

Floxalone-DX Sterile Eye Drops

Moxifloxacin USP 0.5% W/V & Dexamethasone Phosphate USP 0.1%W/V

Composition : Each ml Eye Drops contains Moxifloxacin 5 mg as Moxifloxacin Hydrochloride USP & Dexamethasone Phosphate 1 mg as Dexamethasone Sodium Phosphate USP.

Pharmacology : This Eye Drops is a combination of a fourth generation fluoroquinolone Moxifloxacin and a potent corticosteroid Dexamethasone. Moxifloxacin controls infection by inhibiting the DNA gyrase & Topoisomerase IV. Dexamethasone effectively controls the inflammation by inhibiting the release inflammatory mediators.

Indications : This Eye Drops is indicated in the treatment of eye infections caused by susceptible microorganisms and in the prevention of inflammation and bacterial infection that may occur after eye surgery.

Dosage and administration : **In the prevention of infection and post-surgical ocular inflammation:** Instill 1 drop, 4 times a day, in the eye to be operated, from 1 day before surgery until 15 days after surgery. **In patients undergoing cataract surgery:** The day of surgery instill the medication immediately after eye surgery. **In patients undergoing LASIK refractive surgery:** On the day of surgery instill the medication at least 15 minutes after ocular surgery. In eye infections caused by susceptible microorganisms: Instill 1 drop, 4 times a day, for up to 7 days. Or, as directed by the registered physician.

Contraindication : Hypersensitivity to quinolones. Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella & other viral diseases of cornea & conjunctiva. Mycobacterial infection of the eye. Fungal diseases of ocular structures. Glaucoma & diseases causing thinning of cornea or sclera.

Precautions : For ophthalmic use only - Solution should not be injected under the conjunctiva, nor introduced directly into the anterior chamber of the eye - Prolonged use of steroids may result in ocular hypertension .

Side effects : Major & minor side effects for Floxalone-DX Eye Drops-

- Blurred vision
- Dry eyes
- Headache
- Eye irritation and discomfort
- Dizziness

Use in Pregnancy and lactation : **Use in pregnancy :** There are no adequate and well-controlled studies in pregnant women. Moxifloxacin & Dexamethasone combination eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Use in lactation :** Caution is advised when Moxifloxacin & Dexamethasone combination eye drops is given to nursing women.

Use in child : Safety and efficacy in infants below the age of 1 year have not been established.

Drug interactions : No specific drug interaction has been demonstrated.

Overdose : Not known and not likely about overdose.

Storage : Store in a cool & dry place. Protected from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. Do not use after 1 month of first opening.

Packing : 5 ml plastic dropper bottle.

Manufactured by



DRUG INTERNATIONAL LTD.

Tongi, Gazipur, Bangladesh

12/2024/Nil