

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PATIENT MEDICATION INFORMATION

#### CIPRODEX®

#### Ciprofloxacin/Dexamethasone Otic Suspension

Read this carefully before you start taking **CIPRODEX®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CIPRODEX**.

#### What is CIPRODEX used for?

CIPRODEX is used to treat:

- **Middle Ear Infections with Drainage through a Tube in Patients 6 months and older.** A middle ear infection is a bacterial infection behind the eardrum. People with a tube in the eardrum may notice drainage from the ear canal.
- **Outer Ear Canal Infection in Patients 1 year and older.** An outer ear canal infection, also known as “swimmer’s ear,” is a bacterial infection of the outer ear canal. The ear canal and outer part of the ear may swell, turn red and be painful. A fluid discharge may also appear in the ear canal.

Antibacterial drugs like CIPRODEX treat only bacterial infections. They do not treat viral infections. Although you may feel better early in your treatment, CIPRODEX should be used exactly as directed. Misuse or overuse of CIPRODEX could lead to the growth of bacteria that will not be killed by CIPRODEX (resistance). This means that CIPRODEX may not work for you in the future. Do not share your medicine.

#### How does CIPRODEX work?

CIPRODEX contains two medicinal ingredients. Ciprofloxacin, an antibiotic, kills bacteria. Dexamethasone, a steroid, reduces inflammation.

#### What are the ingredients in CIPRODEX?

Medicinal ingredients: ciprofloxacin hydrochloride and dexamethasone.

Non-medicinal ingredients: acetic acid, benzalkonium chloride (as preservative), boric acid, edetate disodium, hydroxyethyl cellulose, sodium acetate, sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH), tyloxapol, and purified water.

#### CIPRODEX comes in the following dosage forms:

Ear drops, 0.3% w/v ciprofloxacin (as ciprofloxacin hydrochloride) and 0.1% w/v dexamethasone

#### Do not use CIPRODEX if:

- You or your child is allergic to ciprofloxacin, dexamethasone or any other of the ingredients in CIPRODEX (see **What are the ingredients in CIPRODEX?**).
- You or your child is allergic to other quinolone antibiotics, including nalidixic acid.

- You or your child is allergic to other steroids.
- You or your child has a viral infection of the outer ear canal, including herpes simplex (often called a cold sore).
- You or your child has a fungal ear infection.
- You or your child has a parasitic ear infection.
- Your child is under 6 months old.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CIPRODEX. Talk about any health conditions or problems you may have, including if you:**

- Have a skin rash or any other allergic reaction, including hives, itching or breathing problems. You should stop treatment and immediately contact your healthcare professional. You may need emergency treatment.
- Notice your symptoms get worse or suddenly return. You should contact your healthcare professional. You may become more susceptible to infections especially after prolonged use.
- Feel pain, swelling or inflammation of the tendons while, or soon after taking CIPRODEX. You should stop treatment and contact your healthcare professional.
- If you develop another infection, your healthcare professional will prescribe another medicine to treat that infection.
- Are taking another steroid. You may be at a higher risk for developing tendon inflammation.
- Are pregnant or planning to become pregnant. The use of CIPRODEX is not recommended during pregnancy.
- Are breastfeeding or planning to breastfeed. The use of CIPRODEX is not recommended during breastfeeding.

**Other warnings you should know about:**

Only use CIPRODEX in your ear(s).

It is important that you keep your infected ear(s) clean and dry. Avoid getting the infected ear(s) wet. Avoid swimming unless your healthcare professional tells you it is okay. If the infection is not improved after one week, you should consult your healthcare professional. If you have two or more episodes of drainage within six months, it is recommended you see your healthcare professional for further testing.

The preservative in CIPRODEX, benzalkonium chloride, may irritate your skin.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take CIPRODEX?**

- 1. Wash hands.** The person giving CIPRODEX should wash his/her hands.
- 2. Warm and shake bottle.** Warm the CIPRODEX bottle in the hands for 1 to 2 minutes,

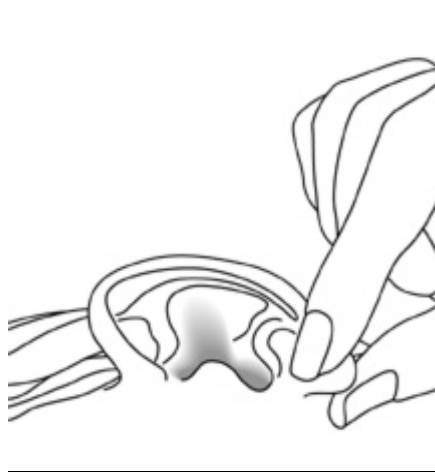
and then shake well.

- 3. Add drops.** The person receiving CIPRODEX should lie on his/her side with the infected ear facing up. Apply 4 drops into the infected ear(s). To avoid contamination, do not let the tip of the bottle touch the fingers, ear or any other surfaces.
- 4. BE SURE TO FOLLOW THE INSTRUCTIONS BELOW FOR THE SPECIFIC TYPE OF EAR INFECTION.**

**Middle Ear Infection with Tubes:** While the person receiving CIPRODEX lies on his/her side, the person giving the drops should gently press the tragus (see image below) 5 times in a pumping motion after the drops have been given. This allows the drops to pass through the tube and into the middle ear.



**Outer Ear Infection:** While the person receiving the drops lies on his/her side, the person giving the drops should gently pull the outer ear lobe upward and backward after the drops have been given (see image below). This allows the drops to flow down into the ear canal.



5. **Stay on side.** The person receiving CIPRODEX should remain on his/her side for at least 1 minute.

6. **Repeat steps 2-5 if both ears are infected.**

**Usual dose:**

4 drops in the infected ear(s), 2 times a day (about 12 hours apart) for 1 week or as long as your healthcare professional has told you. It is very important to use the ear drops as long as your healthcare professional has told you even if your ear infection gets better.

**Overdose:**

If you accidentally ingest CIPRODEX or think you have taken too much CIPRODEX, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If a drop misses your ear, try again.

If you forget to apply a dose of CIPRODEX, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and go back to the regular schedule. Do not use a double dose unless the healthcare professional has instructed you to do so.

**What are possible side effects from using CIPRODEX?**

These are not all the possible side effects you may feel when taking CIPRODEX. If you experience any side effects not listed here, contact your healthcare professional.

**Middle Ear Infections:** The most common side effect is ear discomfort or pain. Other side effects include: white, flaking, scaling material in the ear, irritability and abnormal taste in the mouth.

**Outer Ear Canal Infections:** The most common side effect is itching of the ear. Other side effects include: flaking, scaling material in the ear, fungal infection of the treated ear, feeling of fullness of plugging in the ear, ear pain and skin rash.

Other side effects include discharge from the ear, vomiting, headache, skin peeling and swelling of the ear.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNKNOWN</b> Allergic reaction: swelling of face, lips of tongue; difficulty breathing; hives; itchy skin			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store at room temperature (15°C to 30° C). Avoid freezing. Store the bottle in the carton.

Keep out of reach and sight of children.

### **If you want more information about CIPRODEX:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](https://www.canada.ca/en/health-canada.html) (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website [www.novartis.ca](http://www.novartis.ca) or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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