

OxopTM-D

Eye Drops

Composition:

Each ml of Oxop-D eye drops contains:

Ofloxacin	0.3% w/v
Dexamethasone	0.1% 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/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.

Mechanism of Action:

Ofloxacin has in vitro activity against a broad range of gram-positive and gram negative aerobic and anaerobic bacteria. It 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.

Dexamethasone in Oxop-D is a potent corticosteroid that suppresses the inflammatory response to a variety of agent. Corticosteroids bind to the cytosolic glucocorticoid receptor (GR). This type of receptor is activated by ligand binding. After a hormone binds to the corresponding receptor, the newly formed receptor-ligand complex translocate itself into the cell nucleus, where it binds to glucocorticoid response elements (GRE) in the promoter region of the target genes resulting in the regulation of gene expression and modification of transcription and, hence, protein synthesis in order to achieve inhibition of leukocyte infiltration at the site of inflammation, interference in the function of mediators of inflammatory response, suppression of humoral immune responses, and reduction in edema or scar tissue. The anti-inflammatory actions of dexamethasone are thought to involve



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phospholipase A₂ inhibitory proteins, lipocortins, which control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes.

The combination of Dexamethasone a potent corticosteroid and Ofloxacin a broad spectrum antibacterial in a topical formulation like Oxop-D eye drops will together effectively resolve inflammation and infection in severe eye conditions.

Indication:

Bacterial Conjunctivitis

Keratitis

Post cataract surgery

Contraindication:

The use of Oxop-D eye drops is contraindicated in patients with hypersensitivity to any ingredient of the formulation. The use of Oxop-D eye drops is also contraindicated in epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and in other viral diseases of the conjunctiva and cornea, mycobacterial infection of the eye and fungal diseases of ocular structures.

Adverse effects:

Adverse effects have occurred with steroid/anti-infective combination drugs, which can be attributed to the steroid component, the anti-infective component, or the combination. The most frequently reported drug-related adverse reactions seen with Ofloxacin are: transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, conjunctivitis/keratitis, periocular/facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness, and eye pain. The reactions due to the steroid component are: elevation of intraocular pressure with possible development of glaucoma, and infrequent optic nerve damage, posterior subcapsular cataract formation and delayed wound healing.

Warnings and Precautions:

Oxop-D eye drops solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

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-D eye drops should be supplemented by appropriate systemic medication.



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Prolonged use of Oxop-D eye drops may result in glaucoma and posterior subcapsular cataract formation. If these products are used for 10 days or longer, intra-ocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

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-D eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Dosage:

As directed by physician.

Presentation:

10 ml in plastic bottle.

Storage and handling:

Store at 15° – 25° C.



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