NOVARTIS

CILOXAN® Eye Drops

Each 1,0 mL solution contains ciprofloxacin hydrochloride equivalent to ciprofloxacin 3,0 mg

Patient Information Leaflet

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SCHEDULING STATUS

S4

CILOXAN Eye Drops 0,3 % *w/v*, solution

Ciprofloxacin (as hydrochloride), 3 mg/mL

Read all of this leaflet carefully before you start using CILOXAN Eye Drops

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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 CILOXAN is and what it is used for.
2. What you need to know before you use CILOXAN.
3. How to use CILOXAN.
4. Possible side effects.
5. How to store CILOXAN.
6. Contents of the pack and other information.

1. What CILOXAN is and what it is used for

What CILOXAN is:

- CILOXAN belongs to a group of medicines known as quinolone antibiotics.

What CILOXAN is used for:

- It is used for the treatment of corneal ulcers and some other bacterial infections of the eye(s).

2. What you need to know before you use CILOXAN

Do not use CILOXAN:

- if you are hypersensitive (allergic) to ciprofloxacin or any other quinolone antibiotic or to any of the other ingredients of CILOXAN Eye Drops.

Warnings and precautions

Take special care with CILOXAN:

- you must stop using CILOXAN if you develop a hypersensitivity reaction, such as skin rash, itchiness, tingling feeling, swelling of your face or tongue, or shortness of breath;
- use of CILOXAN for a long time may lead to other infections. If your symptoms get worse or suddenly return tell your doctor;
- CILOXAN is preserved with benzalkonium chloride. You should undergo regular eye examinations if you are using CILOXAN for a prolonged period of time. Benzalkonium chloride may cause side effects on your corneal permeability with prolonged or repeated use *(see section CILOXAN contains benzalkonium chloride*);
- if you feel pain, swelling or inflammation of the tendons while, or soon after taking this medicine, stop treatment and contact your doctor;
- if you are elderly or if you are taking medicines called ´corticosteroids´ used to treat conditions such as pain and inflammation, asthma or skin problems then, you have a

higher risk of getting tendon problems during treatment with CILOXAN. If you experience any inflammation or an inflammatory condition, stop treatment and immediately consult your doctor;

- only use CILOXAN in your eyes;
- **do not wear contact lenses** (hard or soft) during treatment with CILOXAN**.**
- in patients with corneal ulcer and frequent administration of CILOXAN, white medication residue has been observed which resolved after continued application of CILOXAN. The precipitate does not preclude the continued application of CILOXAN, nor does it adversely affect the course of the recovery process.

Other medicines and CILOXAN

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CILOXAN with these medicines may cause undesirable interactions.

Tell your doctor if you are taking any of the following medicines:

CILOXAN can react with some other commonly used medicines, such as:

- Warfarin (used to prevent blood clotting).
- Theophylline (used to treat asthma and included in some cough medicines).
- Caffeine.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding or are planning to have a baby, please consult your doctor, pharmacist or other health care professional before using this medicine.

The safety of CILOXAN in pregnant women and breastfeeding mothers has not been established.

Driving and using machinery

It is not always possible to predict to what extent CILOXAN 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 CILOXAN affects them.

If your sight is affected in any way following use of CILOXAN you should not drive or operate machinery.

CILOXAN contains benzalkonium chloride

There is a preservative in CILOXAN (benzalkonium chloride) that can discolour soft contact lenses and cause eye irritation. Therefore, do not use the drops while contact lenses are in your eyes. Wait at least 15 minutes after using the eye drops before putting your lenses back in.

3. How to use CILOXAN

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

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

The usual dose is:

CILOXAN can be used by adults and children over the age of two years.

This will depend on whether you are being treated for corneal ulcers or for some other bacterial infection in your eye.

Corneal Ulcers

Dosing is continued during the night time.

Day 1:

- Two (2) drops every 15 minutes for the first 6 hours and then 2 drops every 30 minutes.

Day 2:

- Two (2) drops every hour.

Day 3 to Day 14:

- Two (2) drops every 4 hours.

Your doctor will tell you if treatment needs to be continued for longer than 14 days.

Other bacterial infections

- 1 or 2 drops every 2 hours for two days while you are awake, then 1 or 2 drops every four hours while you are awake until the bacterial infection is resolved.

It is important that you continue to use CILOXAN for the full treatment period as advised by your doctor.

You should not use CILOXAN for more than 21 days, unless your doctor says otherwise.

Remove the loose collar from the cap when the bottle is first opened.

Always use CILOXAN exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

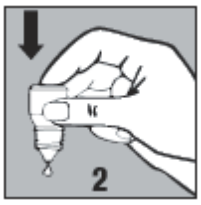
How to use

- Wash your hands before you start.
- Twist off the bottle cap.

- Hold the bottle pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).



- Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
- Gently press on the base of the bottle to release one drop at a time (picture 2).



- Do not squeeze the bottle, only a gentle press on the bottom is needed.
- If you use drops in both eyes, repeat the steps for your other eye. Put the bottle cap firmly back on immediately after use.
- If a drop misses your eye, try again.

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

If you use more CILOXAN than you should

If you use more CILOXAN than you should it can be washed out of your eye with warm water.

If you or someone else accidentally drinks the contents of CILOXAN, consult your doctor or pharmacist.

If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to use CILOXAN

If you forget to use CILOXAN, skip the missed dose and wait until your next dose is due. Do not use a double dose to make up for forgotten individual doses.

If you stop using CILOXAN

Do not stop using this medicine early, even if your symptoms have disappeared. If you stop using this medicine before you are supposed to, your symptoms may re-occur.

4. Possible side effects

CILOXAN can have side effects.

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

If any of the following happens, stop taking CILOXAN 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;

- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CILOXAN. 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:

- Burning;
- discomfort;
- redness of the eye or inside of the eyelid;
- white particles in your eyes.If you notice white particles in your eyes, continue to use CILOXAN but tell your doctor immediately;
- bad taste in your mouth.

The following side effects have been reported less frequently:

- Itching;
- feeling of something in the eye;
- crusting on the eyelid;
- swollen eyelid(s);
- decreased vision;
- watery eyes;
- sensitivity to light;
- damage to or staining of the eye surface (cornea);
- eye pain;
- dry eye;

- eye discharge;
- eyelid scales;
- eyelid redness;
- headache;
- dizziness;
- ear pain;
- inflammation inside the nose;
- nasal sinus discharge;
- diarrhoea;
- abdominal pain;
- skin inflammation;
- nausea.

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

- Tendon disorder

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/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CILOXAN.

5. How to store CILOXAN

- Store at or below 25 °C.
- Do not refrigerate or freeze.
- Keep all medicines out of the reach of children.
- Do not use the drops after the expiry date (marked 'Exp') on the bottle and the carton. The expiry date refers to the last day of that month.
- Discard the bottle 30 days after first opening, to prevent infections.
- Medicines should not be disposed of via waste water or household waste.
- Store in the original package / container.
- Do not store in a bathroom
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CILOXAN contains:

- The active substance is:

Ciprofloxacin hydrochloride 3,5 mg equivalent to 3,0 mg ciprofloxacin base in every mL of solution.

- The other ingredients are*:*

edetate disodium, sodium acetate, acetic acid, mannitol, hydrochloric acid and/or sodium

hydroxide (to adjust pH) and purified water.

CILOXAN Eye Drops contain benzalkonium chloride 0,06 mg/mL as a preservative

What CILOXAN looks like and contents of the pack

CILOXAN Eye Drops is a colourless, clear solution.

CILOXAN Eye Drops is supplied in low density polyethylene bottles containing 5 mL solution.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg

2090

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