NOVARTIS

CILOXAN® Eye Ointment

Each 1,0 g ointment contains ciprofloxacin hydrochloride equivalent to ciprofloxacin base 3,0 mg

Patient Information Leaflet

Document status:	Final
Release date:	30 November 2021

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CILOXAN® Eye Ointment 3 mg/g

Ciprofloxacin (as hydrochloride)

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 for eye infections called quinolones.
- It works by killing the germs that have caused the infection in the eye.

What CILOXAN is used for:

- It is used to treat infections on the outside of the eye.

2. What you need to know before you use CILOXAN

Do not use CILOXAN:

- If you are allergic (hypersensitive) to ciprofloxacin or any of the other ingredients of CILOXAN.
- If you are allergic to medicines called quinolones. CILOXAN may cause the same allergy.

Warnings and precautions

Take special care with CILOXAN:

- in case of prolonged use. As with all antibiotics, prolonged use may lead to overgrowth with non-susceptible bacteria or fungi;
- if you wear contact lenses. Wearing lenses is discouraged during treatment of an eye infection, as your condition may worsen. Ask your doctor for advice;
- if you notice the first signs of a skin rash or any other hypersensitivity reaction. Stop treatment with CILOXAN and immediately consult the attending doctor or your pharmacist;
- serious and occasionally fatal hypersensitivity reactions, sometimes after the first dose, have occurred in patients receiving systemic (oral, intramuscular or intravenous) doses of fluoroquinolone antibiotics. If serious hypersensitivity reactions occur, immediate emergency treatment is necessary;

- 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;
- 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;consult your doctor if one of the above-mentioned warnings is applicable to you, or has been applicable to you in the past.

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.

CILOXAN should only be used if the attending doctor deems it necessary.

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 vision is temporally blurred after having used CILOXAN Eye Ointment, do not drive or use machines until your vision is clear again *(see section 4 Possible side effects*).

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.

The usual dosage for adults and children over the age of two years is:

Corneal ulcers:

- Apply a 1.25 cm ribbon into the eye(s) every 1 – 2 hours for 2 days, then every 4 hours for 12 additional days.

Bacterial conjunctivitis:

- Apply a 1.25 cm ribbon into the eye(s) 3 times daily for 2 days, then twice daily for 5 additional days.
- Use the indicated dose unless your doctor has advised you differently. Only use CILOXAN in your eye(s).
- Use it for as long as your doctor has prescribed.
- If you have the impression that the effect of CILOXAN is too strong or too weak, talk to your doctor or pharmacist.

		
Take the CILOXAN tube and a mirror. Wash your hands.	Tilt your head back. Pull down your eyelid with a clean finger until there is a “pocket” between your eyelid and your eye. The ointment ribbon will go here.	Bring the tube tip close to the eye. Use the mirror if it helps. Don’t touch your eye or eyelid, surrounding areas or other surfaces with the tube tip. Gently squeeze the tube to expel the ointment ribbon.

If you use more CILOXAN than you should

If you have used more CILOXAN in your eye than necessary, it can be rinsed out of your eye with luke-warm water.

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

If you forget to use CILOXAN

If you forget to use a dose of this medicine, apply it as soon as possible.

However, if it is almost time for your next dose, skip the missed dose and go back to the regular dosage schedule.

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

If you stop using CILOXAN

No symptoms are expected when the use of CILOXAN is stopped. Follow the treatment till the end, even if your symptoms have disappeared, to fully cure your infection.

If you stop using this medicine too early, your symptoms may re-occur. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

CILOXAN can have side effects.

Not all side effects reported for CILOXAN are included in this leaflet. Should your general ~~state of~~ 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:

- Eye discomfort (stinging and burning may occur upon application);
- white precipitate in patients with corneal ulcer or frequent administration of CILOXAN Eye ointment have been observed, which resolved spontaneously with continued application. The precipitate does not stop continued use of CILOXAN Eye ointment, nor does it adversely affect the clinical course of the ulcer or the recovery process.
- red eyes or inside of the eyelid;
- taste perversion (metallic taste).

The following side effects have been reported less frequently:

- Itching;
- feeling of something in the eye;
- crusting on the eyelid;
- swollen eyelid(s);
- blurred vision
- tearing;

- light sensitivity;
- decreased sharpness of sight;
- 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.
- Keep all medicines out of the reach of children.
- The expiry date (marked 'Exp') is printed on the tube and on the outer carton. Do not use the product after the expiry date. The expiry date refers to the last day of that month.
- You must throw away the tube one month (4 weeks) 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 in an anhydrous ophthalmic ointment base. It does not contain a preservative.

- The other ingredients are*:*

liquid paraffin and white vaseline.

What CILOXAN looks like and contents of the pack

CILOXAN is a homogenous, white to off-white ointment.

CILOXAN is a sterile ointment in a 3.5 g tube with a screw cap.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

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Johannesburg

2090

This leaflet was last revised in

Date of registration: 1 October 2004

Date of revision of text: 30 November 2021

Registration number

35/15.1/0410

Ciloxan® Eye Ointment
Botswana: S2
Reg. No.: BOT0701052

Namibia: NS2
Reg. No.: 06/15.1/0180