



## **1. Composition**

Each ml of Oxop eye drops contains:

Ofloxacin 0.3% w/v

## **2. Dosage form and strength**

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

## **3. Clinical particulars**

### **3.1 Therapeutic indication**

Oxop eye drops are indicated in:

- In conjunctivitis
- Foreign body eye
- Hordeolum

### **3.2 Posology and method of administration**

As directed by physician.

### **3.3 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.

### **3.4 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.

### **3.5 Drug interactions**

None are reported.

### **3.6 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.

### **3.7 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.

### **3.8 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.

### **3.9 Overdose**

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

## **4. Pharmacological properties**

### **4.1 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.

### **4.2 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.

#### **4.3 Pharmacokinetic properties**

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

The mean serum Ofloxacin concentration ranged from 0.4 ng/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.

### **5. Nonclinical properties**

#### **5.1 Animal Toxicology or Pharmacology**

Not required.

### **6. Description**

Already mentioned and covered in the above points.

### **7. Pharmaceutical particulars**

#### **7.1 Incompatibilities**

There are no known incompatibilities.

#### **7.2 Shelf-life**

36 months.

#### **7.3 Storage and handling instructions**

Store in cool and dry place.