

FLOROMOX-D

Moxifloxacin & Dexamethasone Phosphate

Composition

FLOROMOX-D Eye Drops: Each ml contains Moxifloxacin Hydrochloride BP equivalent to Moxifloxacin 5 mg & Dexamethasone Sodium Phosphate USP equivalent to Dexamethasone Phosphate 1 mg.

Description

The mechanism of action of Moxifloxacin involves the inhibition of topoisomerase IV and DNA gyrase, Dexamethasone inhibits phospholipase A2 enzyme and thus inhibits prostaglandin synthesis and gives anti-inflammatory action.

Indication & Uses

FLOROMOX-D 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 & 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.

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.

Warning and Precaution

- 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 Effect

Moxifloxacin: Conjunctivitis decreased visual acuity, dry eye, keratitis, Ocular discomfort, hyperemia, pain, Subconjunctival hemorrhage and tearing. Dexamethasone: Visual acuity & field defects, cataract formation, secondary ocular infection following suppression of host response & perforation of the globe.

Use in Pregnancy and Lactation

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 elderly

No change in dosage is required when the product is administered in elderly patients.

Use in Children & adolescents

The efficacy and safety of Moxifloxacin & Dexamethasone combination eye drops in pediatric patients have not been established.

Drug Interaction

Moxifloxacin: Drug-drug interaction studies have not been conducted with moxifloxacin.
Dexamethasone: The risk of increased intraocular pressure associated with prolonged corticosteroid therapy.

Overdose

No information available.

Storage

Store below 30° C at cool and dry place, protect from light. Keep out of reach of children.

Packing

FLOROMOX-D Eye Drops: Each plastic dropper bottle contains 5 ml sterile & pyrogen free eye drops.

**Manufactured by**

The **IBN SINA** Pharmaceutical Industry Ltd.
Shafipur, Kaliakoir, Gazipur, Bangladesh.