FML®

(fluorometholone 0.1%)
LIQUIFILM™
Sterile Ophthalmic Suspension

Each mL contains: fluorometholone 1 mg with: LIQUIFILM™ (polyvinyl alcohol) 14 mg, benzalkonium chloride 0.04 mg, edetate disodium, sodium chloride, sodium phosphate monobasic, sodium phosphate dibasic, polysorbate 80, and purified water.

ACTIONS

Inhibition of the inflammatory response to inciting agents of mechanical, chemical or immunological nature. No generally accepted explanation of this steroid property has been advanced. However, corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2. Adrenocorticosteroids and their derivatives are capable of producing a rise in intraocular pressure. In clinical studies on patients' eyes treated with both dexamethasone and fluorometholone, fluorometholone demonstrated a lower propensity to increase intraocular pressure than did dexamethasone.

INDICATIONS

For steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

CONTRAINDICATIONS

Acute superficial (or epithelial) herpes simplex keratitis (dendritic keratitis).
Fungal diseases of ocular structures.
Vaccinia, varicella and most other viral diseases of the cornea and conjunctiva.
Mycobacterial infection such as tuberculosis of the eye. Hypersensitivity to the constituents of this medication.

WARNINGS

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution.
Prolonged use may cause increased intraocular pressure in susceptible individuals resulting in glaucoma and infrequent damage to the optic nerve, defects in visual acuity and fields of vision; posterior subcapsular cataract formation and delayed wound healing; or may aid in the establishment of secondary ocular infections from fungi or viruses liberated from ocular tissues. Steroids should be used with caution in the presence of glaucoma; intraocular pressure should be checked frequently. Eye drops containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for intraocular pressure.
Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.
Acute purulent untreated infection of the eye may be masked or activity enhanced by presence of steroid medication.

Pediatric Use: Safety and effectiveness have not been demonstrated in children of the age group 2 years or below.
Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Use in Pregnancy and Lactation: There are no adequate and well controlled studies in pregnant women. Administration of corticosteroids to pregnant animals has been associated with abnormalities of fetal development. Fluorometholone has been shown to be embryocidal, fetotoxic, and teratogenic in rabbits when administered by ocular instillation. FML® LIQUIFILM™ should be used with caution during pregnancy only if the potential benefit outweighs the potential risk to the fetus.
It is not known whether topical ophthalmic administration of FML® LIQUIFILM™ could result in sufficient systemic absorption to produce detectable quantities in human breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from fluorometholone, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Effects on Ability to Drive and Use Machines: As with any ocular medication, if transient blurred vision occurs at instillation, the patient should wait until the vision clears before driving or using machinery.

PRECAUTIONS

Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections. As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid applications, fungal invasion must be suspected in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.
Intraocular pressure should be checked frequently.
Use of intraocular steroids may prolong the course and may exacerbate the severity of many viral infections on the eye (including herpes simplex). Use of a corticosteroid medication in the treatment of the patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.

Use with Contact Lenses: The preservative in FML® LIQUIFILM™, benzalkonium chloride, may be absorbed by and cause discoloration of soft contact lenses. Patients wearing soft contact lenses should be instructed to remove contact lenses prior to administration of the solution and wait at least 15 minutes after instilling FML® LIQUIFILM™ before reinserting soft contact lenses.

Visual disturbance: Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, consider evaluating for possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Potential for Eye Injury and Contamination: To prevent eye injury or contamination, care should be taken to avoid touching the bottle or tube tip to the eye or to any other surface. The use of the bottle or tube by more than one person may spread infection. Keep bottle or tube tightly closed when not in use. Keep out of the reach of children.

DRUG INTERACTIONS

Although the systemic exposure is expected to be low with topical ophthalmic corticosteroid administration, co-treatment with CYP3A inhibitors may increase the risk of systemic corticosteroid-related side-effects.

ADVERSE REACTIONS

Elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage, posterior subcapsular cataract formation, secondary ocular infection from pathogens liberated from ocular tissues, perforation of the globe and delayed wound healing.

Class Effects

Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticoidism after use of topical steroids.

Postmarketing Experience

The following adverse reactions have been identified during postmarketing use of FML® LIQUIFILM™. Because postmarketing reporting is voluntary and from a population of uncertain size, it is not possible to reliably estimate the frequency of these reactions:
Investigations: Intraocular pressure increased
Eye disorders: Eye irritation, Conjunctival/Ocular hyperemia, Eye pain, Visual disturbance, Foreign body sensation, Eyelid edema, Blurred vision, Eye discharge, Eye pruritis, Lacrimation increased, Eye edema/Eye swelling, Mydriasis, Cataract (including subcapsular), Ulcerative keratitis, Ocular infection (including bacterial, fungal, and viral infections), Visual field defect, Punctate keratitis, Erythema of eyelid (ointment only).
Immune system disorders: Hypersensitivity
Nervous system disorders: Dysgeusia
Skin and subcutaneous tissue disorders: Rash

OVERDOSE

Overdose by the topical ophthalmic route will not ordinarily cause acute problems. If accidentally ingested, drink fluids to dilute.

DOSAGE AND ADMINISTRATION

1 to 2 drops instilled into the conjunctival sac two to four times daily. During the initial 24 to 48 hours the dosage may be safely increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

HOW SUPPLIED

As a sterile suspension in 5 mL and 10 mL plastic dropper bottles.
Note: Do not store above 25°C. Protect from freezing. Store upright. On prescription only.
Keep out of the reach of children. Shake well before use.

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Allergan™

Manufactured by:
Allergan Pharmaceuticals Ireland,
Westport, Ireland