

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

CILOXAN® Ciprofloxacin Ophthalmic Solution

Read this carefully before you start taking **CILOXAN®** 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 **CILOXAN**.

What is CILOXAN used for?

CILOXAN is used to treat corneal ulcers and conjunctivitis caused by bacterial infections of the eye.

Antibacterial drugs like CILOXAN treat only bacterial infections. They do not treat viral infections.

How does CILOXAN work?

CILOXAN is an antibiotic that stops the growth of bacteria.

What are the ingredients in CILOXAN?

Medicinal ingredient: Ciprofloxacin hydrochloride

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

CILOXAN comes in the following dosage forms:

0.3% ophthalmic solution (eye drops)

Do not use CILOXAN if you are:

- Allergic to ciprofloxacin or any of the other ingredients in CILOXAN.
- Allergic to other quinolone antibiotics, including nalidixic acid.

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

- 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.
- Develop another infection, your healthcare professional will prescribe another medicine to treat that infection.
- 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.

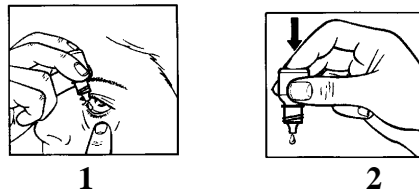
- Feel pain, swelling or inflammation of the tendons while, or soon after taking CILOXAN. You should stop treatment and contact your healthcare professional.
- Are pregnant or planning to become pregnant.
- Are breastfeeding or planning to breastfeed.
- Are elderly or if you are taking corticosteroids. You are more likely to get pain or swelling in your tendons during treatment with CILOXAN.

Other warnings you should know about:

- Only use CILOXAN in children younger than 1 year if prescribed by your healthcare professional.
- Do NOT wear contact lenses while using CILOXAN unless otherwise instructed by your healthcare professional.
- Your vision may be temporarily blurry after using CILOXAN. Do not drive or use machines until your vision is clear.
- The preservative in CILOXAN, benzalkonium chloride, may cause eye irritation and discolour contact lenses

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

How to take CILOXAN:



- Only use CILOXAN in your eyes.
- Get the CILOXAN bottle and a mirror (if needed).
- Wash your hands.
- Twist off the cap.
- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).
- Bring the bottle close to the eye. Use the mirror if it helps.
- Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could contaminate the drops.
- Gently press on the base of the bottle to release one drop of CILOXAN at a time (picture 2). Do not squeeze the bottle. It is designed so that a gentle press on the bottom of the bottle is all that it needs.
- If you take drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- If you are using other eye medicines, the medicines must be used at least 5 minutes apart. Eye ointments should be administered last.

Although you may feel better early in treatment, CILOXAN should be used exactly as directed.

Misuse or overuse of CILOXAN could lead to the growth of bacteria that will not be killed by CILOXAN (resistance). This means that CILOXAN may not work for you in the future.

Do not share your medicine.

Usual dose:

Conjunctivitis (Adults and Children 1 year and older):

Days 1 and 2: Apply 1 or 2 drops in the eye(s) every 2 hours while you are awake.

Days 3 to 7: Apply 2 drops in the eye(s) every 4 hours while you are awake.

Corneal Ulcer (Adults and Children 12 years and older):

Day 1: Apply 2 drops in the eye(s) every 15 minutes for the first 6 hours. Then apply 2 drops in the eye(s) every 30 minutes for the rest of the day.

Day 2: Apply 2 drops in the eye(s) every hour.

Days 3 to 14: Apply 2 drops in the affected eye(s) every 4 hours.

If your eye(s) do not get better after 14 days, talk to your healthcare professional.

Overdose:

If you think you have applied too much CILOXAN, rinse it all out with warm water. Do not apply any more CILOXAN until it is time for your next dose.

If you or your child accidentally ingest CILOXAN, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

- If you forget to apply a dose of CILOXAN, take it as soon as you remember.
- However, if it is almost time for your next dose, do not take the missed dose. Instead, continue with your next scheduled dose.
- Do not use a double dose to make up for a missed dose.

What are possible side effects from using CILOXAN?

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

Side effects may include:

In the eye:

- white deposits on the eye surface (cornea)
- eye discomfort such as stinging, burning, irritation, itching
- staining of the eye surface (cornea)
- dry eye
- tearing (watering of the eye)

- eye discharge
- eyelid crusting
- eyelid scales
- eyelid redness
- eye redness
- damage of the eye
- eye inflammation
- sensitivity to light
- eye pain
- reduced or blurred vision
- double vision
- decreased eye sensation
- bump on the eyelid (stye)
- tired eyes

Other areas of your body:

- bad taste
- headache
- dizziness
- ear pain
- nasal sinus discharge
- diarrhea
- abdominal pain

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

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 health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store the bottle in the carton at room temperature (2°C-30°C).

Keep out of reach and sight of children.

If you want more information about CILOXAN:

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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Antibacterial drugs like CILOXAN treat only bacterial infections. They do not treat viral infections.

How does CILOXAN work?

CILOXAN is an antibiotic that stops the growth of bacteria.

What are the ingredients in CILOXAN?

Medicinal ingredient: Ciprofloxacin hydrochloride

Non-medicinal ingredients: Mineral oil, white petrolatum

CILOXAN comes in the following dosage forms:

0.3% ophthalmic ointment (eye ointment)

Do not use CILOXAN if you are:

- Allergic to ciprofloxacin or any of the other ingredients in CILOXAN.
- Allergic to other quinolone antibiotics, including nalidixic acid.

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

- 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.
- Develop another infection, your healthcare professional will prescribe another medicine to treat that infection.
- 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.
- Feel pain, swelling or inflammation of the tendons while, or soon after taking CILOXAN.

You should stop treatment and contact your healthcare professional.

- Are pregnant or planning to become pregnant.
- Are breastfeeding or planning to breastfeed.
- Are elderly or if you are taking corticosteroids. You are more likely to get pain or swelling in your tendons during treatment with CILOXAN.

Other warnings you should know about:

- Only use CILOXAN in children younger than 1 year if prescribed by your healthcare professional.
- Do NOT wear contact lenses while using CILOXAN unless otherwise instructed by your healthcare professional.
- Your vision may be temporarily blurry after using CILOXAN. Do not drive or use machines until your vision is clear.

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

How to take CILOXAN:



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- Only use CILOXAN in your eyes.
- Wash your hands.
- Remove the cap from the tube.
- Tilt your head back.
- Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The ointment will go in here (picture 1).
- Do not touch your eye or eyelid, surrounding areas or other surfaces with the tube tip. It could contaminate the ointment.
- Place a small amount of CILOXAN in the 'pocket.'
- Look down before closing your eye.
- If you take CILOXAN for both eyes, repeat the steps for your other eye.
- Replace the cap of the tube immediately after use.
- If you are using other eye medicines, the medicines must be used at least 5 minutes apart. Eye ointments should be administered last.

Although you may feel better early in treatment, CILOXAN should be used exactly as directed.

Misuse or overuse of CILOXAN could lead to the growth of bacteria that will not be killed by CILOXAN (resistance). This means that CILOXAN may not work for you in the future.

Do not share your medicine.

Usual dose:

Conjunctivitis (Adults and Children 1 year and older):

Days 1 and 2: Apply a half inch (1.27 cm) ribbon of ointment into the eye(s) 3 times a day.

Days 3 to 7: Apply a half inch (1.27 cm) ribbon of ointment into the eye(s) 2 times a day.

Corneal Ulcer (Adults and Children 12 years and older):

Days 1 and 2: Apply a half inch ribbon of ointment into the eye(s) every 1 to 2 hours throughout the day.

Days 3 to 14: Apply a half inch ribbon of ointment into the eye(s) every 4 hours.

If your eye(s) do not get better after 12 days, talk to your healthcare professional.

Overdose:

If you think you have applied too much CILOXAN, rinse it all out with warm water. Do not apply any more CILOXAN until it is time for your next dose.

If you or your child accidentally ingest CILOXAN, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

- If you forget to apply a dose of CILOXAN, take it as soon as you remember.
- However, if it is almost time for your next dose, do not take the missed dose. Instead, continue with your next scheduled dose.
- Do not use a double dose to make up for a missed dose.

What are possible side effects from using CILOXAN?

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

Side effects may include:

In the eye:

- white deposits on the eye surface (cornea)
- eye discomfort, itching
- eye redness
- blurred vision
- eye pain
- tearing (watering of the eye)
- sensitivity to light
- dry eye
- reduced vision
- swelling of the eyelid
- damage to or staining of the eye surface (cornea)

- foreign body sensation
- tired eyes
- decreased eye sensation

Other areas of your body:

- bad taste
- skin irritation
- dizziness
- ear pain
- nasal sinus discharge
- diarrhea
- abdominal pain

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