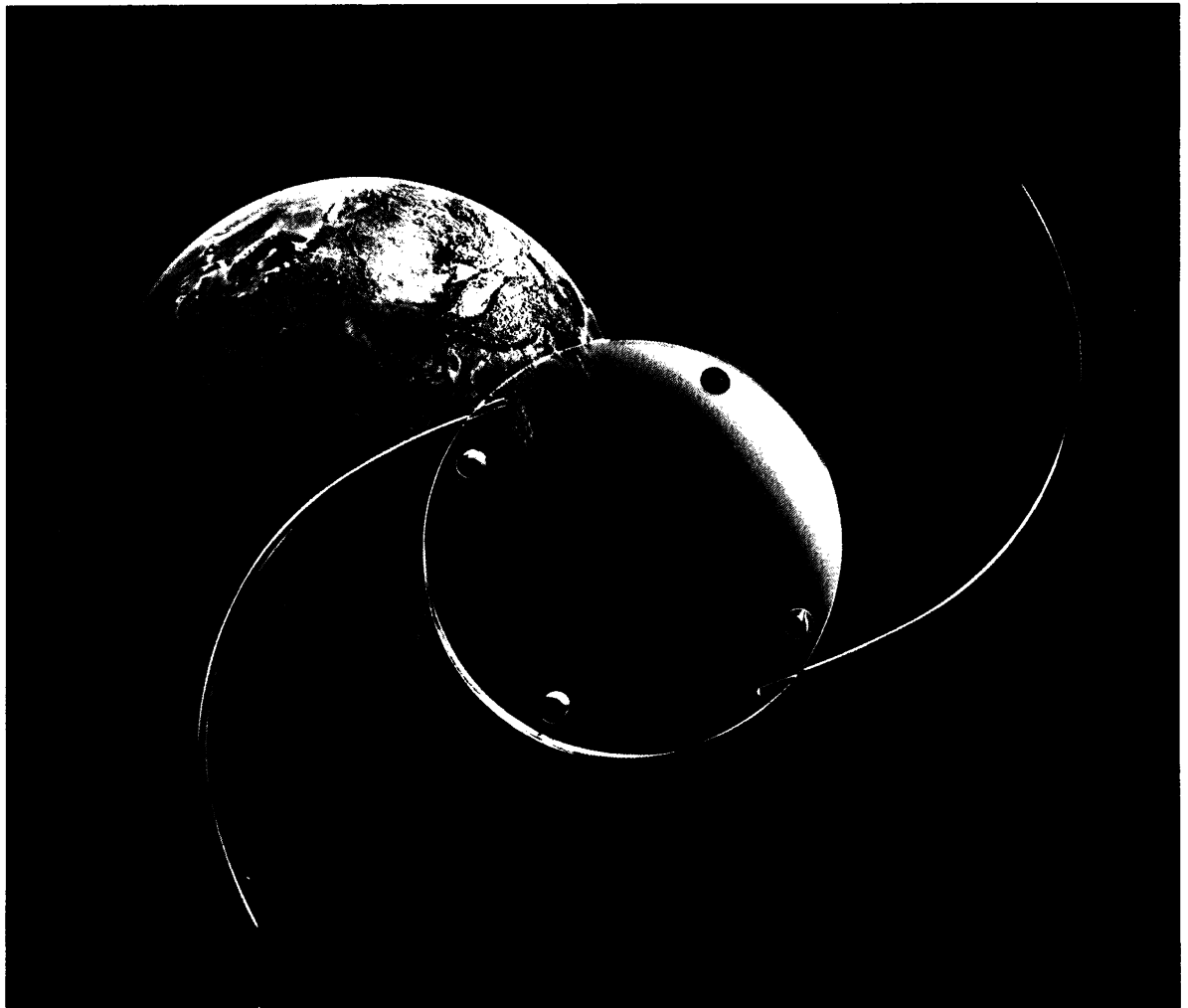


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FML™ PRESCRIBING INFORMATION

Presentation White, microfine, sterile ophthalmic suspension containing fluorometholone (0.1%). **Uses** Topical ophthalmic suspension for steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe. **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. **Contra-indications, Warnings, etc.** CONTRA-INDICATIONS: Acute superficial herpes simplex keratitis. Fungal diseases of ocular structures, vaccinia, varicella and most other viral diseases of the cornea and conjunctiva. Tuberculosis of the eye. Hypersensitivity to the constituents of this medication. **Warnings** Steroid medication in the treatment of herpes simplex keratitis involving the cornea 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. Safety and effectiveness have not been demonstrated in children of the age group two years or below. This preparation contains benzalkonium chloride and should be used with caution in association with hydrophilic contact lenses. **Use in Pregnancy** Safety of the use of topical steroids during pregnancy has not been established. **Precautions** As fungal infections of the cornea are particularly prone to develop coincidentally with long-term steroid applications, fungus invasion must be suspected in any persistent corneal ulceration where a steroid has been used or is in use. Intra-ocular 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 tissues, perforation of the globe. Local side effects of steroid therapy, ie skin atrophy, striae and telangiectasia, are especially likely to affect facial skin. **Pharmaceutical Precautions** Protect from freezing. **Legal Category** POM. **Package Quantities** Supplied in plastic dropper bottles of 5ml and 10ml. Basic NHS cost (as at July 1984) 5ml £1.78, 10ml £2.83. PL 0426/0026. Full prescribing information is available on request.

Trade Mark

FML-NEO™ PRESCRIBING INFORMATION

Presentation Sterile, white, microfine ophthalmic suspension containing fluorometholone, NF0.1% and neomycin sulphate, BP0.5% (equivalent to 0.35% neomycin base). **Uses** FML-NEO™ is indicated for the management of steroid responsive inflammation of the palpebral or bulbar conjunctiva, cornea and anterior segment of the globe, when threatened or complicated by infection with neomycin-sensitive organisms. **Dosage and Administration** One or two drops in the conjunctival sac two to four times daily. During the initial 24 to 48 hours, the dosage may be safely increased to one drop every hour. Care should be taken not to discontinue treatment prematurely. Shake well before using. **Contra-indications, Warnings, etc.** Acute untreated purulent ocular infection. Acute superficial herpes simplex (dendritic keratitis), vaccinia, varicella and most other viral diseases of the conjunctiva and cornea. Ocular tuberculosis, fungal diseases of the eye and hypersensitivity to any of the components of the drug. **Warnings** As for FML above and, in addition in diseases due to micro-organisms resistant to neomycin, infection may be masked or enhanced or activated by the steroid. Prolonged use may result in overgrowth of non-susceptible organisms. Articles in current medical literature indicate increase in the prevalence of persons sensitive to neomycin. The possibility of such a reaction should be borne in mind. If sensitisation or other untoward reactions occur, discontinue the medication. **Precautions** Patients with histories of herpes simplex keratitis should be treated with caution. Use of topical steroids may increase intraocular pressure. Safety of intensive or protracted use of topical steroids during pregnancy has not been substantiated. Local side effects of steroid therapy, ie skin atrophy, striae and telangiectasia, are especially likely to affect facial skin. **Pharmaceutical Precautions** Shake well before using. Do not freeze. **Legal Category** POM. **Package Quantities** Available in 5ml plastic dropper bottles. Basic NHS cost (as at July 1984) £1.90. PL 0426/0043. Prescribing information is available on request.

*Trade Mark

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