PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

Pr SANDOZ CIPROFLOXACIN

Ciprofloxacin Hydrochloride
Ophthalmic Solution
(0.3% as ciprofloxacin)

Antibacterial Agent

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Nonmedicinal Ingredients
Ophthalmic (topical)	Solution/ 0.3% w/v ciprofloxacin (as ciprofloxacin hydrochloride)	Benzalkonium chloride as preservative. Sodium acetate, acetic acid, mannitol, edetate disodium, hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water

INDICATIONS AND CLINICAL USE

Sandoz Ciprofloxacin (ciprofloxacin ophthalmic solution) is indicated for the treatment of the following infections of the eye and its adnexae when caused by susceptible strains of the designated bacteria.

Corneal Ulcers: *Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae.*

Conjunctivitis: *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus (Viridans group), Streptococcus pneumoniae, Haemophilus influenzae.*

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Sandoz Ciprofloxacin and other antibacterial drugs, Sandoz Ciprofloxacin should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

Pediatrics (< 1 year of age): The safety and efficacy of Sandoz Ciprofloxacin in children less than one year of age have not been demonstrated.

CONTRAINDICATIONS

Sandoz Ciprofloxacin is contraindicated in patients with:

- Hypersensitivity to ciprofloxacin or to any ingredient in the formulation or component of the container. For a complete listing, see *Dosage Forms, Composition and Packaging* section.

- Hypersensitivity to other quinolones, including nalidixic acid.

WARNINGS AND PRECAUTIONS

NOT FOR INJECTION INTO THE EYE.

FOR TOPICAL OCULAR USE ONLY.

General

Whenever clinical judgement dictates, the patient should be examined with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving therapy with quinolones by systemic administration. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, tingling, pharyngeal or facial edema, dyspnea, urticaria, and itching. Only a few patients had a history of hypersensitivity reactions. Anaphylactic reactions may require epinephrine and other emergency measures. Ciprofloxacin should be discontinued at the first sign of hypersensitivity or allergy and the patient monitored until the risk of anaphylaxis is no longer present.

Severe hypersensitivity reactions characterized by rash, fever, eosinophilia, jaundice, and hepatic necrosis with fatal outcome have been reported rarely (less than one per million prescriptions) in patients receiving systemically administered ciprofloxacin along with other drugs. One report exists of anaphylaxis in a patient treated with topical ciprofloxacin concomitantly with several other antibiotics and medications. The possibility that these reactions were related to ciprofloxacin cannot be excluded. Ciprofloxacin should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity reaction.

Tendon inflammation and rupture may occur with systemic fluoroquinolone therapy including ciprofloxacin, particularly in elderly patients and in those treated concurrently with corticosteroids. Therefore treatment with ciprofloxacin ophthalmic solution should be discontinued at the first sign of tendon inflammation.

Driving and Using Machinery:
Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs upon administration, the patient must wait until vision clears before driving or using machinery.

Susceptibility/ Resistance

Development of Drug Resistant Bacteria:
Prescribing ciprofloxacin ophthalmic solution in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for Microbial Overgrowth:
As with other antibacterial preparations, prolonged use of ciprofloxacin ophthalmic solution may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy.

Ophthalmologic

In clinical studies of patients with bacterial corneal ulcer, a white crystalline precipitate located in the superficial portion of the corneal defect was observed in 29 (18.8%) out of 154 patients administered ciprofloxacin ophthalmic solution. The onset of the precipitate was within 24 hours to 7 days after starting therapy. In 16 patients administered ciprofloxacin ophthalmic solution, resolution of the precipitate was seen in 1 to 8 days (seven within the first 24-72 hours). In four patients, resolution was noted in 10-13 days. In one patient, the precipitate was immediately irrigated out upon its appearance. In six patients, exact resolution days were unavailable; however, at follow-up examinations 18-44 days after onset of the event, complete resolution of the precipitate was noted. In two patients, outcome information was unavailable. The presence of the white precipitate did not preclude continued use of ciprofloxacin ophthalmic solution, nor did it adversely affect the clinical course of the ulcer or visual outcome. A literature report exists of a single case of ciprofloxacin-associated dense precipitate apparently interfering with re-epithelialization.

Contact lens wear is not recommended during treatment of an ocular infection. Therefore, patients should be advised not to wear contact lenses during treatment with ciprofloxacin ophthalmic solution.

Ciprofloxacin ophthalmic solution contains the preservative benzalkonium chloride, which may cause eye irritation and is known to bind to and discolour soft contact lenses. Avoid contact of ciprofloxacin ophthalmic solution with soft contact lenses. In case patients are allowed to wear contact lenses, they must be instructed to remove contact lenses prior to application of ciprofloxacin ophthalmic solution and wait at least 15 minutes before re-insertion.

Ophthalmic dosage regimens involving solution and formulation of ciprofloxacin 0.3% have not been studied.

In patients with large (> 4mm) and/or deep stromal ulcers, the clinical success rate was lower for both ciprofloxacin and standard (fortified antibiotics) therapy.

Sexual Function/Reproduction
Studies have not been performed in humans to evaluate the effect of topical administration of ciprofloxacin on fertility. Reproduction studies of systemic ciprofloxacin exposure have been performed in rats and mice at doses up to 6 times the usual daily human dose and have revealed no evidence of impaired fertility.

Special Populations

Pregnant Women: There are no adequate and well controlled studies of ciprofloxacin ophthalmic solution in pregnant women. Ciprofloxacin ophthalmic solution should be used in pregnant women only if in the physician's opinion, the benefit clearly outweighs any potential unknown risks.

Reproduction studies of systemic ciprofloxacin exposure have been performed in rats and mice at doses up to 6 times the usual daily human dose and have revealed no evidence of harm to the fetus due to ciprofloxacin. In rabbits, as with most antimicrobial agents, ciprofloxacin (30 and 100 mg/kg orally) produced gastrointestinal disturbances resulting in maternal weight loss and an increased incidence of abortion. No teratogenicity was observed at either dose. After intravenous administration in rabbits, at doses up to 20 mg/kg, no maternal toxicity was produced and no embryotoxicity or teratogenicity was observed.

Nursing Women: It is not known whether topically applied ciprofloxacin ophthalmic solution is excreted in human milk; however, it is known that orally administered ciprofloxacin is excreted in the milk of lactating rats and that other drugs of this class are excreted in human milk. For this reason, and because of the potential for serious adverse reactions from ciprofloxacin in nursing infants, a decision should be made to discontinue nursing or to discontinue the drug, taking into consideration the importance of the drug to the mother.

Pediatrics (< 1 years of age): The safety and efficacy of ciprofloxacin ophthalmic solution in children less than one year of age have not been demonstrated.

Pediatrics (≥ 1 years of age): Ciprofloxacin ophthalmic solution has been used to treat conjunctivitis in 123 children between the ages of one and twelve years. No serious adverse event was reported in these patients.

Ciprofloxacin and quinolone-related drugs have been shown to cause arthropathy in immature animals of most species tested following oral administration. Topical ocular administration of ciprofloxacin to immature animals (Beagle dogs) did not cause arthropathy or demonstrate any articular lesions, and there is no evidence that the ophthalmic dosage form has any effect on the weight bearing joints.
In 634 children treated orally with ciprofloxacin, clinical and radiologic monitoring did not reveal any skeletal toxicity felt to be quinolone-related. However, there are a small number of reports of arthralgia in children, associated with oral ciprofloxacin therapy. This arthralgia has been shown to be reversible on discontinuation of the systemic medication.

ADVERSE REACTIONS

Clinical Trial Adverse Drug Reactions

Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

During clinical studies, treatment related adverse events to ciprofloxacin ophthalmic solution were mild, infrequent in occurrence and non-serious in nature, and did not lead to premature discontinuation of therapy.

The most frequently reported adverse events that were considered related or possibly related to ciprofloxacin ophthalmic solution were: transient discomfort, i.e., stinging, burning, irritation (8.6%), noticeable taste (4.5%), foreign body sensation (1.8%), and itching (1.2%). Treatment-related or possibly related medical events occurring between 0.5 and 1% incidence were: lid margin crusting, crystals/ scales, erythema/redness, dryness, discharge, corneal staining, keratopathy/keratitis, hyperemia/congestion and tearing.

In clinical trials in which 154 patients were treated for bacterial corneal ulcers, the most frequently reported adverse event related or possibly related to therapy was a white crystalline precipitate seen in 29 (18.8%) patients. The precipitate required no adjunctive therapy and resolved spontaneously with continued ciprofloxacin use.

Other rarely reported events related or possibly related to ciprofloxacin ophthalmic solution included: ocular congestion, photophobia, pain, vision decrease, chemosis, corneal infiltrate, inflammation, blurred vision, corneal toxicity, allergy, intolerance, lid edema, heavy sensation, swelling, conjunctival reaction, numbing sensation, conjunctivitis, punctate epithelial erosion, worsened infiltrate, and headache.

Post-Market Adverse Drug Reactions

The following additional adverse reactions were seen with ciprofloxacin ophthalmic solution in subsequent clinical trials:
Ear and labyrinth disorders: ear pain;
Eye disorders: asthenopia, conjunctival edema, corneal epithelium defect, diplopia, eyelid exfoliation, hordeolum, hypoesthesia eye, punctate keratitis, vital dye staining cornea present;
Gastrointestinal disorders: abdominal pain, diarrhea;
Nervous system disorders: dizziness;
Respiratory, thoracic and mediastinal disorders: paranasal sinus hypersecretion, rhinitis.

The following additional adverse reactions were seen with ciprofloxacin ophthalmic solution via spontaneous reporting. Reliable estimates of the frequencies of spontaneous reactions cannot be determined because they are reported voluntarily from a population of uncertain size:
Musculoskeletal and connective tissue disorders: tendon disorder.

DRUG INTERACTIONS

Specific drug interaction studies have not been conducted with ciprofloxacin ophthalmic solution. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, enhance the effects of the oral anticoagulant, warfarin and its derivatives, and has been associated with transient elevations in serum creatinine in patients receiving cyclosporin concomitantly.

DOSAGE AND ADMINISTRATION

Recommended Dose
Conjunctivitis (Adults and Children 1 year and older):
Instill one or two drops of Sandoz Ciprofloxacin into the conjunctival sac(s) every two hours while awake for two days and then two drops every four hours while awake for 5 days.

Corneal Ulcer (Adults and Children 12 years and older):
Instill two drops of Sandoz Ciprofloxacin into the affected eye(s) every 15 minutes for the first six hours and then two drops into the affected eye(s) every 30 minutes for the remainder of the first day. On the second day, instill two drops in the affected eye(s) hourly. On the third through the fourteenth day, place two drops in the affected eye(s) every four hours. If corneal reepithelialization has not occurred after 14 days, the continuation of the dosing regimen is at the discretion of the attending physician.

Missed Dose:
If a dose is missed, treatment should be continued as soon as possible. However if it is almost time for the next dose, the missed dose should be skipped. Do not use a double dose to make up for the one missed.

Administration

Patients should be advised to avoid contamination of the dispensing tip.

OVERDOSAGE

A topical overdosage of ciprofloxacin ophthalmic solution is considered to be a remote possibility. Discontinue medication when heavy or protracted use is suspected. A topical overdosage may be flushed from the eye(s) with warm tap water. Accidental ingestion of the content of one dispenser (5 mL size) would result in ingestion of up to 15 mg ciprofloxacin.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

The bactericidal action of ciprofloxacin results from inhibition of the enzyme, DNA gyrase, which is required for the synthesis of bacterial DNA.

Pharmacokinetics:

Topically applied ciprofloxacin ophthalmic solution is absorbed systemically with ciprofloxacin plasma concentrations approaching steady state at the end of dosing each day. Ciprofloxacin plasma concentrations following a routine ophthalmic treatment regimen were in the range of nonquantifiable to 4.7 ng/mL with the majority of levels falling between 1.5 to 2.5 ng/mL. Maximum serum concentration following a single oral administration of a 250 mg ciprofloxacin tablet is about 1200 ng/mL.

STORAGE AND STABILITY

Store in the carton at room temperature ($2^{o}C – 30^{o}C$). Keep out of reach and sight of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Each mL of Sandoz Ciprofloxacin (Ciprofloxacin Hydrochloride) ophthalmic solution contains:
Medicinal ingredient: Ciprofloxacin hydrochloride 3.5 mg equivalent to 3 mg base.
Preservative: Benzalkonium chloride 0.006% w/v.
Non-medicinal ingredients: Sodium acetate, acetic acid, mannitol, edetate disodium, hydrochloric acid and/or sodium hydroxide (to adjust pH) and purified water.

Sandoz Ciprofloxacin (Ciprofloxacin Hydrochloride) ophthalmic solution is available in 5mL plastic Droptainer dispensers.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

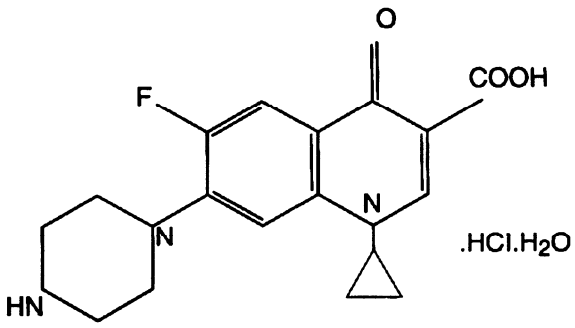
Drug Substance:

Proper name: Ciprofloxacin Hydrochloride

Chemical Name: 1 cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid, hydrochloride monohydrate.

Molecular formula and molecular mass: $C_{17}H_{18}FN_30_3.HCl\cdot H_20$; 385.8

Structural Formula:



Physicochemical properties: Ciprofloxacin is a faintly yellowish to light yellow crystalline substance. Ciprofloxacin is readily water soluble and the pH of a 2.5% solution is about 4.

DETAILED PHARMACOLOGY

Animal Pharmacology:

After topical application of ciprofloxacin 0.3%, (1 drop every 30 minutes for a total of 6 doses), the concentration of ciprofloxacin achieved in the aqueous humor of rabbits when the corneal epithelium was intact, was 4.8 µg/mL and when debrided was 12.9 µg/mL.

Human Pharmacology:

Topically applied ciprofloxacin ophthalmic solution is absorbed systemically with ciprofloxacin plasma concentrations approaching steady state at the end of dosing each day. Ciprofloxacin plasma concentrations following a routine ophthalmic treatment regimen were in the range of non-quantifiable to 4.7 ng/mL with the majority of levels falling between 1.5 to 2.5 ng/mL. Maximum serum

concentration following a single oral administration of a 250 mg ciprofloxacin tablet is about 1200 ng/mL.

MICROBIOLOGY

Ciprofloxacin has *in vitro* activity against both gram-positive and gram-negative organisms. The bactericidal action of ciprofloxacin results from interference of the enzyme, DNA gyrase, needed for the synthesis of bacterial DNA. The *in vitro* activity of ciprofloxacin against various strains of microorganisms is listed in Table 1.

The minimum bactericidal concentration (MBC) generally does not exceed the minimum inhibitory concentration (MIC) by more than a factor of 2. Resistance to ciprofloxacin *in vitro* develops slowly (multiple-step mutation). Rapid one-step development of resistance has not been observed.

Cross-resistance with other quinolones has been observed. However, organisms resistant to antimicrobial agents having other mechanisms of action (e.g. beta-lactam and aminoglycoside antibiotics) may be sensitive to ciprofloxacin. Conversely, organisms resistant to ciprofloxacin might be sensitive to antimicrobial agents having other mechanisms of action.

Table 1: MIC_{90}S for Potential Ocular Pathogens

	No. of Strains	MIC_{90} (µg/mL)	MIC range (µg/mL)
A. Gram-positive aerobic bacteria			
Staphylococcus aureus	397	0.5	0.25 - 4.0
Staphylococcus aureus (methicillin-susceptible)	287	0.5	0.5
Staphylococcus aureus (methicillin-resistant)	339	0.25	0.25 - 4.0
S. epidermidis	136	0.25	0.25 – 2.0
Staphylococcus, other coagulase-negative	432	0.25	0.25 -1.0
Streptococcus pneumonia	331	1.0	1.0 -2.0
S. pyogenes	215	0.25	0.25 - 2.0
Streptococcus, Viridans group	87	2.0	2.0 – 4.0
Enterococcus spp	580	0.06	0.06 – 8.0
Corynebacterium spp including JKs	52	0.5	0.5 – 1.0
B. Gram-negative aerobic bacteria			
Neisseria gonorrhoeae	335	0.004	0.002 – 0.06
N. meningitidis	215	0.06	0.008 – 0.06
Haemophilus influenzae	717	0.06	0.00 – 0.003
Moraxella (Branhamella) catarrhalis	246	0.06	0.015 – 0.5
Acinetobacter spp	279	1.0	0.5 – 2.0
Pseudomonas aeruginosa	801	1.0	0.012 – 1.0
P. aeruginosa (gentamicin-resistant)	11	4.0	4.0
Escherichia coli	634	0.25	0.004 – 0.25
Klebsiella pneumoniae	376	0.125	0.015 – 0.5
Proteus mirabilis	464	0.125	0.015 – 0.25
Serratia marcescens	238	1.0	0.125
C. Anaerobes			
Bacteroides spp	365	16.0	0.015 – 32.0
*Clostridium spp (*excluding *C. difficile)*	156	8.0	0.5 – 32.0
Peptostreptococcus spp	30	4.0	2.0 – 4.0
D. Chlamydia spp.	68	2.0	1.0 – 2.0

TOXICOLOGY

Ciprofloxacin has been shown to cause arthropathy in immature animals of most species tested following oral administration. However, in a one-month topical ocular study, 0.3% or 0.75% Ciprofloxacin Hydrochloride Ophthalmic Solution administered four times per day to immature Beagle dogs did not demonstrate any articular lesions. Based on ocular toxicology studies performed in rabbits, the ocular effects produced by an exaggerated topical ocular exposure to 0.3%, 0.75% or 1.5% Ciprofloxacin Hydrochloride Ophthalmic Solution were minimal and transient in nature, confined to the conjunctiva, and generally comparable to those effects observed in the untreated control and vehicle control groups. In a sub-chronic, one-month topical ocular irritation study, 0.3% to 1.5% Ciprofloxacin Hydrochloride Ophthalmic Solution did not demonstrate a cumulative ocular irritation potential and did not demonstrate any apparent systemic or ocular toxicity in rabbits.

The cataractogenic potential of oral ciprofloxacin in rats was evaluated. The results indicate that ciprofloxacin was not co-cataractogenic. An intravenous study of ciprofloxacin at levels up to 20 mg/kg over a six month period in Rhesus monkeys indicated that there were no signs of changes in lens transparency due to the administration of ciprofloxacin.

Mutagenicity
Eight *in vitro* mutagenicity tests have been conducted with ciprofloxacin and the test results are listed below:
Salmonella/Microsome Test (Negative)
E. coli DNA Repair Assay (Negative)
Mouse Lymphoma Cell Forward Mutation Assay (Positive)
Chinese Hamster V79 Cell HGPRT Test (Negative)
Syrian Hamster Embryo Cell Transformation Assay (Negative)
Saccharomyces cerevisiae Point Mutation Assay (Negative)
Saccharomyces cerevisiae Mitotic Crossover and Gene Conversion Assay (Negative)
Rat Hepatocyte DNA Repair Assay (Positive)

Thus 2 of the 8 tests were positive but results of the following 3 *in vivo* test systems gave negative results:
Rat Hepatocyte DNA Repair Assay
Micronucleus Test (Mice)
Dominant Lethal Test (Mice)

Carcinogenicity
Long-term carcinogenicity studies in mice and rats have been completed. After oral dosing for up to 2 years, there is no evidence that ciprofloxacin had any carcinogenic or tumorigenic effects in these species.

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11. PrCILOXAN® Product Monograph- Novartis Pharmaceuticals Canada Inc., Date of Revision: May 22, 2018, Control number: 210590.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Sandoz Ciprofloxacin
Ciprofloxacin Ophthalmic Solution

Read this carefully before you start taking **Sandoz Ciprofloxacin** 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 **Sandoz Ciprofloxacin**.

What is Sandoz Ciprofloxacin used for?
Sandoz Ciprofloxacin is used to treat corneal ulcers and conjunctivitis caused by bacterial infections of the eye

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

How does Sandoz Ciprofloxacin work?
Sandoz Ciprofloxacin is an antibiotic that stops the growth of bacteria.

What are the ingredients in Sandoz Ciprofloxacin?
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.

Sandoz Ciprofloxacin comes in the following dosage forms:
0.3% ophthalmic solution (eye drops)

Do not use Sandoz Ciprofloxacin if you are:
- Allergic to ciprofloxacin or any of the other ingredients in Sandoz Ciprofloxacin.
- 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 Sandoz Ciprofloxacin. 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 Sandoz Ciprofloxacin. 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 Sandoz Ciprofloxacin.

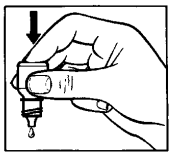
Other warnings you should know about:

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

1



2

- Only use Sandoz Ciprofloxacin in your eyes.
- Get the Sandoz Ciprofloxacin 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 Sandoz Ciprofloxacin 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, Sandoz Ciprofloxacin should be used exactly as directed.

Misuse or overuse of Sandoz Ciprofloxacin could lead to the growth of bacteria that will not be killed by Sandoz Ciprofloxacin (resistance). This means that Sandoz Ciprofloxacin 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 Sandoz Ciprofloxacin, rinse it all out with warm water. Do not apply any more Sandoz Ciprofloxacin until it is time for your next dose.

If you or your child accidentally ingest Sandoz Ciprofloxacin, 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 Sandoz Ciprofloxacin, 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 Sandoz Ciprofloxacin?

These are not all the possible side effects you may feel when taking Sandoz Ciprofloxacin. 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^{o}C-30^{o}C).

Keep out of reach and sight of children.

If you want more information about Sandoz Ciprofloxacin:

- 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.sandoz.ca, or by calling 1-800-363-8883.

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