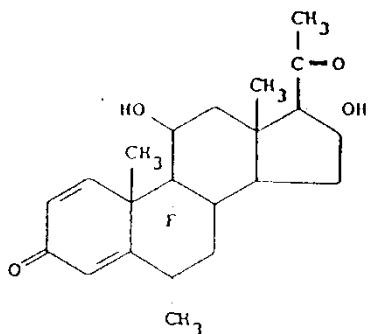


NEW ZEALAND DATA SHEET

FML[®]

Name of the Drug

The active constituent of FML[®] eye drops is fluorometholone.



(structure of fluorometholone)

Description

Fluorometholone is an anti-inflammatory glucocorticoid.

Chemical Name: 9-fluoro-11 β ,17-dihydroxy-6 α -methyl pregna-1,4-diene-3,20-dione.

Empirical formula: C₂₂H₂₉FO₄

FML[®] eye drops contain fluorometholone 1 mg/mL (0.1%), LIQUIFILM[®] (polyvinyl alcohol) 1.4%, benzalkonium chloride 0.004%, disodium edetate, sodium chloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, polysorbate 80, purified water and sodium hydroxide if needed to adjust pH.

Pharmacology

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 A₂ 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 A₂.

Corticosteroids are capable of producing a rise in intraocular pressure. In clinical studies on patient's eyes treated with both dexamethasone and fluorometholone suspensions, 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

FML[®] is contraindicated in patients with acute superficial *Herpes simplex* keratitis, fungal diseases of ocular structures, vaccinia, varicella, mycobacterial infection of the eye and most other viral diseases of the cornea and conjunctiva, tuberculosis of the eye, or hypersensitivity to the constituents of this medication.

Precautions

Steroid medication in the treatment of patients with a history of *Herpes simplex* keratitis requires great caution. Frequent slit lamp microscopy is mandatory. (See Contraindications)

Eye drops contain a corticosteroid should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for intraocular pressure.

Prolonged use may cause increased intraocular pressure in susceptible individuals resulting in glaucoma, with 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.

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 tissues may lead to perforation.

Acute purulent untreated infection of the eye may be masked or activity enhanced by presence of steroid medication.

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. Intraocular pressure should be checked frequently.

Information for patients:

To prevent contamination, care should be taken to avoid touching the bottle to the eye or to any other surface. The use of the bottle by more than one person may spread infection. Keep bottle tightly closed when not in use. Keep out of the reach of children.

The preservative in FML[®], benzalkonium chloride, may be absorbed by soft contact lenses. Patients wearing soft contact lenses should be instructed to wait at least 15 minutes after instilling FML[®] to insert soft contact lenses.

Use in pregnancy: (Category B3)

Fluorometholone has been shown to be teratogenic, fetotoxic, and embryocidal in rabbits when given in doses approximating the human dose and above. Safety of the use of topical steroids during pregnancy has not been established. Fluorometholone was ocularly applied to both eyes of pregnant rabbits on days 6 to 18 of gestation. A significant dose-related increase in foetal abnormalities and in foetal loss was observed.

FML[®] should be used with caution during pregnancy only if the potential benefit outweighs the potential risk to the foetus.

Use in lactation:

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from flurometholone, 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.

Use in children:

Safety and effectiveness have not been demonstrated in children under 2 years of age.

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.

Adverse Reactions

Elevation of intraocular pressure (IOP) with possible development of glaucoma, and optic nerve damage, loss of visual acuity or defects in fields of vision, eye irritation, conjunctival/ocular hyperaemia, eye pain, visual disturbance, foreign body sensation, eyelid oedema, blurred vision, eye discharge, eye pruritus, lacrimation increased, eye oedema/eye swelling, mydriasis, posterior subcapsular cataract formation, ulcerative keratitis, ocular infection (including bacterial fungal and viral infections), punctate keratitis, hypersensitivity, dysgeusia, rash and delayed wound healing. The following have also been reported after the use of topical corticosteroids - secondary ocular infection from pathogens liberated from ocular tissues, perforation of the globe where there is thinning of the cornea or sclera, and rare occurrences of systemic hypercorticism.

Dosage and Administration

Bottle should be shaken before use.

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. In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of applications.

In order to minimise systemic absorption of FML[®] eye drops, apply pressure to the tear duct immediately following administration of the drug.

Overdosage

If accidentally ingested, drink fluids to dilute. Should an excess amount of drops be inadvertently administered, flush the eyes with water.

Presentation/Package Quantities

Eye drops: A sterile suspension in 5 mL plastic dropper bottles.
Storage: Store below 25°C. Protect from freezing. Store upright.
Shelf life: 3 years.
Discard unused contents 4 weeks after opening.
Contents are sterile if seal is intact.

Name and Address

Allergan New Zealand Limited,
Corner of Manu Tapu Drive and
Joseph Hammond Place
Auckland International Airport
Mangere
AUCKLAND

Toll free telephone: 0800 659 912

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