

Composition:

Each ml of Oxop eye drops contains:

Ofloxacin 0.3% w/v

Sterile aqueous vehicle q.s

Pharmacokinetic:

Findings of Serum, urine and tear concentrations of Ofloxacin: (10-day course) The mean serum Ofloxacin concentration ranged from 0.4 ng/m 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.

Mechanism of Action:

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.

Indication:

- In conjunctivitis
- Foreign body eye
- Hordeolum

Contraindication:

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.



Adverse effects:

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.

Warnings and 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.

Use in special population:

- **1. Pediatric:** Safety and effectiveness in infants below the age of one year have not been established.
- **2. Geriatric:** No overall clinical differences in safety or effectiveness have been observed between elderly and younger patients.
- 3. Liver impairment: No data found.
- 4. Renal failure: No data found.
- **5. Pregnancy and 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.

Dosage:

As directed by physician.

Presentation:

10ml in plastic bottle.

Storage and handling:

Store at 15° – 25° C.

