2314

護目寧點眼懸浮液
FML® Liquifilm® Ophthalmic Suspension

衛署藥字第018656號

FRONT

TITLE PANEL (IF NEEDED)

主成分： Each ml contains:
Fluorometholone 1mg
With: Liquifilm® (Polyvinyl alcohol) 14mg
benzalkonium chloride 0.04mg
edetate disodium; sodium chloride;
sodium phosphate monobasic, monohydrate;
sodium phosphate dibasic anhydrous;
polysorbate 80; sodium hydroxide to adjust PH;
and purified water.

作　　用：本品能治療由物理，化學或天然免疫等刺激物所引起的發炎現象。雖然腎上腺皮質類固醇製劑易使眼內壓增高，但臨床研究以dexamethasone及fluorometholone治療眼疾時證明fluorometholone所引起眼內壓增高的傾向比dexamethasone低。

適 應 症：眼瞼炎、結膜炎、強膜炎、上強膜炎、虹彩炎、虹彩毛樣體炎。

禁 忌 症：急性淺部單純性疱疹角膜炎、眼黴菌感染、牛痘、水痘及角膜、結膜之病毒性感染、眼結核、或對主成分過敏者。

注意事項：
1. 以類固醇治療單純性疱疹角膜炎(包括基質)時必須非常小心，同時應常用裂隙燈顯微鏡檢查。
2. 長期使用可能導致青光眼，視神經損壞，視力敏度減弱，視野障礙，後囊下白內障，及促使黴菌或病毒引起眼部再度感染。
3. 有些疾病會使角膜或鞏膜變薄，則使用局部類固醇製劑時易產生角膜穿孔。
4. 局部類固醇製劑可能會隱蔽或加重急性化膿性感染之眼疾。
5. 對於兩歲以下的兒童或孕婦，使用局部類固醇的安全性仍未確定。
6. 曾有報告在長期使用局部類固醇時角膜易受黴菌感染，因此對於持續性角膜潰瘍，不論是曾經或正在使用局部類固醇治療，均須檢查是否有黴菌感染。
7. 時常檢查眼內壓。

副 作 用：視神經損壞、青光眼，視力敏度減弱，視野障礙，後囊下白內障或使黴菌、病毒引起眼部之再度感染。

用法、用量：每次1-2滴，每天2-4次，開始治療24-48小時內劑量可安全地增加到每小時2滴，但須注意不可過早停藥。

本藥須由醫師處方使用

包　　裝：5ml，10ml 塑膠滴瓶。

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INSERT STANDARDIZED,
4" X 10"
0284301

FML®
(fluorometholone 0.1%)
LIQUIFILM®
Sterile Ophthalmic Suspension

ALLERGAN®

BACK

Each mL contains: fluorometholone 1 mg with: Liquifilm (polyvinyl alcohol) 14 mg, benzalkonium chloride 0.04 mg, edetate disodium, sodium chloride, sodium phosphate monobasic, sodium phosphate dibasic, polysorbate 80, and purified water.

ACTIONS
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. Adrenocorticosteroids and their derivatives are capable of producing a rise in intraocular pressure. In clinical studies on patients' eyes treated with both dexamethasone and fluorometholone, 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 the constituents of this medication.

WARNINGS
Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution.
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; or may aid in the establishment of secondary ocular infections from fungi or viruses liberated from ocular tissues.
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 tissue may lead to perforation.
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.

PRECAUTIONS
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.
Intraocular pressure should be checked frequently.

ADVERSE REACTIONS
Elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage, posterior subcapsular cataract formation, secondary ocular infection from pathogens liberated from ocular tissues, perforation of the globe and delayed wound healing.

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.

HOW SUPPLIED
As a sterile suspension in 5 mL and 10 mL plastic dropper bottles.
Note: Store between 15° - 25°C. Protect from freezing. Store upright. On prescription only.
Keep out of the reach of children. **Shake well before use.**
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ALLERGAN®
Manufactured by:
Allergan Pharmaceuticals Ireland,
Westport, Ireland

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