Ofloxacin Ophthalmic Solution 0.3% is a sterile ophthalmic solution. It is a fluorinated carboxyquinolone anti-infective for topical ophthalmic use.

**Description**

**Chemical Name:**

\(\text{C}_{18}\text{H}_{20}\text{FN}_{3}\text{O}_{4}\), Mol. Wt. 361.37

**Chemical Name:**

-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7-\textit{H}-pyrido[1,2,3-\textit{H}]de

**CONTAINS ACTIVE:**

- Ofl oxacin 0.3% (3 mg/mL)

- Sodium chloride and purified water. May also contain hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

**INACTIVES:**

- Benzalkonium chloride (0.005%)

**PRESERVATIVE ADDED:**

- Sodium chloride and purified water. May also contain hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

**Pharmacokinetics**

- Serum, urine, and tear concentrations of ofloxacin were measured in 30 healthy women at various time points during a ten-day course of treatment with Ofl oxacin Ophthalmic Solution. The mean serum ofloxacin concentration ranged from 0.4 ng/mL to 19 ng/mL.

**Duration of Treatment**

- Maximum ofloxacin concentration measured after topical ocular dosing was 9.2 mcg/mL.

**Conjunctivitis**

- Ofloxacin Ophthalmic Solution is indicated for the treatment of infections caused by susceptible strains of the following bacteria in the conjunctival and/or corneal conditions listed below:

**STAPHYLOCOCCUS AUREUS**

**STAPHYLOCOCCUS EPIDERMIS**

**S. PNEUMONIAE**

**S. SIMULANS**

**S. HOMINIS**

**MICROBIOLOGY**

- Ofloxacin has in vitro activity against a broad range of gram-positive and gram-negative aerobic and anaerobic bacteria. Ofloxacin is bactericidal at concentrations equal to or slightly greater than inhibitory concentrations. Ofloxacin is thought to exert a bactericidal effect on susceptible bacterial cells by inhibiting DNA gyrase, an essential bacterial enzyme which is a critical catalyst in the duplication, transcription, and repair of bacterial DNA.

- Cross-resistance has been observed between ofloxacin and other fluoroquinolones. There is generally no cross-resistance between ofloxacin and other classes of antibacterial agents such as beta-lactams or aminoglycosides.

- Ofloxacin has been shown to be active against most strains of the following organisms both in vitro and clinically, and in conjunctival and/or corneal ulcer infections (see INDICATIONS AND USAGE):

**Microbiology**

- 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.

**PHARMACOKINETICS**

- In a randomized, double-masked, multicenter clinical trial, Ofl oxacin Ophthalmic Solution was superior to its vehicle after 2 days of treatment in patients with conjunctivitis and conjunctival discharge. Clinical outcomes for the trial demonstrated an eradication rate for causative pathogens of 65% (41/63) for the ofloxacin treated group versus 25% (17/67) for the vehicle treated group after 2 days of therapy. Please note that microbiologic eradication does not always correlate with clinical outcome in anti-infective trials. Ofl oxacin Ophthalmic Solution has not been shown to be active in vitro against most strains of these organisms but the clinical significance in ophthalmologic infections is unknown.

**Clinical Studies**

- In a randomized, double-masked, multicenter clinical trial, Ofl oxacin Ophthalmic Solution was superior to its vehicle after 2 days of treatment in patients with conjunctivitis and conjunctival discharge. Clinical outcomes for the trial demonstrated an eradication rate for causative pathogens of 65% (41/63) for the ofloxacin treated group versus 25% (17/67) for the vehicle treated group after 2 days of therapy. Please note that microbiologic eradication does not always correlate with clinical outcome in anti-infective trials.

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**ANAEROBIC SPECIES:**

- Propionibacterium acnes

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

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CONTRAINdications
Ofloxacin Ophthalmic Solution is contraindicated in patients with a history of hypersensitivity to ofloxacin, to other quinolones, or to any of the components in this medication (see WARnings).

WARNINGS
NOT FOR INJECTION.
Ofloxacin Ophthalmic Solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.
There are rare reports of anaphylactic shock/choke and fatal hypersensitivity reactions in patients receiving systemic quinolones, some of which have resulted in death.
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 had previously received 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
At-risk for other infections, prolonged use may result in overgrowth of non- susceptible organisms, including fungi. If superinfection occurs discontinue use and institute appropriate therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining. 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 led to lesions or erosions of the cartilage in weight-bearing joints and other signs of arthropathy in immature animals of various species. Ofloxacin, administered systemically at 30 mg/kg/day in young dogs (equivalent to 110 times the maximum recommended daily adult ophthalmic dose) has been associated with these types of effects.

Information for Patients
Avoid contaminating the applicator tip with material from the eye, fingers or other source.

Systemic quinolones, including ofloxacin, have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

Drug Interactions
Specific drug interaction studies have not been conducted with Ofloxacin Ophthalmic Solution. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, and enhance the effects of the oral anticoagulant warfarin and its derivatives, and has been associated with transient elevations in serum creatinine in patients receiving cyclosporine concomitantly.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long term studies to determine the carcinogenic potential of ofloxacin have not been conducted.

Ofloxacin was not mutagenic in the Ames test, in vitro and in vivo cytogenetic assay, sister chromatide exchange assay (Chinese hamster and human cell lines), unscheduled DNA synthesis (UDS) assay using human fibroblasts, the dominant lethal assay, or mouse micronucleus assay. Ofloxacin was positive in the UDS test, using rat hepatocytes, and in the mouse lymphoma assay.

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).

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

<table>
<thead>
<tr>
<th>Dosage</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days 1 and 2</td>
<td>Instill one to two drops every two to four hours in the affected eye(s)</td>
</tr>
<tr>
<td>Days 3 through 7</td>
<td>Instill one to two drops four times daily</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
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<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days 1 and 2</td>
<td>Instill one to two drops into the affected eye every 30 minutes, while awake. Awaken at approximately four and six hours after retiring and instill one to two drops.</td>
</tr>
<tr>
<td>Days 3 through 7 to 9</td>
<td>Instill one to two drops hourly, while awake</td>
</tr>
<tr>
<td>Days 7 to 9</td>
<td>Instill one to two drops, four times daily</td>
</tr>
</tbody>
</table>

DO NOT USE IF IMPRINTED “Protective Seal” WITH YELLOW IS NOT INTACT.

HOW SUPPLIED
Ofloxacin Ophthalmic Solution 0.3% is supplied sterile in plastic dropper bottles with tan caps in the following sizes:
5 mL NDC 24208-434-05
10 mL NDC 24208-434-10

NOTE: Store at 15°C to 25°C (59°F to 77°F).

KEEP OUT OF REACH OF CHILDREN.

FOR OPHTHALMIC USE ONLY.

Manufactured by:
Bausch & Lomb Incorporated
Tampa, FL 33637 USA

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Rev. 06/2019

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9181204 (flat)

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