**DESCRIPTION**

Each mL contains:
- Flurometholone USP 1 mg
- Benzalkonium Chloride IP/USNF 0.04 mg
- Purified Water IP q.s.

**ACTIONS**

Corticosteroids, such as Flurometholone, inhibit the inflammatory response to a variety of inciting agents. They inhibit the exudation of fluid, fibrin deposition, capillary dilation, leukocyte migration, phagocytic activity, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation.

Corticosteroids inhibit the synthesis of histamine within mast cells by blocking the action of histidine decarboxylase. Corticosteroids also decrease prostaglandin synthesis and retard epithelial regeneration.

Corticosteroids and their derivatives are capable of producing a rise in intraocular pressure. In clinical studies on patients' eyes treated with both Dexamethasone 0.1% and Flurometholone 0.1%, Flurometholone demonstrated a lower propensity to increase intraocular pressure than did Dexamethasone.

**INDICATIONS**

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

**CONTRAINDICATIONS**

Acute superficial herpes simplex keratitis, Fungal disease of ocular structures, Vaccinia, Varicella and most other viral diseases of the cornea and conjunctiva. Tuberculosis of the eye Hypersensitivity to drug.

**WARNINGS**

Steroid medication in the treatment of herpes simplex keratitis (involving the stroma) requires great caution; frequent slit-lamp microscopy is mandatory.

Prolonged use may result in glaucoma, damage to the optic nerve, defects in visual acuity and fields of vision, posterior subcapsular cataract formation, or may aid in the establishment of secondary ocular infections from fungi or viruses liberated from ocular tissue. In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with use of topical steroids.

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

Safety and effectiveness have not been demonstrated in children of the age group 2 years or below.

**Use in Pregnancy:** Safety of the use of topical steroids during pregnancy has not been established.

NOT FOR INJECTION. Use the solution within one month after opening the container. Do not touch the nozzle tip to any surface since this may contaminate solution. If irritation persists or increases discontinue use and consult physician. Indiscriminate and prolonged use of the preparation may lead to glaucoma, cataract and fungal infections.

**PRECAUTIONS**

As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid applications; fungus 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.

**ADVERSE REACTIONS**

Glaucoma with optic nerve damage, visual acuity or field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens liberated from ocular tissue, perforation of the globe.

**Dosage and Administration**

1 to 2 drops to be instilled into 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**

FML™ is available as a sterile ophthalmic suspension in 5mL plastic dropper bottle.

**NOTE:** Store in a cool place. Protect from freezing. On prescription only. Shake well before use.

**Keep Medicament Out of Reach of Children**

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