

OXOP Eye Drops

Introduction:

OXOP eye drop is a fluorinated carboxyquinolone antiinfective for topical ophthalmic use. Ofloxacin is a fluorinated 4-quinolone which differs from other fluorinated 4-quinolones in that there is a six-member (pyridobenzoxazine) ring from positions 1 to 8 of the basic ring structure.

Composition

Each ml of **OXOP eye drop** contains:

Ofloxacin USP 0.3% w/v in a sterile aqueous base

Pharmacology

Pharmacokinetics: Findings of Serum, urine and tear concentrations of ofloxacin: (10-day course)

The mean serum ofloxacin concentration ranged from 0.4 ng/ml to 1.9 ng/mL.

Tear ofloxacin concentrations ranged from 5.7 to 31 mcg/g during the 40-minute period.

Mean tear concentration measured 4 hours after topical ophthalmic dosing - 9.2 mcg/g.

Corneal tissue concentrations- 4.4 mcg/mL 4 hours after topical ophthalmic dosing
Ofloxacin was excreted in the urine primarily unmodified.

Microbiology: OXOP eye drop (Ofloxacin) has in vitro activity against a broad range of gram-positive and gram-negative aerobic and anaerobic bacteria. Ofloxacin is bactericidal at concentrations equal to or slightly greater than inhibitory concentrations.

Ofloxacin is thought to exert a bactericidal effect on susceptible bacterial cells by inhibiting DNA gyrase, an essential bacterial enzyme that is a critical catalyst in the duplication, transcription, and repair of bacterial DNA.

OXOP eye drop (Ofloxacin) has been shown to be active against most strains of the following organisms both in vitro and clinically, in conjunctival and/or corneal ulcer infections.

AEROBES, GRAM-POSITIVE:

Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pneumoniae

ANAEROBIC SPECIES:

Propionibacterium acnes

AEROBES, GRAM -NEGATIVE:

Enterobacter cloacae
Haemophilus influenzae
Proteus mirabilis
Pseudomonas aeruginosa
Serratia marcescens

CONJUNCTIVITIS: CORNEAL ULCERS:

AEROBES, GRAM-POSITIVE:

Enterococcus faecalis
Listeria monocytogenes
Staphylococcus capitis

Staphylococcus hominus
Staphylococcus simulans
Streptococcus pyogenes

AEROBES, GRAM-NEGATIVE:

Acinetobacter calcoaceticus var. anitratus
Acinetobacter calcoaceticus var. Iwoffii
catarrhalis
Citrobacter diversus
Citrobacter freundii
Enterobacter aerogenes
Enterobacter agglomerans
Escherichia coli
Haemophilus parainfluenzae
Klebsiella pneumoniae

Klebsiella oxytoca
Moraxella (Branhamella)

Moraxella lacunata
Morganella morganii
Neisseria gonorrhoeae
Pseudomonas acidovorans
Pseudomonas fluorescens
Shigella sonnei

OTHERS:

Chlamydia trachomatis

Indications

OXOP eye drop is indicated for the conditions listed below:

1. Conjunctivitis:

Gram-positive bacteria: Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae

Gram-negative bacteria: Enterobacter cloacae, Haemophilus influenzae, Proteus mirabilis, Pseudomonas aeruginosa

2. Corneal Ulcers:

Gram-positive bacteria: Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae

Gram-negative bacteria: Pseudomonas aeruginosa, Serratia marcescens

Anaerobic species: Propionibacterium acnes

3. Blepharitis

4. Pre – operative care.

Contraindications

The use of **OXOP eye drop (Ofloxacin)** is contraindicated in patients with hypersensitivity to Ofloxacin or to other quinolones or to any of the components of the medication.

Warnings: (Not for injection.)

OXOP eye drop (Ofloxacin) solution should not be injected sub-conjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

Precautions

The prolonged use of antibiotics may occasionally result in overgrowth of non-susceptible organisms, including fungi. If new infections appear, the drug should be discontinued and appropriate measures instituted.

In all serious infections the topical use of **OXOP eye drop** (Ofloxacin) should be supplemented by appropriate systemic medication.

Pregnancy & Lactation

There are no adequate and well-controlled studies in pregnant women. **OXOP eye drop** (Ofloxacin) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Adverse Reactions

The most frequently reported drug-related adverse reaction to **OXOP eye drop** (Ofloxacin) is transient ocular burning or stinging. However, these adverse reactions are addressed in **OXOP eye drop** (Ofloxacin) with specially formulated **LUBIFILM**.

Other reported reactions include redness, itching, chemical conjunctivitis/keratitis, periocular/facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness, and eye pain. Rare reports of dizziness have been received.

Dosage & Administration

The recommended dosage regimen for the treatment of **bacterial conjunctivitis** is:

Days 1 and 2: Instill one to two drops every two to four hours in the affected eye(s).

Days 3 through 7: Instill one to two drops four times daily.

The recommended dosage regimen for the treatment of **bacterial corneal ulcer** is:

Days 1 and 2: Instill one to two drops into the affected eye every 30 minutes, while awake. Awaken at approximately four and six hours after retiring and instill one to two drops.

Days 3 through 7 to 9: Instill one to two drops hourly, while awake.

Days 7 to 9 through treatment completion: Instill one to two drops, four times daily.

Presentation

OXOP Eye/Ear Drops is available in **10 ml** lupolen vial.

Note: Store at 15 – 25 ° C.