Each mL contains:
- Flurometholone USP: 1mg
- Neomycin Sulfate IP equivalent to Neomycin: 3.5 mg
- Benzalkonium Chloride IP: USNF: 0.04 mg
- Purified Water IP: q.s.

**DESCRIPTION**

Corticosteroids, such as Flurometholone, inhibit the inflammatory response to a variety of inciting agents. They 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 demonstrated a lower propensity to increase intraocular pressure than did Dexamethasone.

Neomycin is a broad spectrum bactericidal antibiotic effective against a variety of gram-positive and gram-negative organisms such as Staphylococcus aureus, Escherichia coli, Haemophilus influenzae, Klebsiella/Enterobacter species, Neisseria species, Proteus and Corynebacterium.

Putatively, and bacteria growth products do not inactivate the antibiotic.

**INDICATIONS**

1. FML NEO is effective in the treatment of infectious conjunctivitis due to organisms sensitive to Neomycin.
2. FML NEO may be used as the treatment of the anterior segment inflammatory disorders which may be threatened with or complicated by bacteria sensitive to Neomycin.
3. FML NEO is effective following removal of foreign bodies as well as before and after surgery where the possibility of infection with susceptible organisms exists.

**CONTRAINDICATIONS**

Acute untreated purulent ocular infections caused by microorganisms not sensitive to Neomycin. Acute superficial herpes simplex (dendritic keratitis), vaccinia, varicella, and most viral diseases of the conjunctiva and cornea. Ocular tuberculosis, Fungal diseases of the eye. Hypersensitivity to drug.

**WARNINGS**

1. In diseases due to microorganisms resistant to Neomycin, infection may be masked, enhanced or activated by the steroids. Prolonged use may result in overgrowth of non-susceptible organisms.
2. Articles in current medical literature indicate an increase in the prevalence of persons sensitive to Neomycin. The possibility of such a reaction should be borne in mind.
3. If sensitivity or other untoward reactions occur, discontinue the medication.
4. As fungal infections of the cornea have been reported coincidentally with long-term topical steroid applications, fungal invasion may be suspected in any persistent corneal ulceration where a steroid has been used, or is in use, over a prolonged period of time.
5. 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 cornea and scleral tissue may lead to perforation.
6. Acute purulent untreated infections of the eye may be masked, enhanced, or activated by the presence of steroid medication. Secondary ocular infection may occur from pathogens liberated from ocular tissues.
7. Use of steroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit-lamp microscopy is required.
8. Reports in the literature indicate that posterior subcapsular lenticular opacities have occurred after heavy or prolonged use of topical ophthalmic corticosteroids.
9. Prolonged use of topical steroids may increase intraocular pressure. Although currently available data indicate that intraocular pressure rise is generally not a problem with patients being treated with Flurometholone 0.1% their intraocular pressure should be checked periodically.

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 the 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.

**USE IN PREGNANCY**

Safety of intensified or protracted uses of topical steroids during pregnancy has not been substantiated.

Use of topical steroid may increase intraocular pressure. With prolonged use of FML NEO the Intraocular pressure and lens should be examined periodically.

**DOSAGE AND ADMINISTRATION**

1 to 2 drops in the conjunctival sac two to four times daily. During the initial 24-48 hours, the dosage may be safely increased to 1 drop every hour. Care should be taken not to discontinue treatment prematurely.

**HOW SUPPLIED**

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

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

**KEEP MEDICATION OUT OF REACH OF CHILDREN**

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**FLUROMETHOLONE AND NEOXYCIN SULPHATE OPHTHALMIC SUSPENSION**

FML NEO™ (Liquifilm™)
Sterile ophthalmic suspension

State of the art technology
From Allergan India Private Limited

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