is equivalent to 95% w/v.

3. How to use Chloramphenicol 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.

Instructions for use

1. Wash your hands well before use
2. Remove the outer cap on the bottle
3. Insert the nozzle into the affected ear and apply drops as advised by your doctor
4. Repeat in the other ear if you have been told to use Chloramphenicol Ear Drops in both ears
5. Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including the fingers
6. Wash your hands.

How much to use

Three to four drops should be applied into the affected ear up to two to three times daily for up to one week.

Continued overleaf

Do not use Chloramphenicol Ear Drops for more than a one week period unless your doctor has told you otherwise.

If you use more chloramphenicol than you should

Chloramphenicol Ear Drops are for external use only. If you suspect someone has swallowed any Chloramphenicol Ear Drops, contact your doctor or go to the accident and emergency department of your local hospital at once. Always take the container with you, if possible, even if empty.

If you forget to use Chloramphenicol Ear Drops

Try not to miss doses. If you do miss a dose do not worry, take your next dose at the normal time. Do not use extra drops to make up.

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 Chloramphenicol Ear Drops can cause side effects, although not everyone gets them.

Stop using your medicine and tell your doctor or pharmacist immediately if you experience the following side effects:

- Wheeziness (shortness of breath), fever, swelling of your face, lips or tongue, itching or rash with swelling of skin (the rash could be puffy (swollen) or blotchy, or look like little blisters).
- A sore throat, bruising or being unable to overcome an infection. On very rare occasions, patients using chloramphenicol have had changes in their blood cells causing severe tiredness or easy bruising.

Possible side effects include:

- inflammation of the skin (dermatitis).

Rare side effects include:

- bone marrow depression (a condition where the marrow is unable to produce blood cells)
- a reduced production and death of red blood cells (anaemia)

Long term use of this product can stop it having any effect.

Serious side effects are possible if you are pregnant. If you become pregnant during your course of treatment, stop immediately and consult your doctor.

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 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 Chloramphenicol Ear Drops

Keep out of the sight and reach of children.

Do not use Chloramphenicol Ear Drops after the expiry date printed on the bottle label. The expiry date refers to the last day of that month.

This medicine needs to be stored upright between 2-8°C (in a refrigerator). Protect from light. Do not allow it to freeze.

Once you have opened the bottle it should not be used after four weeks.

Do not throw away any medicines 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 Chloramphenicol Ear Drops contain**

The active ingredient is Chloramphenicol 5% w/v. The other ingredient is Propylene Glycol (95%).

What Chloramphenicol Ear Drops look like and contents of the pack
Chloramphenicol Ear Drops are supplied in plastic bottles, each bottle containing 10ml of solution.

Marketing Authorisation Holder and Manufacturer

Martindale Pharmaceuticals Ltd.
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If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at the above address.

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