

Ofloxacin 0.3% eye drops

Newborn use only

2022

Alert	Ofloxacin eye drops are not recommended for empirical treatment of bacterial conjunctivitis in neonates. Use under close supervision and in consultation with an ophthalmologist.
Indication	Treatment of external bacterial eye infections including keratitis and bacterial conjunctivitis.
Action	Bactericidal by inhibiting bacterial DNA synthesis by blocking DNA gyrase and topoisomerase IV.
Drug type	Broad spectrum fluoroquinolone antibiotic
Trade name	Ocuflox
Presentation	0.3% (3 mg/mL ofloxacin), 5 mL dropper bottle
Dose	Dose frequency depends on severity of infection and response to treatment ^{1,2} First 48 hours: 1 drop every 2-4 hours in the affected eye and, if clinical improvement, From Day 3 and up to day 10: 1 drop every 6 hours. May require more frequently (e.g. every 1 hour) in severe infections.
Dose adjustment	Therapeutic hypothermia – Not applicable ECMO – Not applicable Renal impairment – Not applicable Hepatic impairment – Not applicable
Maximum dose	
Total cumulative dose	
Route	Topical
Preparation	Not required.
Administration	Instil 1 eye drop in the affected eye/s. After administering eye drop, gently press against the inner corner of eye to reduce systemic absorption. If other eye drop(s) are administered, wait for 5 minutes between drops.
Monitoring	
Contraindications	History of hypersensitivity with quinolone use or any other component of the formulation.
Precautions	
Drug interactions	
Adverse reactions	Mild transient ocular irritation, white corneal precipitates, keratitis, allergic reactions {hypersensitivity (very rare) including angioedema, anaphylaxis and Stevens-Johnson syndrome}
Compatibility	Not applicable
Incompatibility	Not applicable
Stability	
Storage	Store below 25°C. Protect from light and excessive heat. To avoid contamination of the solution, keep container tightly closed. Discard container 4 weeks after opening.
Excipients	Ocuflox eye drops contain 0.05 mg/mL benzalkonium chloride.
Special comments	

Evidence	<p>Efficacy</p> <p>Topical 0.3% ofloxacin is an effective and safe treatment for conjunctivitis and blepharoconjunctivitis in paediatric and adult patients. Data in neonates are very limited.</p> <p>Bron et al compared a 7 day course of 0.3% ofloxacin with chloramphenicol 0.5% in 167 adult patients with suspected bacterial external ocular infection. Patients were instructed to use their eye drops every 2-4 waking hours (according to severity as determined by the physician) on days 1 and 2 and 4 times daily from days 3 to 7. In the study, 63% patients had conjunctivitis, while blepharoconjunctivitis, Keratoconjunctivitis and blepharitis were present in 20%, 7% and 7% respectively. Microbiological improvement rates were 85% and 88% in ofloxacin and chloramphenicol groups respectively. Bacteria were eradicated in 79% and 77% of ofloxacin and chloramphenicol groups respectively. Clinical improvement rates were 100% for ofloxacin, and 95% for chloramphenicol.¹</p> <p>In a randomised controlled trial, Gwon et al administered topical 0.3% ofloxacin in 93 patients with suspected bacterial external ocular infection. One drop of ofloxacin was applied to the affected eye(s) six times daily (every 2 to 4 hours) for 2 days (day 1 and day 2) and then four times daily for the next 8 days (day 3 to day 10). The control group received 0.3% gentamicin in a similar dosage schedule. Baseline culture findings were positive in 56% patients treated with ofloxacin and in 54% subjects in the gentamicin group. Among patients treated with ofloxacin, 98% (51/52) were either clinically cured or improved by day 11, compared with 92% (48/52) of the gentamicin group. Microbiological improvement was achieved in 78% (40/51) of the ofloxacin patients, compared with 67% (35/52) of the gentamicin group. Bacterial proliferation occurred in 16% (8/51) of the ofloxacin group vs 27% (14/52) of gentamicin-treated subjects.² Suggested dose regimens in this formulary are extrapolated from the above 2 studies.^(1,2) However, one study found that administration of topical Ofloxacin 0.3% solution 12 hourly was as efficacious as 6 hourly schedule in clinical and bacteriological improvement in patients with conjunctivitis and blepharoconjunctivitis.⁵</p> <p>Safety</p> <p>Bron et al noted no difference in adverse reactions between ofloxacin and chloramphenicol groups. Of 83 patients receiving ofloxacin, one participant developed haemorrhagic conjunctivitis and marked palpebral oedema.¹ In the RCT by Gwon et al, adverse reactions possibly caused by drug treatment were encountered in 3.2% of oxacillin group and 7.1% of the gentamicin group participants. These reactions included burning, stinging, and photophobia necessitating discontinuation of the drug. No drug treatment related effects on visual acuity, ophthalmoscopy findings, or lens pathology were observed. There was no notable difference between treatment groups in comfort of drug application. In one study, ofloxacin 0.3% or azithromycin eye drops were administered for 7 days for postoperative endophthalmitis prophylaxis after intravitreal injections. Five patients in the ofloxacin group and two patients in the Azithromycin group developed endophthalmitis following intravitreal Ranibizumab injection (p<0.05).³ In a case report, Claerhout reported corneal deposits in two children with keratoconjunctivitis who received 0.3% ofloxacin.⁴</p>
Practice points	<p>Due to concern about emerging resistance:</p> <ul style="list-style-type: none"> • Reserve quinolones for treatment of bacterial keratitis (under close supervision by, or following discussion with, an ophthalmologist) • Other antibacterials are preferred for empirical treatment of conjunctivitis.
References	<ol style="list-style-type: none"> 1. Bron AJ, Leber G, Rizk SN, Baig H, Elkington AR, Kirkby GR, Neoh C, Harden A, Leong T. Ofloxacin compared with chloramphenicol in the management of external ocular infection. Br J Ophthalmol. 1991 Nov; 75(11):675-9. 2. Gwon A. Topical ofloxacin compared with gentamicin in the treatment of external ocular infection. Ofloxacin Study Group. Br J Ophthalmol. 1992 Dec; 76(12):714-8. 3. Romero-Aroca P, Sararols L, Arias L, et al. Topical azithromycin or ofloxacin for endophthalmitis prophylaxis after intravitreal injection. Clin Ophthalmol. 2012; 6:1595-9. 4. Claerhout I, Kestelyn P, Meire F, et al. Corneal deposits after the topical use of ofloxacin in two children with vernal keratoconjunctivitis. Br J Ophthalmol. 2003 May; 87(5):646. 5. MIMS online. Ocuflux (eye drops). Accessed on 4 August 2022. 6. Therapeutic guidelines. (2022). Keratitis. eTG complete.

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