

# Sterile Eye Drops and Ointment

#### Presentation

**Moxigen Eye Drops:** Each ml sterile eye drops contains Moxifloxacin 5 mg (as Moxifloxacin Hydrochloride BP).

**Moxigen Eye Ointment:** Each gm sterile eye ointment contains Moxifloxacin 5 mg (as Moxifloxacin Hydrochloride BP).

Preservative: Free

# Pharmacology

Moxifloxacin is bactericidal with a broad spectrum of antibacterial activity. The antimicrobial action of Moxifloxacin results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division.

#### Indications

Moxigen ophthalmic solution / Ointment is indicated for the treatment of bacterial infections including bacterial conjunctivitis, blepharitis, and blepharo-conjunctivitis which are due to Moxifloxacin susceptible germs.

## **Dosage and Application**

Moxigen Eye Drops: Instill 1 drop in the affected eye(s) 3 times daily for 7 days.

**Moxigen Eye Ointment:** The usual recommended dose of Moxigen eye Ointment is half an inch ribbon for two to three times daily.

#### Contraindications

Moxifloxacin 0.5% ophthalmic solution / ointment are contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

#### Side Effects

The most frequently reported ocular adverse events were decreased visual acuity, dry eye, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage and tearing. These events occurred in approximately 1-6% of patients.

#### Precautions

As with other anti-infective, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

# **Drug Interactions**

Studies have not been conducted

# Use in Pregnancy and Lactation

Pregnancy: Since there are no adequate and well-controlled studies in pregnant women, Moxifloxacin 0.5% ophthalmic solution / ointment should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Caution should be exercised when Moxifloxacin 0.5% ophthalmic solution / ointment is administered to a nursing mother.

Pediatric Use: The safety and effectiveness of Moxifloxacin 0.5% ophthalmic ointment in infants below 1 year of age have not been established.

#### Overdose

There is practically no risk of adverse effects due to accidental ingestion, since a bottle / Lamitube of 5 ml and 5 gm eye drops solution / ointments contains only 25 mg Moxifloxacin that is much lower than recommended daily oral dose. In case of systemic ingestion, irrigation of the stomach may be appropriate in young children to decrease further absorption.

#### Storage Conditions

Store in a cool (below 30°C) and dry place, away from light. Keep out of the reach of children. Do not touch the tip of the tube or dropper bottle tip since this may contaminate the solution and ointment. After one month of the opening do not use the medicine of dropper or tube.

### **Commercial Pack**

Moxigen Eye Drops: Each plastic dropper bottle containing 5 ml sterile eye drops. Moxigen Eye Ointment: Each lamitube contains 5 gm sterile eye ointment. Manufactured by:

