Oxop™
Eye Drops

1. Generic Names

Ofloxacin

2. Qualitative and Quantitative Composition

Each ml of Oxop eye drops contains:

Ofloxacin	0.3% w/v

3. Dosage form and strength

Topical ophthalmic solution containing Ofloxacin 0.3%(0.3mg/100ml).

4. Clinical particulars

4.1 Therapeutic indication

Oxop eye drops are indicated in:

- In conjunctivitis
- Foreign body eye
- Hordeolum

4.2 Posology and method of administration

As directed by physician.

4.3 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.

4.4 Special warnings and precautions for use

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.

4.5 Drug interactions

None are reported.

4.6 Use in special population

- Paediatric: Safety and effectiveness in infants below the age of one year have not been established.
- Geriatric: No overall clinical differences in safety or effectiveness have been observed between elderly and younger patients.
- Liver impairment: No data found.
- Renal failure: No data found.
- 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 foetus.

4.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Oxop eye drop is known.

4.8 Undesirable 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.

4.9 Overdose

There is limited experience of overdose with Oxop eye drop. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 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.

5.2 Pharmacodynamic properties

Ofloxacin is a quinolone/fluoroquinolone antibiotic. Ofloxacin is bactericidal and its mode of action depends on blocking of bacterial DNA replication by binding itself to an enzyme called DNA gyrase, which allows the untwisting required to replicate one DNA double helix into two. Notably the drug has 100 times higher affinity for bacterial DNA gyrase than for mammalian. Ofloxacin is a broad-spectrum antibiotic that is active against both Gram-positive and Gram-negative bacteria.

5.3 Pharmacokinetic properties

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.

6. Nonclinical properties

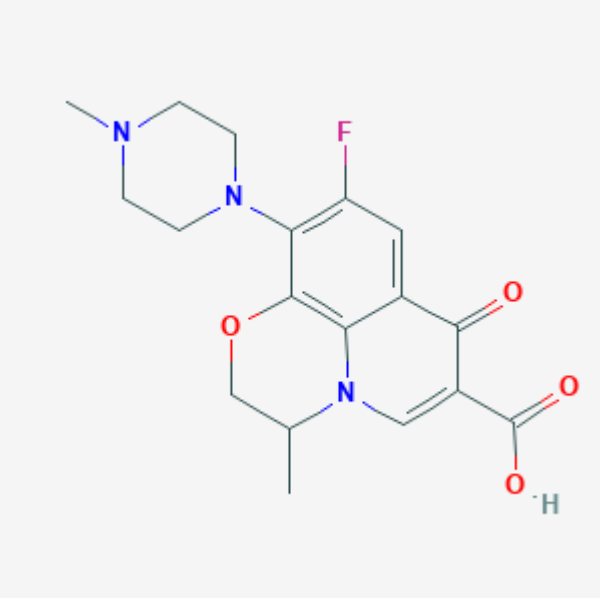
6.1 Animal Toxicology or Pharmacology

Ocular toxicity and systemic adverse effects of 0.3% ofloxacin ophthalmic solution (0.3% ofloxacin) which was administered 3 times daily for one year were studied in dogs.

In general conditions, food intake, behavior and body weights, no significant difference was observed between the non treated group and 0.3% ofloxacin treated group throughout the experimental period. Signs for ocular toxicity such as anterior ocular irritation, abnormality of cornea and lens opacity, as well as fundus abnormality were no observed during ophthalmological examination in either group. Electroretinogram showed no abnormality by administration of 0.3% ofloxacin. Hematological examinations and blood chemistry resulted in normal values in any test item. Autopsy, organ weight, histopathology of ocular tissues and systemic organs showed no change due to ofloxacin.It is concluded from these results that one year application of 0.3% ofloxacin ophthalmic solution to dogs causes neither ocular toxicity nor systemic adverse effect.

7. Description

Ofloxacin is a fluoroquinolone antibacterial antibiotic. Its chemical name is 7-fluoro-2-methyl-6-(4-methylpiperazin-1-yl)-10-oxo-4-oxa-1-azatricyclo[7.3.1.$0^{5,13}$]trideca-5(13),6,8,11-tetraene-11-carboxylic acid. The empirical formula and molecular weight is $C_{18}H_{20}FN_3O_4$ and 361.4 g/mol.



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

36 months.

8.3 Packaging Information

Oxop eye drops is available in 10ml in plastic bottle.

8.4 Storage and handling instructions

Store in cool and dry place.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

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11. Details of permission or license number with date

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