

DOSAGE AND ADMINISTRATION

The recommended dosage regimen for the treatment of bacterial conjunctivitis is:
 Days 1 and 2 : Instill one drop every two hours in the affected eye(s) while awake, up to 8 times daily.

Days 3 through 7: Instill one drop up to four times daily while awake.

Storage : Store in a cool dark place

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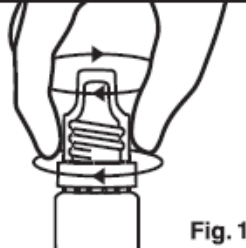
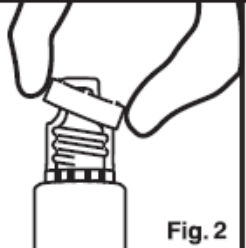
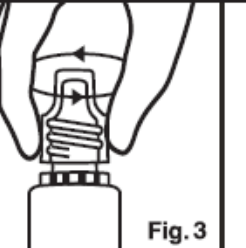
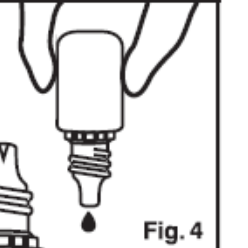
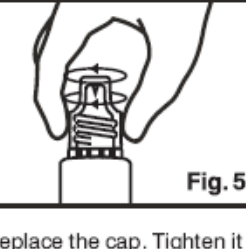
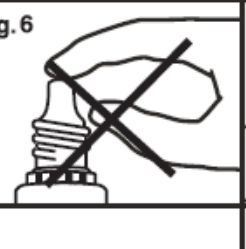
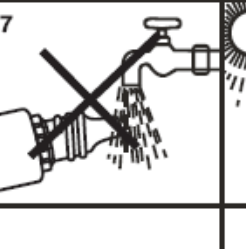
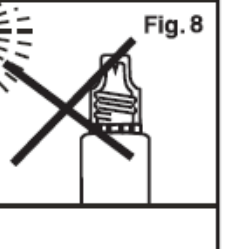

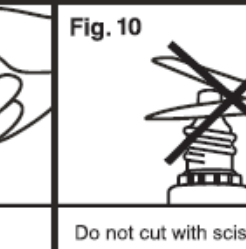
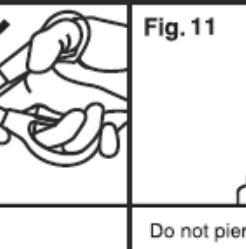
March 2005

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For the use of a registered medical practitioner or laboratory only



INSTRUCTIONS FOR USE		उपयोग संबंधी निर्देश	
 Fig. 1	 Fig. 2	 Fig. 3	 Fig. 4
Turn right (clockwise) to break the seal and make a dispensing hole on the nozzle	Remove the ring and discard	Open the cap by turning left (anti-clockwise) and it is ready for use.	Turn it up side down. Squeeze the walls of the bottle gently to deliver sterile drop into the eye.
सिल तोड़ने एवम नोजल में छिद्र करने के लिये कम्पन को दाहिने तरफ घुमाये।	उसके को निकाल कर फेंक दें।	कम्पन को खोलने के लिये बाँधी तरफ घुमाये। अब बोतल उपयोग के लिये तैयार है।	अब बोतल को उल्टा कर, बोतल की दिवार को हलकेसे दबाएँ और आँखों में दवा की छुटे डालें।
 Fig. 5	 Fig. 6	 Fig. 7	 Fig. 8
Replace the cap. Tighten it firmly and keep the bottle closed for subsequent use.	Do not touch the nozzle.	Do not rinse the nozzle.	Do not expose to Sunlight.
पुनः उपयोग में लाने तक कम्पन को कसकर बोतल वापस बंद कर दें।	बोतल के नोजल को हाथ न लगाएँ।	नोजल को कभी न धोएँ।	बोतल को धूप में न रखें।
 Fig. 9	 Fig. 10	 Fig. 11	
Do not cut with knife	Do not cut with scissor	Do not pierce with needle	
चकू से ना काटे।	कैंची से ना काटे।	सुई से छिद्र न करें।	
State of the art technology From Allergan India Private Limited		अत्याधुनिक तरीके से तैयार किया हुआ अलरगन इंडिया प्राइवेट लिमिटेड द्वारा	

Description

Composition:
 Gatifloxacin Sesquihydrate equivalent to Gatifloxacin IP 0.3%w/v
 Benzalkonium Chloride IP/USNF 0.005%w/v
 Purified Water IP q.s.

CLINICAL PHARMACOLOGY

Pharmacokinetics: Gatifloxacin ophthalmic solution 0.3% or 0.5% was administered to one eye of 6 healthy male subjects each in an escalated dosing regimen starting with a single 2 drop dose, then 2 drops 4 times daily for 7 days and finally 2 drops 8 times daily for 3 days. At all time points, serum gatifloxacin levels were below the lower limit of quantification (5 ng/mL) in all subjects.

Microbiology : Gatifloxacin is an 8-methoxyfluoroquinolone with a 3-methylpiperazinyl substituent at C7. The antibacterial action of gatifloxacin results from inhibition of 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 of fluoroquinolones including gatifloxacin is different from that of aminoglycoside, macrolide, and tetracycline antibiotics. Therefore, gatifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to gatifloxacin. There is no cross-resistance between gatifloxacin and the aforementioned classes of antibiotics. Cross resistance has been observed between systemic gatifloxacin and some other fluoroquinolones. Resistance to gatifloxacin in vitro develops via multiple-step mutations. Resistance to gatifloxacin in vitro occurs at a general frequency of between 1 x 10⁻⁷ to 10⁻¹⁰. Gatifloxacin has been shown to be active against most strains of the following organisms both in vitro and clinically, in conjunctival infections as described in the INDICATIONS AND USAGE section.

Aerobes, Gram-Positive:

*Corynebacterium propinquum** • *Staphylococcus aureus* • *Staphylococcus epidermidis* • *Streptococcusmitis** • *Streptococcus pneumoniae*

Aerobes, Gram-Negative:

Haemophilus influenzae • *Efficacy for this organism was studied in fewer than 10 infections. The following in vitro data are available, but their clinical significance in ophthalmic infections is unknown. The safety and effectiveness of ZYMAR® in treating ophthalmic infections due to the following organisms have not been established in adequate and well-controlled clinical trials. The following organisms are considered susceptible when evaluated using systemic breakpoints. However, a correlation between the in vitro systemic breakpoint and ophthalmological efficacy has not been established. The following list of organisms is provided as guidance only in assessing the potential treatment of conjunctival infections. Gatifloxacin exhibits in vitro minimal inhibitory concentrations (MICs) of 2µg/mL or less (systemic susceptible breakpoint) against most (≥ 90%) strains of the following ocular pathogens.

Aerobes, Gram-Positive:

Listeria monocytogenes • *Staphylococcus saprophyticus* • *Streptococcus agalactiae* • *Streptococcuspyogenes* • *Streptococcus viridans Group* • *Streptococcus Groups C, F, G*•

168 mm

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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