

Moxifloxacin 0.5% (enriched with Xanthan Gum) Ophthalmic Solution

Composition:

Optimox® XG Ophthalmic Solution: Each ml contains Moxifloxacin Hydrochloride USP equivalent to Moxifloxacin 5 mg (enriched with Xanthan Gum BP 0.4%).

Vehicle: Xanthan Gum BP 0.4%.

Preservative Free

Pharmacology:

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

 $\begin{array}{l} \textbf{Indications:} \\ \textbf{Optimox}^{\circledR} \ \textbf{XG} \ \text{is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of} \end{array}$ 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:One drop in the affected eye(s) 2 times daily for 7 days.

Contraindications:

None.

Side-effects:

The most frequently reported ocular side effects are ocular discomfort, irritation etc. may occur.

Precautions:

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

Drug Interaction:

Drug-frug 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

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 is administered to a lactating mother.

The safety and effectiveness of Moxifloxacin in infants below four months of age was not proven. However, several dinical studies show that the drug may be used safely in children even younger than one month of age.

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

Storage:

- Store below 30°C temperature in a dry place, protect from light. Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

Packing: Optimox $^{\odot}$ XG Ophthalmic Solution: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.



