

## **Centaflox 0.5% Eye Drops**

[Moxifloxacin Hydrochloride Ophthalmic Solution]

### **DESCRIPTION**

**Centaflox** [moxifloxacin hydrochloride] 0.5% is a sterile ophthalmic solution containing moxifloxacin, an 8-methoxy fluoroquinolone anti-infective for topical ophthalmic use.

### **COMPOSITION**

Each ml of **Centaflox 0.5% Eye Drops** contains:

Moxifloxacin hydrochloride equivalent to	5 mg moxifloxacin base
Benzalkonium Chloride	0.05mg
Sterile aqueous vehicle	q.s.

### **CLINICAL PHARMACOLOGY**

**Pharmacokinetics:** Following application to both eyes of Moxifloxacin 0.5% ophthalmic solution 3 times a day for 5 days in healthy adults, the mean steady-state C<sub>max</sub> (2.7 ng/mL) and the estimated AUC (45 ng·hr/mL) values were 1,600 and 1,000 times lower respectively, than the values reported after therapeutic 400 mg oral doses of moxifloxacin.

**Microbiology:** The antibacterial 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.

The mechanism of action for quinolones, including moxifloxacin, is different from that of macrolides, aminoglycosides, or tetracyclines. Therefore, moxifloxacin may be active against pathogens that are resistant to these antibiotics. There is no cross-resistance between moxifloxacin and the aforementioned classes of antibiotics. Cross-resistance has been observed between systemic moxifloxacin and some other quinolones. *In vitro* resistance to moxifloxacin develops via multiple-step mutations.

Moxifloxacin has been shown to be active against most strains of the following microorganisms:

#### **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*

### **INDICATIONS & USAGE**

Moxifloxacin 0.5% ophthalmic solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible microorganisms.

#### **DOSAGE & ADMINISTRATION**

Instill one drop in the affected eye 3 times a day for 5 to 7 days.

#### **CONTRAINDICATIONS**

Moxifloxacin 0.5% 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.

#### **PRECAUTIONS**

**General:** As with other anti-infectives, 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.

**Pregnancy:** Since there are no adequate and well-controlled studies in pregnant women, Moxifloxacin 0.5% ophthalmic solution 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 is administered to a nursing mother.

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

#### **WARNINGS**

NOT FOR INJECTION.

Moxifloxacin 0.5% ophthalmic solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment.

#### **DRUG INTERACTIONS**

Drug-drug interaction studies have not been conducted with Moxifloxacin 0.5% ophthalmic solution.

#### **ADVERSE REACTIONS**

In clinical trials the most frequently reported ocular adverse events were: 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.

#### **HOW SUPPLIED**

Moxifloxacin 0.5% ophthalmic solution is supplied as a sterile solution in plastic bottles of 5ml.

**Storage:** Store at 2°C- 25°C (36°F - 77°F).