

Optimox[®]

Moxifloxacin Hydrochloride BP
Eye Drops & Eye Ointment

Composition:

Optimox[®] Eye Drops: Each ml contains Moxifloxacin Hydrochloride BP equivalent to Moxifloxacin 5 mg.

Optimox Eye Ointment: Each gram contains Moxifloxacin Hydrochloride BP equivalent to Moxifloxacin 5 mg.

Preservative free

Pharmacology:

Moxifloxacin shows antibacterial activity by inhibiting the bacterial enzyme topoisomerase -II (DNA gyrase) and topoisomerase - IV.

Indications:

Optimox[®] Eye Drops / Eye Ointment is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of 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 iwoffii*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*.

Dosage and Administration:

For Eye Drops: One drop in the affected eye 3 times per day for 7 days.

For Eye Ointment: It should be applied thinly and evenly to the affected eye three times a day for the first two days and for the next five days apply two times a day or as advised by the registered physician.

Contraindications:

Moxifloxacin is contraindicated in patients with history of hypersensitivity to Moxifloxacin, to other quinolones or to any of components in the medication.

Side-effects:

The most frequently reported ocular side effects were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, sub-conjunctival hemorrhage and tearing. These events occurred in approximately 1-6% of patients.

Precautions:

Prolonged use may result in overgrowth of non-susceptible organisms, including fungi like with other anti-infectives.

Use In Pregnancy:

Moxifloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus as there are no adequate and well-documented studies in pregnant women.

Use in Lactating Mother:

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 eye drops & eye ointment is administered to a lactating mother.

Pediatric Use:

The safety and effectiveness of Moxifloxacin eye drops & eye ointment in infants below one year of age was not proven earlier. However, several latest clinical studies show that the drug can be used safely in children even younger than one month of age.

Geriatric Use:

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

Drug Interaction:

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

Storage:

- Store at 2^o-25^oC.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

Packing:

Optimox[®] Eye Drops: Each LDPE dropper bottle contains 5 ml sterile & pyrogen free eye drops.

Optimox Eye Ointment: Each tube contains 5 g sterile eye ointment.



Manufactured by:
ARISTOPHARMA LTD.
SHAMPLURDHIKA-BANGLADESH

20002419/08