Gatifloxacin Eye Ointment - 0.3% w/w

**Description**
Gatifloxacin 0.3% w/w

**Clinical Pharmacology**

**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 amoxicillin, 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 among 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^-10 to 1 x 10^-11.

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 rhodneum
- Staphylococcus aureus
- Streptococcus epidermidis
- Streptococcus faecalis
- Streptococcus pneumoniae

**Aerobes, Gram-Negative**
- Haemophilus influenzae

**Efficacy**
- Gatifloxacin is active against 10 infections.

**Indications and Usage**
Treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: S. Aureus, S. Epidermidis, S. pneumoniae, S. faecalis, Corynebacterium rhodneum and Haemophilus influenzae.

**Contraindications**
Hypersensitivity to gatifloxacin, to other quinolones or to any other components in this medication.

**Warnings**
- In patients receiving systemic quinolones, including gatifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria and itching. If an allergic reaction to gatifloxacin occurs, discontinue the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

**Precautions**
- General
  - As with other anti-infectives, prolonged use may result in overgrowth of non susceptible organisms, including fungi, if super infection occurs discontinue use and institute alternative therapy. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

**Information for Patients**
- Systemic quinolones, including gatifloxacin, 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 Gatifloxacin eye ointment. However, the systemic administration of some other quinolones has been shown to elevate plasma concentrations of theophylline, interferes with the metabolism of caffeine and enhances the effects of the oral anticoagulant warfarin and its derivatives and has been associated with transient elevations in serum creatinine in patients receiving systemic cyclosporine concomitantly.

**Pregnancy**
- Teratogenic Effects: Pregnancy Category C

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 2mg/mL or less (systemic susceptible breakpoint) against 90% of the following ocular pathogens.

- Aerobes, Gram-Positive
  - Corynebacterium rhodneum
  - Staphylococcus aureus
  - Streptococcus agalactiae
  - Streptococcus pyogenes
  - Neisseria meningitidis
  - Neisseria gonorrhoeae
  - Pseudomonas aeruginosa
  - Staphylococcus aureus
  - Staphylococcus epidermidis
  - Streptococcus faecalis
  - Streptococcus pneumoniae

- Aerobes, Gram-Negative
  - Acinetobacter baumannii
  - Enterobacter aerogenes
  - Escherichia coli
  - Haemophilus influenzae
  - Klebsiella pneumoniae
  - Moraxella catarrhalis
  - Morganella morganii
  - Neisseria gonorrhoeae
  - Pseudomonas aeruginosa
  - Proteus mirabilis
  - Proteus vulgaris
  - Salmonella species
  - Vibrio cholerae
  - Yersinia enterocolitica

Other Microorganisms:
- Chlamydia pneumoniae
- Legionella pneumophila

Additional Information:
- Bacillus sp
- Bacteroides fragilis
- Clostridium perfringens

Because there are no adequate and well-controlled studies in pregnant women, Gatifloxacin ointment should be used during pregnancy only if potential benefit justifies the potential risk to the fetus.

**Nursing Mothers**
It is not known whether gatifloxacin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when gatifloxacin is administered to a nursing woman.

**Pediatric Use**
Safety and effectiveness in infants below the age of two years have not been established.

**Geriatric Use**
No overall differences in safety or effectiveness have been observed between elderly and younger patients.

**Adverse Reactions**
The most frequently reported side effects with the use of gatifloxacin ophthalmic solution were conjunctival irritation, increased lacrimation, keratitis, and papillary conjunctivitis. These events occurred in approximately 5-10% of patients. Other reported reactions occurring in <4% of patients were chemosis, conjunctival hemorrhage, dry eyes, eye discharge, eye irritation, eye pain, eyelid edema, headache, red eye and reduced visual acuity.

**Dosage and Administration**
Recommended dosage regimen for the treatment of bacterial conjunctivitis:
- Apply half inch ribbon three times a day on the first two days. For the next five days apply half inch ribbon two times a day.

**Storage**
Store in a cool dark place. Keep out of reach of children.

**How Supplied**
ZYMAR® Eye Ointment is available in a tube of 5 gms.

**Marketed by**
Allergan India Pvt. Ltd.

**Manufactured in India by**
Bangalore - 562 123