**INSTRUCTIONS FOR USE**

**Fig. 1**

Turn right (clockwise) to break the seal and make a dispensing hole on the nozzle.

**Fig. 2**

Replace the cap. Tighten it firmly and keep the bottle closed for subsequent use.

**Fig. 3**

Open the cap by turning left (anti-clockwise) and it is ready for use.

**Fig. 4**

Turn it up side down. Squirt the wall of the bottle gently to deliver sterile drop int the eye.

**Fig. 5**

Do not cut with knife.

**Fig. 6**

Do not cut with scissors.

**Fig. 7**

Do not touch the nozzle.

**Fig. 8**

Do not rinse the nozzle.

**Fig. 9**

Do not expose to sunlight.

**Fig. 10**

Do not pierce with needle.

**Fig. 11**

State of the art technology

From Allergan India Private Limited

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**DESCRIPTION**

Each mL contains:
- Ofloxacin IP/USP: 3 mg
- Benzalkonium Chloride IP/USNF: 0.05 mg
- Purified Water IP: q.s.

**DESCRIPTION**

**OFLOXACIN OPTHALMIC SOLUTION IP/USP**

**EXOCIN™** sterile ophthalmic solution

**ALLERGAN**

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**AGENTS**

EXOCIN™ is afluorinated 4 - quinolone antibiotic. It is bactericidal in action. It 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.

Oftoxacin 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:

- *AEROBES, GRAM POSITIVE*: Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus pneumoniae.
- *AEROBES, GRAM NEGATIVE*: Enterobacter cloacae, Haemophilus influenzae, Proteus mirabilis, Pseudomonas aeruginosa, Serratia marcescens.
- Anaerobic Species: Propionibacterium acnes.

- *AEROBES, GRAM POSITIVE*: Eubacterium faecalis, Listeria monocytogenes, Staphylococcus capitis, Staphylococcus hominis, Staphylococcus pyogenes.
- *AEROBES, GRAM NEGATIVE*: Acinetobacter baumannii, Acinetobacter calcoaceticus var. anitratus, Acinetobacter calcoaceticus var. Iwawataii, Citrobacter diversus, Citrobacter freundii, Enterobacter aerogenes, Enterobacter agglomerans, Escherichia coli, Haemophilus parainfluenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Moraxella catarrhalis, Moraxella lacunata, Morganella morganii, Neisseria gonorrhoeae, Pseudomonas aeruginosa, Pseudomonas fluorescens, S. Bovis.
- Other: Chlamydia trachomatis.

**INDICATIONS & USAGE**

EXOCIN™ is indicated for the treatment of conjunctivitis, corneal ulcers, external infections of the eye and ocular surface caused by various gram-negative and gram-positive bacterial and anaerobic species.

**CONTRAINDICATIONS**

EXOCIN™ is contraindicated in patients with a history of hypersensitivity to Oftoxacin, to other quinolones, or to any of the components in this medication.

**WARNINGS**

EXOCIN™ should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

Use the solution within one month of opening the container. Do not touch the nozzle tip to any surface since this may contaminate the solution. If irritation persists or increases, discontinue the use and consult a physician.

**PRECAUTIONS**

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones including Oftoxacin. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioneurotic edema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria and itching.

If an anaphylactic reaction 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.

**GENERAL**: As with other anti-infectives, prolonged use may result in overgrowth of nonsusceptible organisms including fungi. If superinfection occurs discontinue use and institute alternative therapy.

**PREGNANCY**: There are no established control studies to date on safety of using Oftoxacin TOPICAL in pregnant women. Hence discretion on the part of the physician is called for in prescribing to pregnant women.

**NURSING MOTHERS**: Because of the potential for adverse reactions from Oftoxacin in nursing infants, a decision should 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.

**ADVERSE REACTIONS**

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

**DOSEAGE & ADMINISTRATION**

One or two drops of EXOCIN™ should be instilled in the infected eye four times a day. Alleviations (increase and decrease) of dosage may be made based upon the clinical response as judged by the physician. Therapy may be continued for 24 to 48 hours after targets are achieved.

**OVERDOSE**

Clinically apparent symptoms of overdose may be seen as punctate keratitis, erethema, lid edema etc. The drug should be withhold and appropriate change in therapy instituted.

**HOW SUPPLIED**

EXOCIN™ is available in a 5 mL plastic dropper bottle.

**NOTE**: Store in a cool place.

**KEEP MEDICATION OUT OF REACH OF CHILDREN**

Marketed by: Allergan India Private Limited
Manufactured in India by: Piramal Healthcare Limited
Plot No. 67-70, Sector 26, Panchkula 134 030, Haryana, India

**Trade Mark**