Chloromycetin® Ear Drops

Chloramphenicol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Chloromycetin Ear Drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Chloromycetin Ear Drops against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Chloromycetin is used for

Chloromycetin Ear Drops are used to treat bacterial infections of the ear.

Chloromycetin belongs to a group of medicines called antibiotics.

It works by stopping the growth of bacteria causing your infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you use it

When you must not use it

Do not use Chloromycetin Ear Drops if you have an allergy to:

- chloramphenicol
- any of the ingredients listed at the end of this leaflet
- any other similar medicines.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Chloromycetin Ear Drops should not be used if you have a burst eardrum.

Do not give Chloromycetin to babies or children, unless your doctor tells you to.

Do not use Chloromycetin Ear Drops after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had anaemia, bleeding or other blood problems.

Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding. Your doctor will discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start using Chloromycetin Ear Drops.

Taking or using other medicines

Tell your doctor or pharmacist if you are taking or using any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Chloromycetin Ear Drops and some other medicines may interfere with each other. These include other ear drops.

These medicines may be affected by Chloromycetin or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Chloromycetin.

How to use Chloromycetin Ear Drops

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to use

The dose of Chloromycetin may be different for different people. Your doctor or pharmacist will tell you the right amount to use.

The usual dose is four drops placed into the infected ear four times a day.

How to use them

Thoroughly clean your ear canal and dry it with a cotton applicator before using Chloromycetin Ear Drops.

You may warm Chloromycetin Ear Drops to body temperature, but no higher, by holding the bottle in your hand for a few minutes.

Lie down or tilt your head so the infected ear is facing upwards. Place the required number of drops into the ear canal. Keep the ear facing up for about 5 minutes to allow the medicine to coat the ear canal. For young children who cannot stay still for 5 minutes, try to keep the ear facing up for 1 to 2 minutes.

To keep the medicine as germ-free as possible do not touch the dropper to any surface (including the ear). Close the container tightly after use.

How long to use them

Continue using Chloromycetin Ear Drops for as long as your doctor tells you.

If you stop using this medicine too soon your symptoms may return.

If you forget to use them

If it is almost time for your next dose (less than 2 hours), skip the dose you missed and instil your next dose when you are meant to.

Otherwise, instil a dose as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26), or the New Zealand National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or go to Accident and Emergency at the nearest hospital if you think an infant or young child may have accidentally swallowed Chloromycetin Ear Drops.

Do this even if there are no signs of discomfort or poisoning. The child may need urgent medical attention.

Contact your doctor or the Australian Poisons Information Centre (telephone 13 11 26), or the New Zealand National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) if you or another adult accidentally swallows Chloromycetin Ear Drops. It is a good idea to do this even if there are no signs of discomfort or poisoning.

While you are using Chloromycetin Ear Drops

Things you must do

Use Chloromycetin Ear Drops exactly as your doctor has told you.

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

Stop using Chloromycetin Ear Drops and tell your doctor if irritation occurs or you experience an allergic reaction.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Chloromycetin Ear Drops.

Tell any other doctors, dentists, and pharmacists who treat you that you are using Chloromycetin.

Keep all of your doctor appointments so that your progress can be checked.

Things you must not do

Do not use Chloromycetin Ear Drops for longer than your doctor has prescribed.

Do not use Chloromycetin Ear Drops to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine or lower the dosage without checking with your doctor. If you do not complete the full course prescribed by your doctor, the infection may not be completely cured. The bacteria may grow again and your symptoms may return.

Things to be careful of

Be careful driving or operating machinery until you know how Chloromycetin Ear Drops affect you.

This medicine generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Chloromycetin may cause tiredness in some people. If you are affected, do not drive, operate machinery or do anything else that could be dangerous.

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Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well during or after using Chloromycetin Ear Drops.

Chloromycetin helps most people with ear infections, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice

any of the following and it worries you:

• temporary itching or burning

Tell your doctor as soon as possible if you notice any of the following:

- worsening of your condition
- skin rash, itching or swelling
- fever
- unusual tiredness, weakness, bleeding or bruising more easily than normal

The above list includes serious side effects, which may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

 allergic reactions including fever, rash, swelling of the face, lips, mouth or sore throat that may cause difficulty in swallowing or breathing, shortness of breath, swelling of the hands, feet or ankles.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some people.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell during or after treatment with Chloromycetin.

After using Chloromycetin Ear Drops

Storage

Keep your Ear Drops in the bottle until it is time to use them. If you take the Ear Drops out of the bottle they may not keep well.

Keep unopened bottles in the refrigerator, where the temperature stays between 2°C and 8°C.

After opening, keep Chloromycetin Ear Drops in a cool dry place where the temperature stays below 25°C. Protect from light.

Discard unused Ear Drops within one month.

Do not store Chloromycetin Ear Drops or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep Chloromycetin Ear Drops where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using Chloromycetin or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Chloromycetin Ear Drops should be discarded within one month after opening.

Product description

What it looks like

Chloromycetin Ear Drops are in a 5 mL white, plastic, dropper bottle with a tamper evident seal.

Ingredients

Each 1 mL contains 5 milligrams of chloramphenicol as the active ingredient. It also contains:

- borax
- boric acid
- phenylmercuric nitrate.
- purified water

Chloromycetin Ear Drops do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Chloromycetin Ear Drops are supplied in Australia by: Pfizer Australia Pty Ltd ABN 50 008 422 348 38-42 Wharf Road West Ryde NSW 2114 Australia Toll Free Number: 1800 675 229 Chloromycetin Ear Drops are supplied in New Zealand by: Pfizer New Zealand Ltd PO Box 3998 Austhened New Zealand

Auckland, New Zealand Toll Free Number: 0800 736 363 Australian Registration Number:

AUST R 57082

This leaflet was revised on 1 March 2005.

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