Iventi® Eye Drops

Moxifloxacin Hydrochloride 0.5%

Sterile Solution

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.

COMPOSITION

Iventi® 0.5% Eye Drops: Each ml contains Moxifloxacin 5 mg as Moxifloxacin Hydrochloride BP.

INDICATION

Iventi® 0.5% 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, Streptococcus* viridans group

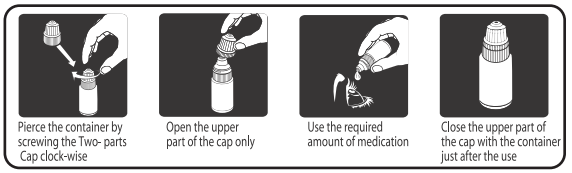
Aerobic Gram-negative microorganisms:

Acinetobacter lwoffii, Haemophilus influenzae, Haemophilus parainfluenzae

Other microorganisms: *Chlamydia trachomatis*

DOSAGE AND ADMINISTRATION

One drop in the affected eye 3 times a day for 7 days.



CONTRAINDICATION

Moxifloxacin Hydrochloride ophthalmic solution is contraindicated in patients with a history of hypersensitivity to Moxifloxacin, to other quinolones, or to any of the components in this medication.

PRECAUTION

As with other anti-infectives, prolonged use 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

Since there are no adequate and well-controlled studies in pregnant women, Moxifloxacin Hydrochloride ophthalmic solution 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 ophthalmic solution is administered to a nursing mother.

SIDE EFFECT

The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients. Nonocular adverse events reported at a rate of 1-4% were fever, increased cough, infection, otitis media, pharyngitis, rash and rhinitis.

DRUG INTERACTION

Drug-drug interaction studies have not been conducted with Moxifloxacin Hydrochloride ophthalmic solution. 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.

STORAGE

Store below 25^0 C in a cool and 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 28 days of first opening.

HOW SUPPLIED

Iventi® 0.5% Eye Drops: Each dropper bottle contains 5 ml of Moxifloxacin Hydrochloride 0.5% sterile solution.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH