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External Disease Portfolio Fact Sheet

Allergan offers a portfolio of external disease products that includes ZYMAR®, ACULAR LS®, and PRED FORTE®. Built upon a nearly 60-year heritage in ophthalmology and with expertise in discovering and developing new therapeutic agents for conditions and diseases of the eye, Allergan is a global leader in eye care.



ZYMAR® (gatifloxacin ophthalmic solution) 0.3%

- ZYMAR® is the first FDA-approved 4th-generation fluoroquinolone indicated for the treatment of bacterial conjunctivitis (also known as pink eye) caused by susceptible strains of the following organisms:
 - Aerobic Gram-Positive Bacteria: *Corynebacterium propinquum**, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus mitis** and *Streptococcus pneumoniae*. (*Efficacy for this organism was studied in fewer than 10 infections.)
 - Aerobic Gram-Negative Bacteria: *Haemophilus influenzae*.

- ZYMAR® ophthalmic solution is an 8-methoxy fluoroquinolone anti-infective for topical ophthalmic use.
- ZYMAR® is well tolerated by patients and approved for children ages 1 and older.
- If an allergic reaction to gatifloxacin occurs, discontinue the drug. NOT FOR INJECTION. ZYMAR® ophthalmic solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye. 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.
- The most frequently reported adverse events, occurring in approximately five to 10 percent of patients, were conjunctival irritation, increased lacrimation, keratitis and papillary conjunctivitis.
- For more information about ZYMAR® ophthalmic solution, please refer to the full [prescribing information](#) and www.allergan.com.

ACULAR LS® (ketorolac tromethamine ophthalmic solution) 0.4%

- ACULAR LS® is a prescription eye drop indicated for the reduction of ocular pain and burning/stinging following corneal refractive surgery.
- ACULAR LS® blocks the source of post-corneal refractive surgery eye pain¹ and has been shown to achieve significant and rapid pain relief² (42 percent of ACULAR LS® patients were pain free by the first 12 hours post-surgery; demonstrated in 156 patients).³



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- ACULAR LS[®] is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation. There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.
- With some nonsteroidal anti-inflammatory drugs (NSAIDs) there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.
- All topical NSAIDs, including ketorolac tromethamine ophthalmic solution, may slow or delay healing.
- Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs and should be closely monitored for corneal health.
- Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.
- Postmarketing experience with topical NSAIDs also suggests that use more than 24 hours prior to surgery or use beyond 14 days post-surgery may increase patient risk for the occurrence and severity of corneal adverse events.
- It is recommended that ACULAR LS[®] ophthalmic solution be used with caution in patients with known bleeding tendencies or who are receiving other medications, which may prolong bleeding time.
- The most frequently reported adverse events for ACULAR LS[®], occurring in approximately one percent to five percent of patients in the overall study population, were conjunctival hyperemia, corneal infiltrates, headache, ocular edema and ocular pain.
- The most frequent adverse events reported with the use of ketorolac tromethamine ophthalmic solutions have been transient stinging and burning on instillation. These events were reported by 20 percent – 40 percent of patients participating in these other clinical trials.
- For more information about ACULAR LS[®] ophthalmic solution, please refer to the full [prescribing information](#) and www.allergan.com.

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- **PRED FORTE[®] (prednisolone acetate ophthalmic suspension, USP) 1%**
- PRED FORTE[®] is a topical anti-inflammatory agent for ophthalmic use that is indicated for the treatment of steroid-responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.
- PRED FORTE[®] ophthalmic suspension is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections. Adverse reactions include, in decreasing order of frequency, elevation of intraocular pressure with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, and delayed wound healing.
- For more information about PRED FORTE[®] ophthalmic suspension, please refer to the full prescribing information.

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Additional Information

For a complete list of products in the Allergan eye care portfolio and further information on each, please visit www.allergan.com.

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ACULAR is a registered trademark of Roche Palo Alto LLC

¹ Nichols J, Snyder RW. Topical nonsteroidal anti-inflammatory agents in ophthalmology. *Curr Opin Ophthalmol*. 1998;9(4):40-44.

² Solomon K, Donnenfeld E, Raizman M, et al. Safety and efficacy of ketorolac tromethamine 0.4% ophthalmic solution in post-photorefractive keratectomy patients. *J Cataract Refract Surg*. 2004;30:1653-1660.

³ Data on file, Allergan, Inc., 2003; Pivotal Clinical Studies 191578-002 and 191578-003.