DOSE 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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INSTRUCTIONS FOR USE

Fig. 1
Turn right (clockwise) to break the seal and make a dispensing hole on the nozzle.

Fig. 2
Remove the ring and discard.

Fig. 3
Open the cap by turning left (anti-clockwise) and it is ready for use.

Fig. 4
Turn it up side down. Squeeze the walls of the bottle gently to deliver sterile drop into the eye.

Fig. 5
Replace the cap. Tighten it firmly and keep the bottle closed for subsequent use.

Fig. 6
Do not touch the nozzle.

Fig. 7
Do not rinse the nozzle.

Fig. 8
Do not expose to Sunlight.

Fig. 9
Do not cut with knife.

Fig. 10
Do not cut with scissors.

Fig. 11
Do not pierce with needle.

State of the art technology
From Allergan India Private Limited

ZYMAR
Gatifloxacin Eye Drops 0.3%

Description
Composition:
Gatifloxacin Sesquihydrate equivalent to Gatifloxacin 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 escalating dose 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 aminoglycoside, macrolide, and tetracycline antibiotics. Cross resistance has been observed between systemic gatifloxacin and 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 propinquiurn
- Staphylococcus aureus
- Staphylococcus epidermidis
- Streptococcus pneumonia

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 2 μg/mL or less (systemic susceptible breakpoint) against most (≥ 90%) strains of the following ocular pathogens.

Aerobes, Gram-Positive:
- Listeria monocytogenes
- Staphylococcus saprophyticus
- Streptococcus agalactiae
- Streptococcus pyogenes
- Streptococcus viridans Group
- Streptococcus Groups C, F, G,

Manufactured in India by:
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