INSTRUCTIONS FOR USE

उपयोग संबंधी निर्देश

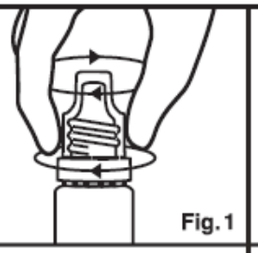

Fig. 1

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

सिल तोड़ने एवम नोज़ल में छिद्र करने के लिये ढक्कन को दाइने तरफ घुमायें।

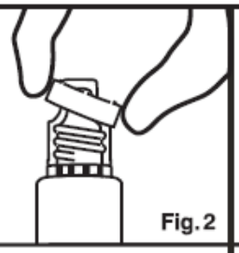

Fig. 2

Remove the ring and discard

छल्ले को निकाल कर फेंक दें।

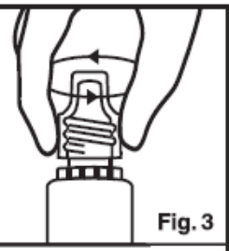

Fig. 3

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

ढक्कन को खोलने के लिये बांयी तरफ घुमायें। अब बोतल उपयोग के लिये तैयार है।

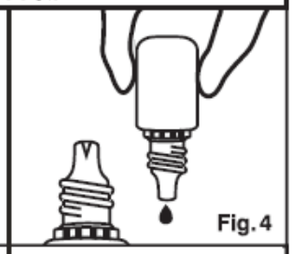

Fig. 4

Turn it up side down. Squeeze the walls of the bottle gently to deliver sterile drop into the eye.

अब बोतल को उल्टा करें, बोतल की दिवार को हलकेसे दबाएँ और आँखों में दवा की बुंदे डालें।

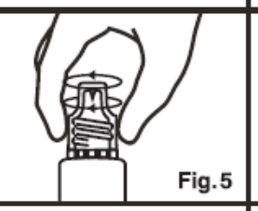

Fig. 5

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

पुनः उपयोग में लाने तक ढक्कन को कसकर बोतल वापस बंद कर दें।

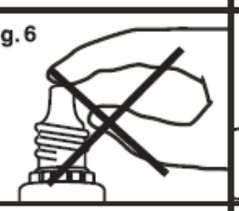

Fig. 6

Do not touch the nozzle.

बोतल के नोज़ल को हाथ न लगाएँ।

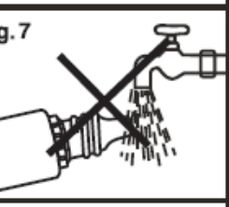

Fig. 7

Do not rinse the nozzle.

नोज़ल को कभी न धोएँ।

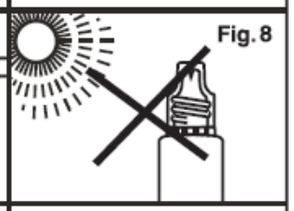

Fig. 8

Do not expose to Sunlight.

बोतल को धूप में न रखें।

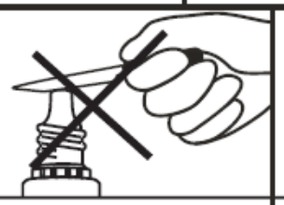

Fig. 9

Do not cut with knife

धारु से ना काटें।

Fig. 10

Do not cut with scissor

कैंची से ना काटें।

Fig. 11

Do not pierce with needle

सुई से छिद्र न करें।

State of the art technology
From Allergan India Private Limited

अत्याधुनिक तरीके से तैयार किया हुआ
अलरगन इंडिया प्राईवेट लिमिटेड द्वारा

A33/d

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

OFLOXACIN OPHTHALMIC SOLUTION IP/USP

EXOCIN™

sterile ophthalmic solution

ALLERGAN

DESCRIPTION

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

ACTIONS

EXOCIN™ is fluorinated 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.

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.

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 : Exterococcus faecalis, Listeria monocytogenes, Staphylococcus capitis, Staphylococcus hominus Staphylococcus simulans, Staphylococcus pyrogenes.

AEROBES, GRAM NEGATIVE : Acinetobacter, calcoaceticus var. anitratus, Acinetobacter calcoacetcus var. Iwoffii Citrobacter diversus, Citrobacter freundii, Enterobacter aerogenes, Enterobacter agglomerans, Escherichia coli, Haemophilus parainfluenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Moraxella (Branhamella) catarrhatis, Moraxella lacunata, Monganilla morganii, Neisseria gonorrhoeae, Pseudomonas acidovorans, Pseudomonas fluorescens, Shigella sonnei.

Other : Chalmydia 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 bacteria and anaerobic species.

CONTRAINDICATIONS

EXOCIN™ is contraindicated in patients with a history of hypersensitivity to Ofloxacin, to other quinolones, or to any of the com--ponents in this medication.

WARNINGS

NOT FOR INJECTION. **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 after opening the container. Do not touch the nozzle tip to any surface since this may contaminate solution. If irriration persist or increases, discontinue the use and consult physician.

PRECAUTIONS

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, angioneurotic edema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, uriticaria and itching.

If an allergic reaction to oflaxacin occurs, discontinue th drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management, including incubation 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 ofloxacin 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 Ofloxacin 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.

PAEDIATRIC 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, periocular / facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness and eye pain. Rare reports of dizziness have been received.

DOSAGE & ADMINISTRATION

One or two drops of **EXOCIN™** should be instilled in the infected eye four times a day. Alterations (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.

OVERDOSAGE

Clinically apparent symptoms of overdosage may be seen as punctate keratitis, erethema, lid edema etc. The drug should be withheld 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 MEDICAMENT OUT OF REACH OF CHILDREN

Marketed by : Allergan India Private Limited

Manufactured in India by : Piramal Healthcare Limited
Plot No. 67-70, Sector 2, Pithampur 454 775, Dist. Dhar, Madhya Pradesh

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