As with other anti-infectives, *Staphylococcus epidermidis*, *Staphylococcus aureus*, and aerobic Gram-positive bacteria: susceptible strains of the following organisms:

- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*
- *Streptococcus mitis*
- *Streptococcus oralis*
- *Streptococcus anginosus*

Specific drug interaction studies have not been conducted with gatifloxacin ophthalmic solution.

### Adverse Reactions

 Conjunctival hemorrhage, dry eye, eye discharge, eyelid edema, headache, increased lacrimation, keratitis, papillary changes, and photophobia are typically observed at 200 mg/kg/day (approximately 4000-fold higher than the maximum recommended ophthalmic dose). In a perinatal/postnatal study, increased late post-implantation loss and neonatal/perinatal mortalities were observed at 150 mg/kg/day (approximately 3000-fold higher than the maximum recommended ophthalmic dose). However, in an in vitro study, gatifloxacin was positive in the mouse lymphoma assay and was negative in the Ames Salmonella/microsome assay. The safety and effectiveness of gatifloxacin in infants below one year of age have not been established. No significant differences in toxicity or effectiveness have been observed between elderly and younger patients.

### Dosage and Administration

- ***Topical Use***
  - Instill one drop two to four times daily in the affected eye.

### Use in Specific Populations

#### Pregnancy

Pregnant females: There is no adequate and well-controlled study in pregnant women. Animal data: In rats given 50 mg/kg/day of gatifloxacin (approximately 1000-fold higher than the maximum recommended ophthalmic dose), no adverse effects on reproductive performance were observed, including effects on conception, gestation, parturition, and offspring development. However, in rats given up to 50 mg/kg/day of gatifloxacin (approximately 1000-fold higher than the maximum recommended ophthalmic dose), increased late post-implantation loss and neonatal/perinatal mortalities were observed at 150 mg/kg/day (approximately 3000-fold higher than the maximum recommended ophthalmic dose).

#### Nursing Mothers

Gatifloxacin is excreted in the breast milk of rats. It is unknown whether the drug 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.

#### Children

No specific data are available, but no significant differences in toxicity or effectiveness have been observed between children and adult patients.

Gatifloxacin ophthalmic solution is a sterile, fluorinated, synthetic, flavin analog. The active ingredient is gatifloxacin methanesulfonate, a 6-fluoro-7-(3-methyl-1-piperazinyl)quinolone. It is a yellow powder, or a yellow, odorless, water-soluble, crystalline solid. Gatifloxacin is supplied as 0.5% topical ophthalmic solution.

### CLINICAL PHARMACOLOGY

#### Mechanism of Action

Gatifloxacin is a broad-spectrum, fluoroquinolone antibiotic agent. The antibiotic effect of gatifloxacin results from inhibition of DNA gyrase and topoisomerase IV, which are key enzymes in DNA replication and transcription.

#### Microbiology

Gatifloxacin is active against a wide variety of Gram-positive bacteria, including anaerobic and aerobic species. It is also active against susceptible strains of *Staphylococcus aureus* and *Staphylococcus epidermidis*.

### CONTRAINdications

- Patients with a history of photosensitivity reactions to other fluoroquinolone antibiotics.
- Patients with a history of reactive airway disease.
- Patients with a history of prolonged use of ophthalmic solutions containing benzalkonium chloride.

### WARNINGS AND PRECAUTIONS

- Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis or during the course of therapy with gatifloxacin ophthalmic solution.
- Avoidance of contamination of the product.
- Use of contact lenses while using gatifloxacin ophthalmic solution.

### CLINICAL STUDIES

- In clinical studies with gatifloxacin, the most frequently reported adverse reactions occurring in ≥5% of treated patients were:
  - Headache
  - Conjunctivitis
  - Increased lacrimation
  - Conjunctival hemorrhage
  - Eyelid edema
  - Eye discharge
  - Photophobia

### CLINICAL STUDIES

- To report SUSPECTED ADVERSE REACTIONS, contact Allergan. See: www.allergan.com/products/patent_notices

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