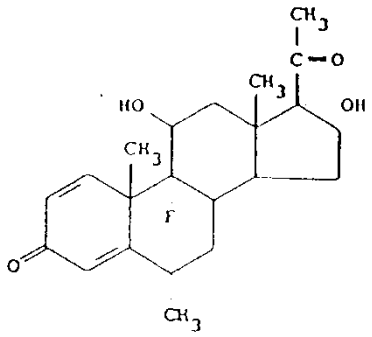
FML®

NAME OF THE DRUG
The active constituent of FML® eye drops is fluorometholone.



(structure of fluorometholone)

DESCRIPTION
Fluorometholone is an anti-inflammatory glucosteroid.
Chemical Name: 9-fluoro-11β,17-dihydroxy-6∝-methyl pregna-1,4-diene-3,20-dione.
Empirical formula: $C_{22}H_{29}FO_4$

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 , 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 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.
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 (or epithelial) *Herpes simplex* keratitis (dendritic 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 in patients with 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 containing 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. Fungal cultures should be taken when appropriate.

Intraocular pressure should be checked frequently.

Information for patients:

To prevent eye injury or contamination, care should be taken to avoid touching the bottle tip 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 and cause discolouration 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® before reinserting soft contact lenses.

Use in pregnancy: (Category B3)
There are no adequate well-controlled studies in pregnant women. 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 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.

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 disturbances, 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 hypercorticoidism.

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

OVERDOSAGE

Should an excess amount of drops be inadvertently administered, flush the eyes with water.

PRESENTATION

Eye drops:	A sterile suspension in 5 mL plastic dropper bottles.
Storage:	Store below 25°C. Protect from freezing.
Shelf life:	3 years.

Discard unused contents 4 weeks after opening.
Contents are sterile if seal is intact. Store upright.

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DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (the ARTG) 10 October 1991

Date of Most Recent Amendment: 20 October 2014

Poisons schedule: S4.