

# CILODEX<sup>®</sup> EAR DROPS

Ciprofloxacin hydrochloride 0.3% and dexamethasone 0.1%

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## What is in this leaflet

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This leaflet answers some common questions about Cilodex<sup>®</sup> 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 benefits and risks. Your doctor has weighed the risks of you using Cilodex<sup>®</sup> Ear Drops against the expected benefits of using this medicine.

**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.

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## What CILODEX<sup>®</sup> Ear Drops is used for

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Cilodex<sup>®</sup> Ear Drops is used to treat acute middle ear infection in patients with draining ear tubes (tympanostomy tubes or "Grommets") or to treat an outer ear infection.

Cilodex<sup>®</sup> contains two active substances:

A substance called ciprofloxacin hydrochloride which is an antibiotic that belongs to a group of medicines called fluoroquinolones. This antibiotic is effective against many types of germs that can cause bacterial infection in your ear(s).

A substance called dexamethasone, which is a corticosteroid or anti-inflammatory agent that will help to relieve inflammation and redness.

Cilodex<sup>®</sup> Ear Drops will not work against infections caused by viruses, such as colds or the flu or fungal infections.

Before prescribing Cilodex<sup>®</sup> Ear Drops, the doctor will have examined your ear(s) and decided that Cilodex<sup>®</sup> Ear Drops is the right medicine.

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

Your doctor may have prescribed Cilodex<sup>®</sup> Ear Drops for another reason.

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## Before you use CILODEX<sup>®</sup> EAR DROPS

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### ***When you must not use it***

**Do not use Cilodex<sup>®</sup> Ear Drops if you have an allergy to:**

- ciprofloxacin, other fluoroquinolone antibiotics, dexamethasone or any of the ingredients in Cilodex<sup>®</sup> Ear Drops listed under *Product Description* 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.

Ask your doctor or pharmacist to be sure you do not have any of these conditions.

**Do not use Cilodex<sup>®</sup> Ear Drops if:**

- the seal around the cap is broken
- the bottle/packaging shows signs of tampering

- the expiry date on the bottle/carton has passed.
- If you use this medicine after the expiry date has passed, it may not work.

Do not use Cilodex<sup>®</sup> Ear Drops just before having a bath, shower or going swimming. If you do, you may reduce the effectiveness of this medicine.

**If you are not sure whether you should start using Cilodex<sup>®</sup> Ear Drops, talk to your doctor.**

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## **Before you start to use it**

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**Tell your doctor if you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.**

**Tell your doctor if you have or have had any medical conditions.**

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.** Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you use Cilodex<sup>®</sup> Ear Drops.**

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## **Using other medicines**

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

Some medicines and Cilodex<sup>®</sup> Ear Drops may interfere with each other. These include:

- medicines to thin your blood (e.g. warfarin)
- medicines to prevent tissue or transplant rejection (e.g. cyclosporin)
- theophylline for asthma or breathing problems
- caffeine for the treatment of migraines.

These medicines may be affected by Cilodex<sup>®</sup> Ear Drops, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

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## **How to use CILODEX<sup>®</sup> EAR DROPS**

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**Follow all directions given to you by your doctor and pharmacist carefully.** They may differ from the information contained in this leaflet.

If you are being changed from one ear drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

**If you do not understand the instructions on the carton / bottle, ask your doctor or pharmacist for help.**

### ***How much to use***

Use Cilodex<sup>®</sup> Ear Drops only when prescribed by your doctor.

The usual dose for adults and children is four drops of Cilodex<sup>®</sup> Ear Drops in the affected ear(s), twice each day for seven days – morning and evening.

**Your doctor will tell you how many drops you need to use each day.** These dosing instructions will be printed on the label your pharmacist puts on the bottle or carton.

## ***How to use it***

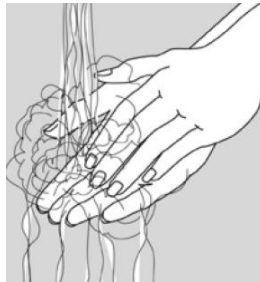
It is important to use Cilodex<sup>®</sup> Ear Drops exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and the ear problem may not improve. Using it more often than you should may not improve the ear problem any faster and may cause increased side effects.

**Before opening the bottle for the first time, make sure the safety seal joining the cap to the bottle is not broken. If it is, do not use the bottle and return it to your pharmacist.**

To open a new bottle of Cilodex<sup>®</sup> Ear Drops, break the safety seal by removing the cap from the bottle. Remove the lower portion of the safety seal and discard.

Follow these steps to use the ear drops:

1. Wash your hands thoroughly with soap and water.



2. Hold the bottle in the hand for one or two minutes to warm the ear drops, then shake well.



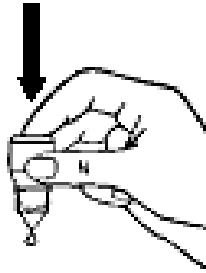
3. Remove the cap from the bottle. Hold the bottle upside down in one hand between your thumb and middle finger.



4. Tilt your head to one side so that the affected ear is facing up. This may be easier in the sitting or lying down position.



5. Place the dropper tip close to, but not touching, your ear and gently tap or press the base of the bottle with your forefinger to release drops.



**BE SURE TO FOLLOW INSTRUCTIONS BELOW FOR THE PATIENT'S SPECIFIC EAR INFECTION.**

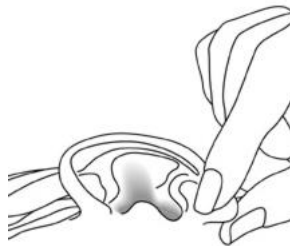
**For Patients with Middle Ear Infection with Draining Ear Tubes (Tympanostomy tubes or "Grommets"):**

6. While the patient lies on his/her side, the person giving the drops should gently press the tragus (see diagram) 5 times in a pumping motion. This will allow the drops to pass through the tube in the eardrum and into the middle ear.



**For Patients with Outer Ear Infection.**

6. While the patient lies on his/her side, the person giving Cilodex<sup>®</sup> Ear Drops should gently pull the outer ear lobe upward and backward. This will allow the ear drops to flow down into the ear canal.



7. Hold the head in the same position for about one minute. This will help the drops to reach deeper into the ear.
8. Repeat the above steps for the other ear if necessary.
9. Place the cap on the bottle and close it tightly.
10. Wash your hands again with soap and water to remove any residue.

There might be a slightly unpleasant feeling as the drops flow all the way into the ear. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the dropper tip against your fingers or the ear, or anything else. **This will help prevent the ear drops becoming dirty or contaminated.**

### ***When to use it***

**Use Cilodex<sup>®</sup> Ear Drops, at about the same time every day unless your doctor tells you otherwise.** Using your ear drops at the same time each day will have the best effect on your ear infection. It will also help you remember when to use it.

### ***How long to use it***

**Keep using Cilodex<sup>®</sup> Ear Drops for the full time of treatment, even if you begin to feel better after a few days.** If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

**Do not use Cilodex<sup>®</sup> Ear Drops longer than your doctor tells you.** If you use it longer than your doctor or pharmacist tells you, the chance of side effects may increase.

**If you are unsure about when or how to stop using Cilodex<sup>®</sup> Ear Drops you should talk to your doctor or pharmacist.**

### ***If you forget to use it***

**If it is almost time for your next drop(s), skip the drop(s) you missed and use your next drop(s) when you are meant to.**

**Otherwise, use the drop(s) as soon as you remember, and then go back to using them as you would normally.**

**Do not use a double dose to make up for the drop(s) 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 use too much (overdose)***

If you accidentally put too many Cilodex<sup>®</sup> Ear Drops in your ear(s) immediately rinse your ear(s) with warm water. Talk to a doctor or pharmacist.

**If you think that you or someone else has swallowed any or all of the contents of Cilodex<sup>®</sup> Ear Drops or used too many drops, immediately telephone your doctor or the Poisons Information Centre.**

**In Australia call 13 1126; in New Zealand call 0800 POISON or 0800 764 766 for advice or go to Accident & Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.**

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## **While using CILODEX<sup>®</sup> EAR DROPS**

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### ***Things you must do***

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

**If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking Cilodex<sup>®</sup> Ear Drops.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are using Cilodex<sup>®</sup> Ear Drops.**

**Tell your doctor if, for any reason, you have not used Cilodex<sup>®</sup> Ear Drops exactly as prescribed.** Otherwise your doctor may think that it was not effective and change the treatment unnecessarily.

If you become pregnant while using Cilodex<sup>®</sup> Ear Drops tell your doctor.

### ***Things you must not do***

Do not use Cilodex<sup>®</sup> Ear Drops to treat any other complaints unless your doctor tells you to.

Do not give Cilodex<sup>®</sup> Ear Drops to anyone else, even if they have the same condition as you.

Do not stop using Cilodex<sup>®</sup> Ear Drops or lower the dosage because you are feeling better, unless advised by your doctor. If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.

### ***Things to be careful of***

Be careful driving or operating machinery until you know how Cilodex<sup>®</sup> Ear Drops affects you and your hearing. This medicine may cause dizziness or light-headedness in some people. Make sure you know how you react to the ear drops before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If you drink alcohol, dizziness or light-headedness may be worse.

Be careful of sun exposure. These medicines cause some people to sunburn more readily.

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## **Side effects**

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Cilodex<sup>®</sup> Ear Drops.

This medicine helps most people with middle or outer ear infection, 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 treatment if you get some of the side effects.

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

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

**Common side effects** of your medicine (one or more of these may affect about 3 in every 100 people). They are usually mild and short-lived:

- ear pain
- ear discomfort
- ear itching

**Uncommon side effects** of your medicine (one or more of these may affect about 1 in every 100 people):

#### In the ears:

- ringing
- residue of medication
- blockage of tympanostomy tube
- fungal infection of outer ear
- tingling
- impacted ear wax
- congested ear
- reduced hearing
- rash in ear

#### In the body:

- candida infection

- irritability
- crying
- abnormal taste
- dizziness
- flushing of skin

**If any of the following happen, stop using Cilodex<sup>®</sup> Ear Drops and tell your doctor immediately or go to Accident & Emergency at your nearest hospital:**

- skin rash
- swelling of the face, hands or feet (*peripheral oedema*)
- wheezing, difficulty in breathing (*bronchospasm, exacerbation of asthma, respiratory failure, pulmonary distress*)
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash (*urticaria*)

These hypersensitivity reactions can be very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.** Other side effects not listed above may also occur in some people.

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## After Using CILODEX<sup>®</sup> EAR DROPS

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### **Storage**

Store Cilodex<sup>®</sup> Ear Drops in a cool dry place where the temperature stays below 25°C. **It is not necessary to store Cilodex<sup>®</sup> Ear Drops in the refrigerator. Do not freeze. Cold ear drops may hurt your ear(s).**

Cilodex<sup>®</sup> Ear Drops should be protected from light (**store the bottle in the carton**).

Do not store Cilodex<sup>®</sup> 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.**

Do not carry the ear drops in pockets of your clothes.

Do not leave the cap off the bottle for any length of time to avoid contaminating the ear drops.

Keep it where children can not reach it. **A locked cupboard at least one-and a half meters above the ground is a good place to store medicines.**

### **Disposal**

Write the date on the bottle when you open the ear drops and throw out any remaining solution after four weeks. **Cilodex<sup>®</sup> Ear Drops contains a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an ear infection. A new bottle should be opened.**

If your doctor tells you to stop using Cilodex<sup>®</sup> Ear Drops or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## Product Description

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### **What it looks like**

Cilodex<sup>®</sup> Ear Drops comes in a 5 mL oval dropper<sup>®</sup> bottle (DROP-TAINER<sup>®</sup>) with screw cap. The safety seal must be removed before use.

## ***Ingredients***

### **Active ingredients**

- ciprofloxacin hydrochloride (equiv. to 3 mg/mL ciprofloxacin)
- dexamethasone (1 mg/mL)

### **Other ingredients:**

It also contains:

- benzalkonium chloride (0.01mg/mL) as a preservative
- hydroxyethyl cellulose
- sodium acetate
- acetic acid
- sodium chloride
- disodium edentate
- tyloxapol
- boric acid
- hydrochloride acid / sodium hydroxide (to adjust pH)
- purified water

## ***Supplier***

**In New Zealand this product is distributed by:**

Alcon New Zealand Limited  
c/o Pharmaco (NZ) Ltd  
4 Fisher Crescent  
Mt Wellington Auckland

This leaflet was revised in April 2009

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