

# ciPROFLOXAcin 0.3% Topical

## Newborn use only

2022

<b>Alert</b>	Ciprofloxacin eye drops are not recommended for empirical treatment of bacterial conjunctivitis in neonates. Use under close supervision and in consultation with an ophthalmologist.
<b>Indication</b>	Treatment of external bacterial eye infections including bacterial keratitis and conjunctivitis
<b>Action</b>	Bactericidal by inhibiting bacterial DNA synthesis by blocking DNA gyrase and topoisomerase IV.
<b>Drug type</b>	Broad spectrum fluoroquinolone antibiotic
<b>Trade name</b>	Ciloquin, Ciloxan
<b>Presentation</b>	Eye drop: 0.3% (3 mg/mL ciprofloxacin base), 5 mL drop-tainer dispenser Ointment: 3 mg/gm ciprofloxacin base in 3.5 gm ophthalmic tubes (SAS product)
<b>Dose</b>	Dose frequency depends on severity of infection and response to treatment.  <b>Severe bacterial conjunctivitis<sup>1,2</sup></b> <b>First 48 hours:</b> 1 drop every 2–4 hours in the affected eye and, if clinical improvement, <b>From day 3 up to day 7:</b> 1 drop 6 hourly.  <b>Bacterial keratitis<sup>3</sup></b> <b>First 24 hours:</b> 1 drop every 15 minutes for the first 6 hours, then once every 30 minutes, <b>From day 2:</b> 1 drop every hour, and <b>From day 3 until healed:</b> 1 eye drop every 4 hours.
<b>Dose adjustment</b>	Therapeutic hypothermia – Not applicable ECMO – Not applicable Renal impairment – Not applicable Hepatic impairment - Not applicable
<b>Maximum dose</b>	
<b>Total cumulative dose</b>	
<b>Route</b>	Topical
<b>Preparation</b>	Not required.
<b>Administration</b>	<b>Eye drops</b> Instil one eye drop into the affected eye/s by gently tapping or pressing the base of the bottle with your forefinger. After administering eye drop, gently press against the inner corner of eye to reduce systemic absorption. If other eye drop(s) are administered, wait 5 minutes between drops <b>Ointment</b> Apply a small ribbon of ointment into the conjunctival sac.
<b>Monitoring</b>	
<b>Contraindications</b>	History of hypersensitivity with quinolone use, or any components of the formulation.
<b>Precautions</b>	Ciprofloxacin commonly forms a transient, white precipitate on corneal ulcers that may slow the rate of corneal epithelial healing.
<b>Drug interactions</b>	No data available
<b>Adverse reactions</b>	Unpleasant taste, mild transient ocular irritation, white corneal precipitates (reversible after cessation of therapy), keratitis, allergic reactions (very rare reports of severe hypersensitivity including angioedema, anaphylaxis, Stevens-Johnson syndrome)
<b>Compatibility</b>	Not applicable
<b>Incompatibility</b>	Not applicable
<b>Stability</b>	
<b>Storage</b>	Store below 25°C. Do not refrigerate or freeze. Protect from light. Discard container 4 weeks after opening.
<b>Excipients</b>	Sodium acetate, glacial acetic acid, mannitol, disodium edetate, hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water and benzalkonium chloride (0.06 mg/mL).
<b>Special comments</b>	<ul style="list-style-type: none"> <li>Ciloquin Eye Drops in ophthalmia neonatorum of gonococcal or chlamydial origin is not recommended.</li> <li>Ciprofloxacin eye drops are supplied in a round DROP-TAINER container which requires user to press the bottom of the bottle instead of squeezing the sides to dispense a drop of medication.</li> </ul>
<b>Evidence</b>	<b>Efficacy</b>

	<p>Topical Ciprofloxacin is effective in the management of acute conjunctivitis in children. In a randomised control trial, Gross et al used topical 0.3% Ciprofloxacin in 128 and Tobramycin in 129 children aged 0-12 years for 7 days. In ciprofloxacin arm, clinical cure was observed in 87%, microbiological eradication in 90% and microbiological reduction in 2.8% participants. Treatment failure was noted in 7% children. Predominant organisms cultured during the study were <i>Hemophilus Influenzae</i> and <i>Streptococcus Pneumoniae</i>.<sup>1</sup></p> <p>In one study, bacteriological evaluation was obtained for each eye in 99 patients with bacterial conjunctivitis and 48 patients awaiting cataract surgery. Following treatment with ciprofloxacin 0.3% ophthalmic solution 4 times a day for 7 days, a complete eradication of bacterial flora was achieved in 96% of the participants<sup>2</sup></p> <p>In a multicentre prospective study, 148 culture-proven cases of bacterial keratitis were treated with 0.3% topical Ciprofloxacin. The control group received topically administered fortified cefazolin (33 mg/mL) and fortified gentamicin or tobramycin (14 mg/mL). Treatment with ciprofloxacin yielded a 91.9% success rate compared to the success rate of 88.2% among the control group. Ciprofloxacin 0.3% is effective as a single agent for the treatment of bacterial keratitis.<sup>3</sup></p> <p><b>Safety</b></p> <p>In a study exploring efficacy and safety of 0.3% Ciprofloxacin ophthalmic solution for treatment of bacterial conjunctivitis and blepharitis, Adenis noted mild discomfort, stinging and edema in 2/39 participants and clinical improvement was noted in 95% participants.<sup>4</sup></p> <p>Power et al compared topical Ciprofloxacin and Chloramphenicol for efficacy and safety in patients with bacterial conjunctivitis. Ciprofloxacin was more effective than Chloramphenicol (93.5 vs 84.5%) in achieving clinical cure. In each group, local transient chemosis and erythema were noted in one patient in each group.<sup>5</sup></p> <p><b>Pharmacokinetics</b></p> <p>Price et al compared 3 different treatment schedules for determination of ciprofloxacin concentration in the cornea of patients undergoing penetrating keratoplasty. In group 1, 2 drops were administered 4 hourly for 24 hours by family members. In group 2 and 3, the eye drops were administered every 15 min over 4 hours by technicians. In group 1 and 2, the corneal epithelium was intact whilst in group 3 the corneal epithelium was abraded. Corneal penetration was better when ciprofloxacin was administered in a controlled setting every 15 min (8.8 vs 166 mcg/gm) and corneal epithelial integrity was compromised (166 vs 938 mcg/gm). In this study, the corneal Ciprofloxacin concentration exceeded MIC<sub>90</sub> for most common ocular pathogens across all three regimens.<sup>6</sup></p>
<b>Practice points</b>	<p>Due to concern about emerging resistance:</p> <ul style="list-style-type: none"> <li>• Reserve quinolones for treatment of bacterial keratitis (under close supervision and in consultation with an ophthalmologist)</li> <li>• Other antibacterials are preferred for empirical treatment of conjunctivitis.</li> </ul>
<b>References</b>	<ol style="list-style-type: none"> <li>1. Gross RD, Hoffman RO, Lindsay RN. A comparison of ciprofloxacin and tobramycin in bacterial conjunctivitis in children. Clin Pediatr (Phila). 1997 Aug; 36(8):435-44.</li> <li>2. Stankiewicz A, Kosatka M, Goś A. et al. Clinical efficacy of ciprofloxacin 0.3% in the treatment of bacterial infections of the external eye segment. Klin Oczna. 2003; 105(6):407-9.</li> <li>3. Leibowitz HM. Clinical evaluation of ciprofloxacin 0.3% ophthalmic solution for treatment of bacterial keratitis. Am J Ophthalmol. 1991 Oct; 112(4 Suppl):34S-47S.</li> <li>4. Adenis JP, Colin J, Verin P, et al. Ciprofloxacin ophthalmic solution in the treatment of conjunctivitis and blepharitis: a comparison with fusidic acid. Eur J Ophthalmol. 1996 Oct-Dec; 6(4):368-74.</li> <li>5. Power WJ, Collum LM, Easty DL, et al. Evaluation of efficacy and safety of ciprofloxacin ophthalmic solution versus chloramphenicol. Eur J Ophthalmol. 1993 Apr-Jun; 3(2):77-82.</li> <li>6. Price FW Jr, Whitson WE, Collins KS, Gonzales JS. Corneal tissue levels of topically applied ciprofloxacin. Cornea. 1995 Mar; 14(2):152-6.</li> <li>7. MIMS online. Ciloquin (eye drops). Accessed on 3 August 2022.</li> <li>8. Therapeutic guidelines. (2022). Keratitis. eTG complete. Accessed on 3 August 2022.</li> </ol>

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