

**DESCRIPTION:**

Each ml contains:

- Prednisolone Acetate USP 10 mg
- Benzalkonium Chloride USP 0.06 mg

**ACTIONS:**

Prednisolone Acetate is a glucocorticoid that, on the basis of weight, has 3 to 5 times the anti-inflammatory potency of hydrocortisone. Glucocorticoids inhibit the edema, fibrin deposition, capillary dilation and phagocytic migration of the acute inflammatory response as well as capillary proliferation, deposition of collagen and scar formation.

**INDICATIONS:**

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

**CONTRAINDICATIONS:**

Acute untreated purulent ocular infections, acute superficial herpes simplex (dendritic keratitis), vaccinia, varicella and most other viral diseases of the cornea and conjunctiva, ocular tuberculosis, and fungal diseases of the eye, and sensitivity to the drug.

**WARNINGS:**

1. In those diseases causing thinning of the cornea, perforation has been reported with the use of topical steroids.

2. Since Pred. Acetate contains no antimicrobial, if infection is present appropriate measures must be taken to counteract the organisms involved.

3. Acute purulent infections of the eye may be masked or



**Prednisolone Acetate**  
(Prednisolone Acetate 1.0%)

enhanced by the use of topical steroids.

4. Use of steroid medication in the presence of stromal herpes simplex requires caution and should be followed by frequent mandatory slit-lamp microscopy.

5, As fungal infections of the cornea have been reported coincidentally with long term local steroid applications, fungal invasion may be suspected in any persistent corneal ulceration where a steroid has been used, or is in use.

6. Use of topical corticosteroids may cause increased intraocular pressure in certain individuals. This may result in damage to the optic nerve with defects in the visual fields. It is advisable that the intraocular pressure be checked frequently.

7. **Use in pregnancy** - Safety of intensive or protracted use of topical steroids during pregnancy has not been substantiated.

**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.

#### **PRECAUTIONS:**

Posterior subcapsular cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids.

Patients with histories of herpes simplex keratitis should be treated with caution.

#### **ADVERSE REACTIONS:**

Increased intraocular pressure, with optic nerve damage, defects in the visual fields. Also, posterior subcapsular cataract formation, secondary ocular infections from fungi or viruses liberated from ocular tissues, and perforation of the globe when used in conditions where there is thinning of the cornea and

sclera. Systemic side effects may occur with extensive use of steroids.

**DOSAGE & 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 two drops every hour. Care should be taken not to discontinue therapy prematurely.

**HOW SUPPLIED:**

**Pred. Acetate** is available as a sterile suspension in 5ml plastic dropper bottles.

**Note:** Store in a cool place, protect from freezing. On prescription only. Shake well before use.

DESCRIPTION:

Each ml contains

- Fluorometholone USP I mg
- Ecozalkonium Chloride USP 0.04 mg

ACTIONS:

Corticosteroids, such as Fluorometholone, inhibit the inflammatory response to a variety of inciting agents. They inhibit the edema, fibrine 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 Fluorometholone 0.1%, 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:

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 drug.

WARNINGS:

Steroid medication in the treatment of herpes simplex



**FML™**  
 (Fluorometholone 0.1%)  
 Liquifilm™ Sterile Ophthalmic Suspension

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 sub-capsular 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 this 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 application; 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

**ADVERSE REACTIONS:**

Glaucoma with optic nerve damage, visual acuity or field defects, posterior sub-capsular cataract formation, secondary ocular infection from pathogens liberated from ocular tissues,

perforation of the globe.

**DOSAGE & ADMINISTRATION:**

1 drop 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 sterile suspension in 5 ml plastic dropper bottles.

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**DESCRIPTION:**

Each ml contains

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

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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 drug.

**WARNINGS:**

Steroid medication in the treatment of herpes simplex



**FML FORTE™**

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