

CENTAFLOX 0.5% EYE OINTMENT

[Moxifloxacin Hydrochloride Ophthalmic Ointment]

COMPOSITION

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

Moxifloxacin hydrochloride equivalent to 5 mg moxifloxacin base

DESCRIPTION

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

CLINICAL PHARMACOLOGY

Pharmacokinetics: Following application to both eyes of Moxifloxacin 0.5% ophthalmic ointment 3 times a day for 5 days in healthy adults, the mean steady-state C_{max} (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.

Centaflox 0.5% Eye Ointment provides prolonged contact with ocular surface that ensures longer duration of action

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

Aerobic Gram-positive microorganism	Aerobic Gram-negative microorganism	Other microorganisms:
<i>Corynebacterium</i> species	<i>Acinetobacter lwoffii</i>	<i>Chlamydia trachomatis</i>
<i>Micrococcus luteus</i>	<i>Haemophilus influenzae</i>	
<i>Staphylococcus aureus</i>	<i>Haemophilus parainfluenzae</i>	
<i>Staphylococcus epidermidis</i>		
<i>Staphylococcus haemolyticus</i>		
<i>Staphylococcus hominis</i>		
<i>Staphylococcus warneri</i>		
<i>Streptococcus pneumoniae</i>		
<i>Streptococcus viridans group</i>		

INDICATIONS & USAGE

Moxifloxacin 0.5% ophthalmic ointment is indicated for the treatment of bacterial conjunctivitis caused by susceptible microorganisms, corneal ulcers, blepharitis.

DOSAGE & ADMINISTRATION

The usual recommended dose of **CENTAFLOX Ointment** is half an inch ribbon, *bid* to *tid*.

CONTRAINDICATIONS

Moxifloxacin 0.5% ophthalmic ointment 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 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 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.

WARNINGS

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 ointment.

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 ointment is supplied as a sterile ointment in plastic bottles of 5ml.

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