NOVARTIS

Cilodex Ear Drops (ciprofloxacin and dexamethasone)

3 mg ciprofloxacin and 1 mg dexamethasone per mL, ear drops, suspension

Patient Information Leaflet

Document status: Final

Release date: 13 April 2022

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CILODEX Ear Drops (suspension)

Each 1,0 mL of suspension contains 3,0 mg ciprofloxacin (as hydrochloride) and 1,0 mg dexamethasone

Read all of this leaflet carefully before you start using CILODEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CILODEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CILODEX is and what it is used for.

2. What you need to know before you use CILODEX.

3. How to use CILODEX

4. Possible side effects.

5. How to store CILODEX.

6. Contents of the pack and other information.

1. What CILODEX is and what it is used for

What CILODEX is:

CILODEX is a suspension for use only in the ear.

It contains:

- ciprofloxacin, an antibiotic belonging to the group fluoroquinolones. Ciprofloxacin works by killing bacteria that cause infections
- and dexamethasone, a corticosteroid or anti-inflammatory agent that will help to relieve inflammation and redness.

What it is used for:

CILODEX is an ear drop. This medicine is used to treat acute middle ear infection (otitis media or OM) in patients with draining ear tubes (tympanostomy tubes or “Grommets”) or to treat an outer ear infection (acute otitis externa or AOE). It has been shown to be safe and effective in paediatric patients 6 months of age and older for the treatment of middle ear infections with tympanostomy tubes, (small plastic tube inserted into the eardrum to keep the middle ear aerated for a prolonged period of time) (AOMT) and 1 year of age and older for the treatment of outer (external) ear infections (AOE).

2. What you need to know before you use CILODEX

Do not use CILODEX:

- if you are hypersensitive (allergic) to ciprofloxacin or dexamethasone or any of the other ingredients of CILODEX;
- if you are allergic to other antibiotics called quinolones;
- if you have a viral or fungal ear infection or an untreated parasitic ear infection.

Warnings and precautions

Take special care with CILODEX:

- If you notice the first signs of a skin rash or any other allergic reaction, including hives, itching or breathing problems, stop treatment and immediately contact your doctor.
- If you have a serious allergic reaction, then you may need emergency treatment.
- If your symptoms get worse or suddenly return, please contact your doctor. You may become more susceptible to infections especially after prolonged use.
- If you feel pain, swelling or inflammation of the tendons while, or soon after taking this medicine, stop treatment immediately and contact your doctor.
- If you have an infection, your doctor will prescribe another medicine to treat that infection.

Children/ and adolescents

There is insufficient clinical experience available on the use of CILODEX in children below 6 months.

Other medicines and CILODEX

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Pregnancy and breastfeeding and fertility

You should not use CILODEX if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, you 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 machinery

It is not always possible to predict to what extent CILODEX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CILODEX affects them.

CILODEX contains benzalkonium chloride

A preservative in CILODEX (benzalkonium chloride) may cause skin reactions.

3. How to use CILODEX

Do not share medicines prescribed for you with any other person.

Always use CILODEX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- Only use CILODEX EAR DROPS in your ear(s).

- The recommended dose for adults and children is 4 drops in the ear canal, twice a day – morning and evening for 7 days.

Instructions for use and handling:

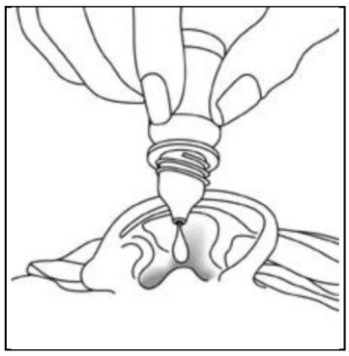
- Wash hands
- Shake well before use.
- The suspension should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness, which may result from the instillation of a cold suspension.



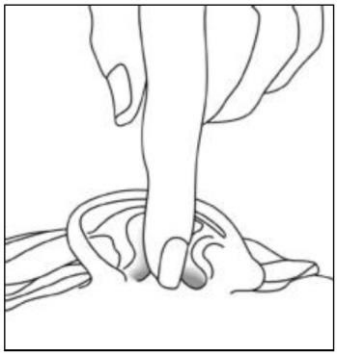
- The patient should lie with the affected ear upward and then the drops should be instilled.



- Put 4 drops of CILODEX into the infected ear. Do not touch the fingers or the ear or any other surfaces with the tip of the bottle as it could infect the drops.



- For patients with acute otitis media with tympanostomy tubes, the flap of skin at the entrance to the ear canal should be gently pressed 5 times in a pumping motion to facilitate penetration of the drops into the middle ear.



- This position should be maintained for 60 seconds.
- Repeat, if necessary, for the opposite ear.
- If a drop misses your ear, try again.

Your doctor will tell you how long your treatment with CILODEX will last.

If you have the impression that the effect of CILODEX is too strong or too weak, tell your doctor or pharmacist.

If you use more CILODEX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of CILODEX

Do not take a double dose to make up for forgotten individual doses.

Continue with the next dose as planned. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.

If you stop using CILODEX

Do not stop using this medicine without telling your doctor or pharmacist. If your ear(s) do not feel better after 7 days of treatment go back to your doctor.

4. Possible side effects

CILODEX can have side effects.

Not all side effects reported for CILODEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CILODEX, please consult your healthcare professional for advice.

If any of the following happens, stop using CILODEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching, scaly rash;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CILODEX. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Ear pain;

The following side effects have been reported less frequently:

- Ear discharge;
- itchy ear;
- ear discomfort;
- ear congestion;
- blockage of tympanostomy tube (small plastic tube inserted into the eardrum to keep the middle ear aerated for a prolonged period of time);
- fungal infection of outer ear;
- scaling in ear;
- reduced hearing;
- ringing in ears;
- medication residue;
- redness in ear;
- dizziness;
- headache;
- fungal infection;
- irritability;

- vomiting;
- crying;
- fatigue;
- bad taste.

The following side effects have been reported but the frequency is unknown:

- Auricular inflammation (pain and swelling due to the composition and environmental exposures experienced by the constituent parts of the ear)
- Hyperglycaemia (high levels of sugar in the blood),
- Hypoglycaemic coma (Coma as a result of low levels of sugar in the blood),
- Hypersensitivity (symptoms such as swelling or a skin rash around the area the medicine is applied).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/. By reporting side effects, you can help provide more information on the safety of CILODEX.

5. How to store CILODEX

- Store all medicines out of reach of children.
- Store between 2 °C – 30 °C.
- Do not freeze.

- Store in the original package / container.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Discard four weeks after first opening.

6. Contents of the pack and other information

What CILODEX contains:

- The active substance is:

1 mL of suspension contains 3 mg ciprofloxacin (as hydrochloride) and 1 mg dexamethasone

- The other ingredients are*:*

Benzalkonium chloride, hydroxyethyl cellulose, sodium acetate, acetic acid, sodium chloride, disodium edetate, tyloxapol, boric acid, hydrochloric acid / sodium hydroxide and purified water.

What CILODEX looks like and contents of the pack

What CILODEX looks like:

CILODEX is a white to off-white suspension.

Contents of the pack:

Colourless 5 mL low density polyethylene plastic bottle and plug. White polypropylene closure.

Holder of Certificate of Registration and Manufacturer

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei view

2090

This leaflet was last revised in

Date of revision of text: 13 April 2022

Registration number

A39/16.2/0544

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website