

Package Leaflet - Information for the User

CILOXAN® 0.3% EYE DROPS SOLUTION (ciprofloxacin (as hydrochloride))

Your medicine is available using the name Ciloxan 0.3% Eye Drops Solution but will be referred to as Ciloxan throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine.

- **Keep this leaflet.** You may need to read it again.
- **If you have any further questions**, ask your doctor or pharmacist.
- This medicine has been prescribed for you. **Do not pass it on to others.** It may harm them, even if their signs of illness are the same as yours.
- **If any of the side effects get serious**, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Ciloxan belongs to a group of medicines known as **quinolone antibiotics**.

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 **allergic (hypersensitive)** to **ciprofloxacin** or any other **quinolone antibiotic** or to any of the other ingredients listed in section 6.

Ask your doctor for advice.

Take special care...

- Only use Ciloxan in your eyes.
- Only use Ciloxan in children younger than 1 year if prescribed by your doctor.
- As with any antibiotic, **use of Ciloxan for a long time** may lead to other infections. If your symptoms **get worse or suddenly return** tell your doctor. You may become more susceptible to other infections with the use of this medicine, especially after prolonged use.
- If you notice the first signs of a skin rash or any other allergic reaction, including hives, itching, breathing problems stop treatment and immediately contact your doctor. If you have a serious allergic reaction then you may need emergency treatment.
- If you feel pain, swelling or inflammation while or shortly 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 inflammatory condition, stop treatment and immediately consult your doctor.

Pregnancy and breast-feeding

If you are pregnant or might get pregnant, or if you are breast-feeding a baby, **talk to your doctor** before you use Ciloxan.

Driving and using machines

If your sight is temporarily blurred or affected in any way following use of Ciloxan **you should not drive or operate machinery until your vision is clear again.**

Other medicines and Ciloxan

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are using more than one type of eye medicine, the medicines must be used at least 5 minutes apart. Eye ointments should be used last.

Important information if you wear Contact Lenses

There is a preservative in Ciloxan (benzalkonium chloride). This medicine contains 0.3mg benzalkonium chloride in each 5ml which is equivalent to 0.06mg/ml. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. HOW TO USE CILOXAN

The recommended dose

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

Day 2 - 2 drops every hour.

Day 3 to Day 14 - 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 4 times a day. For severe infections the dose for the first 2 days may be increased to 1 or 2 drops every 2 hours, while you are awake.

It is important that you **continue to use Ciloxan** for the **full treatment period** as advised by your doctor even if your symptoms improve. If you stop using this medicine too early, your symptoms may re-occur.

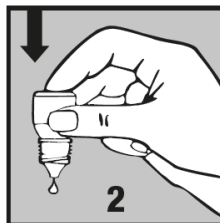
You should not use Ciloxan for more than 21 days, unless your doctor says otherwise.

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 forget to use Ciloxan**, do not worry, just use it when it is next due. **Do not take a double dose to make up.**
 - **If you use more Ciloxan than you should** it can be washed out of your eye with lukewarm water.
 - **If this medicine is accidentally swallowed**, it is not likely to cause any serious problems, but contact your doctor.
- If you have any further questions on the use of Ciloxan, ask your doctor or pharmacist.



4. POSSIBLE SIDE EFFECTS

Like all medicines, Ciloxan can cause side effects, although not everybody gets them.

- **You may experience some or all of the following effects in your eye(s):**
Common (1 to 10 users in 100):
White deposits on the eye surface (cornea), discomfort (stinging or burning, gritty feeling in the eye, irritation), redness.

Uncommon (1 to 10 users in 1,000):
Damage to the eye surface (cornea), sensitivity to light, blurred vision, swelling of the eye or eyelid, pain, dry eye, itchiness, eye discharge, eyelid crusting, eyelids scales, eyelid redness, poor vision, watery eyes, red eyes.

Rare (1 to 10 users in 10,000):
Damage of the eye, inflammation, double vision, decreased eye sensation, tired eyes, stye.

If you notice white particles in your eyes, continue to use Ciloxan but tell your doctor immediately.

- **You may also experience effects in other areas of your body including:**

Common: Bad taste.

Uncommon: Headache, nausea.

Rare: Hypersensitivity, dizziness, ear pain, inflammation inside the nose, nasal sinus discharge, diarrhoea, abdominal pain, skin inflammation, tendon disorder.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

If you experience an allergic reaction, stop using Ciloxan and tell your doctor.

5. HOW TO STORE CILOXAN

- Keep all medicines out of the sight and reach of children.
- Do not refrigerate or freeze.
- Discard 15 days after first opening.
- Do not use after the expiry date printed on the carton or bottle. The expiry date refers to the last day of that month. The medicine must be discarded one month after first opening.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- If your doctor decides to stop treatment, please take the eye drops back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.
- If the medicine become discoloured or show signs of deterioration, take them to your pharmacist who will advise you.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ciloxan contains

Ciloxan is supplied as a sterile solution in a 5ml dropper bottle containing 3.5mg of ciprofloxacin hydrochloride (equivalent to 3.0mg of ciprofloxacin) in every ml of solution.

Other ingredients include sodium acetate, acetic acid, mannitol, edetate disodium and purified water. It also contains 0.06mg of benzalkonium chloride in each ml of solution as a preservative.

Hydrochloric acid and/or sodium hydroxide may also be included in very small quantities to adjust the acidity or alkalinity of the product to ensure comfort of the product in the eye.

What Ciloxan looks like and contents of the pack

Ciloxan is supplied in a 5ml dropper bottle as a clear and colourless to pale yellow solution.

Manufacturer

Your medicine is manufactured by:
Alcon Cusi S.A., Camil Fabra 58, 08320 El Masnou, Barcelona, Spain.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX.

PL No: 21828/0140

POM

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CILOXAN® is a registered trademark of Novartis AG.

Blind or partially sighted?

Is this leaflet hard to see or read?

Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:

Product name:

Ciloxan 0.3% Eye Drops Solution

Reference No: 21828/0140