Moxikem Sterile Eye Drops

Moxifloxacin 0.5%

COMPOSITION:
Each ml of Moxikem Sterile Eye Drops contains Moxifloxacin Hydrochloride USP equivalent to Moxifloxacin 5 mg.

DESCRIPTION:
Moxifloxacin is an 8-methoxy fluoroquinolone with a diazabicyclononyl ring at the C7 position. The antibacterial action of Moxifloxacin results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV.

INDICATION:
Moxikem 0.5% Sterile Eye Drops is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms :

Aerobic Gram-positive microorganisms: *Corynebacterium species, Micrococcus luteus, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus warneri, Streptococcus pneumoniae* and *Streptococcus viridans group.*

Aerobic Gram-negative microorganisms: *Acinetobacter lwoffii,*

Haemophilus influenzae and Haemophilus parainfluenzae.

Other microorganisms: *Chlamydia trachomatis.*

DOSAGE AND ADMINISTRATION:
Instill one drop of Moxikem into the affected eye 3 times a day for 7 days.

CONTRAINDICATION:
Moxifloxacin Hydrochloride eye drops is contraindicated in patients with a history of hypersensitivity to Moxifloxacin and other quinolones or to any of the components of this medication.

SIDE EFFECTS:
The most frequently reported ocular adverse events are decreased visual acuity, dry eyes, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, redness of eye and lacrimation. These events occurred in approximately 1-6% of patients. Non-ocular adverse events are reported at a rate of 1-4% included fever, increased cough, infection, otitis media, pharyngitis, rash and rhinitis.

PRECAUTION:
As with other anti-infectives, prolonged use of Moxikem eye drops may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slitlamp biomicroscopy and where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

USE IN PREGNANCY AND LACTATION:
Moxifloxacin eye drops are considered the medication of pregnancy category C, Moxifloxacin Hydrochloride eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Moxifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when Moxifloxacin hydrochloride eye drops is administered to a nursing mother.

DRUG INTERACTION:
Drug-drug interaction studies have not been conducted with Moxifloxacin Hydrochloride eye drops. In vitro studies indicate that Moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19 or CYP1A2 indicating that Moxifloxacin is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isozymes.

PHARMACEUTICALS PRECAUTION:
Store below 30^0 C in a cool and dry place, away 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 30 days of first opening of the container.

HOW SUPPLIED:
One plastic dropper bottle containing 5 ml of Moxifloxacin USP 0.5% sterile solution.

Manufactured by :
KEMIKO PHARMACEUTICALS LTD.
Bangladesh