Offoxacin Ophthalmic Solution USP, 0.3% Sterile

DESCRIPTION

Offoxacin Ophthalmic Solution USP, 0.3% is a sterile opthalmic solution. It is a fluorinated carbamoylquinoline anti-infective for topical opthalmic use.

INDICATIONS AND USAGE

Ofloxacin has been shown to be active against most strains of the following organisms both in vitro and clinically, in conjunctival and/or corneal ulcer infections as described in the INDICATIONS AND USAGE section.

AEROBES, GRAM-POSITIVE:

Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pneumoniae

AEROBES, GRAM-NEGATIVE:

Enterobacter cloacae
Proteus mirabilis
Pseudomonas aeruginosa
Serratia marcescens

ANAEROBIC SPECIES:

Propionibacterium acnes

*Efficacy for this organism was studied in fewer than 10 infections.

The safety and effectiveness of Offoxacin Ophthalmic Solution in treating ophthalmic infections due to the following organisms have not been established in adequate and well-controlled clinical trials. Ofloxacin Ophthalmic Solution has been shown to be active in vitro against most strains of these organisms but the clinical significance in ophthalmologic infections is unknown.

AEROBES, GRAM-POSITIVE:

Enterococcus faecalis
Listeria monocytogenes
Staphylococcus capitis

AEROBES, GRAM-NEGATIVE:

Acinetobacter calcoaceticus var. anitratus
Acinetobacter calcoaceticus var. lwoffii
Citrobacter diversus
Citrobacter freundii
Enterobacter aerogenes
Enterobacter agglomerans
Echerichia coli
Haemophilus parainfluenzae
Klebsiella oxytoca
Klebsiella pneumoniae
Moraxella (Branhamella) catarrhalis
Moraxella lacunata
Morganella morgani
Klebsiella pneumoniae
Leptotrichaamina
Serratia marcescens
Shigella sonnei

OTHER:

Chlamydia trachomatis

Clinical Studies:

Conjunctivitis: In a randomized, double-masked, multicenter clinical trial, Offoxacin Ophthalmic Solution was superior to its vehicle control on Days 2 and 7 of treatment in patients with concomitant conjunctival cultures. Clinical success rates for the trial demonstrated a clinical improvement rate of 96% (54/56) for the ofloxacin treated group versus 72% (47/66) for the placebo treated group after 2 days of therapy. Microbiological outcomes for the same clinical trial demonstrated an eradication rate for causative pathogens of 65% (41/63) for the ofloxacin treated group versus 25% (17/67) for the placebo treated group after 7 days of therapy. Please note that microbicidal eradication does not always correlate with clinical outcome in anti-infective trials.

Corneal Ulcers: In a randomized, double-masked, multi-center trial of 140 subjects with positive cultures, Offoxacin Ophthalmic Solution treated subjects had an overall clinical success rate complete re-epithelialization and resolution of the infiltrate for two consecutive visits of 82% (61/74) compared to 80% (53/66) for the fortified antibiotic group, consisting of 1.5% tobramycin and 10% cefazolin solutions. The median time to clinical success was 11 days for the fortified antibiotic group after 2 days of therapy. Please note that microbiologic eradication does not always correlate with clinical success in anti-infective trials.

INDICATIONS AND USAGE

Offoxacin Ophthalmic Solution is indicated for the treatment of infectious causes of conjunctivitis in the conditions listed below:

CONJUNCTIVITIS:

Gram-positive bacteria:
Staphylococcus aureus
Streptococcus epidermidis

Gram-negative bacteria:
Enterobacter cloacae
Proteus mirabilis
Pseudomonas aeruginosa

ANACEROSIS:

Pseudomonas aeruginosa

*Efficacy for this organism was studied in fewer than 10 infections.

CONTRAINDICATIONS

Offoxacin Ophthalmic Solution is contraindicated in patients with a history of hypersensitivity to ofloxacin, other quinolones, or to any of the components in this medication.

WARNINGS

NOT FOR INJECTION.

Offoxacin Ophthalmic Solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones, including ofloxacin. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. A rare occurrence of Stevens-Johnson syndrome, which progressed to toxic epidermal necrolysis, has been reported in a patient who was receiving topical ophthalmic ofloxacin. If an allergic reaction to ofloxacin occurs, discontinue the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management, including intubation should be administered as clinically indicated.

PRECAUTIONS

General: As with other anti-infectives, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If fungal infection occurs, concomitant use of an antifungal drug is recommended. Ofloxacin should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity reaction.

The systemic administration of quinolones, including ofloxacin, has caused arthropathy in immature animals after oral administration; therefore, the ophthalmic dosage form of ofloxacin has any effect on weight bearing joints. Cross-resistance has been observed between ofloxacin and other fluorquinolones. There is generally no cross-resistance between ofloxacin and other classes of antibacterial agents such as beta-lactams or aminoglycosides.

In fertility studies in rats, ofloxacin did not affect male or female fertility or morphological or reproductive performance at oral dosing up to 360 mg/kg/day (equivalent to 4000 times the maximum recommended daily ophthalmic dose).

Pregnancy: Teratogenic Effects. Pregnancy Category C: Offoxacin has been shown to have embryocidal effect in rats and rabbits when given in doses of 810 mg/kg/day (equivalent to 9000 times the maximum recommended daily ophthalmic dose) and 160 mg/kg/day (equivalent to 1600 times the maximum recommended daily dose). These doses resulted in decreased fetal body weight and increased fetal mortality in rats and rabbits, respectively. Minor fetal skeletal variations were reported in rats receiving doses of 810 mg/kg/day. Ofloxacin has not been shown to be teratogenic at doses as high as 810 mg/kg/day and 160 mg/kg/day when administered to pregnant rats and rabbits, respectively.

Nonteratogenic Effects: Additional studies in rats with doses up to 360 mg/kg/day during gestation showed no adverse effect on late fetal development, labor, delivery, lactation, neonatal viability, or growth of the newborn.

There are, however, no adequate and well-controlled studies in pregnant women. Ofloxacin Ophthalmic Solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: In nursing women a single 200 mg oral dose resulted in concentrations of ofloxacin in milk which were similar to those found in plasma. It is not known whether ofloxacin is excreted in human milk following topical administration. If the potential for serious adverse reactions from oral administration to the infant is considered, a decision may be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in infants below the age of one year have not been established.

Quinolones, including ofloxacin, have been shown to cause arthropathy in immature animals after oral administration; however, topical ocular administration of ofloxacin to immature animals has not shown any arthropathy. There is no evidence that the ophthalmic dosage form of ofloxacin has any effect on weight bearing joints.

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

Ophthalmic Use: The most frequently reported drug-related adverse reaction was transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, chemical conjunctivitis/keratitis, ocular/periorificial/facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness, and eye pain. Rare reports of dryness and pruritus have been received.

DOSAGE AND ADMINISTRATION

The recommended dosage regimen for the treatment of bacterial conjunctivitis is:

Days 1 and 2  Instill one to two drops every 30 minutes, while awake.

Days 3 through 7  Instill one to two drops four times daily.

The recommended dosage regimen for the treatment of bacterial corneal ulcer is:

Days 1 and 2  Instill one to two drops every two to four hours in the affected eye.

Days 3 through 7  Instill one to two drops four times daily.

HOW SUPPLIED:

Offoxacin Ophthalmic Solution USP, 0.3% is supplied sterile in plastic DROP-TAINER® of the following fill sizes:

5 mL NDC 61314-012-05
10 mL NDC 61314-012-10


Rx Only

*DROP-TAINER® is a registered trademark of Alcon Research, Ltd.

Sandoz

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