

Kilgen-D Sterile & Pyrogen free Eye Drops

Moxifloxacin 0.5% & Dexamethasone Phosphate 0.1%

COMPOSITION:

Kilgen-D eye drops: Each ml contains Moxifloxacin Hydrochloride BP equivalent to Moxifloxacin 5 mg & Dexamethasone Sodium Phosphate USP equivalent to Dexamethasone Phosphate 1 mg.

PHARMACOLOGY:

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.

INDICATIONS:

Kilgen-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 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.

CONTRAINDICATIONS:

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 & 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:

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 SPECIAL GROUPS:

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 elderly:

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

Use in Children:

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

Use in lactation:

Caution is advised when Moxifloxacin & Dexamethasone combination eye drops is given to nursing women.

STORAGE:

Store below 30° C at cool & dry place, protect from light. Do not use longer than 30 days after first opening. Keep out of the reach of children.

PACKING:

Kilgen-D Eye Drops: Each plastic dropper bottle contains 5 ml Sterile & Pyrogen free Eye Drops.



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