

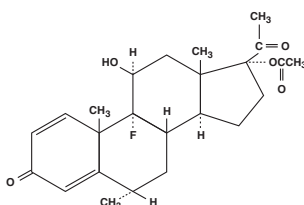


FLAREX[®]

(Fluorometholone Acetate 0.1%)
Sterile Ophthalmic Suspension

DESCRIPTION:

FLAREX[®] (Fluorometholone Acetate) is a corticosteroid prepared as a sterile topical ophthalmic suspension. The active ingredient, fluorometholone acetate, is a white to creamy white powder with an empirical formula of C₂₄H₃₁FO₅ and a molecular weight of 418.5. Its chemical name is 9-fluoro-11β, 17-dihydroxy-6α-methylpregna-1, 4-diene-3, 20-dione 17-acetate. The chemical structure of fluorometholone acetate is presented below:



Each ml contains:

Active: Fluorometholone Acetate 0.1%.

Preservative: Benzalkonium Chloride 0.01%.

Inactives: Sodium Dihydrogen Phosphate monohydrate, Sodium Chloride, Edetate Disodium, Hydroxyethylcellulose, Tyloxapol, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH), and Purified Water.

CLINICAL PHARMACOLOGY:

Corticosteroids suppress the inflammatory response to inciting agents of mechanical, chemical or immunological nature. No generally accepted explanation of this steroid property has been advanced. Clinical studies demonstrate that fluorometholone acetate is significantly more efficacious than fluorometholone for the treatment of external ocular inflammation.¹

Corticosteroids cause a rise in intraocular pressure in susceptible individuals. In a small study, FLAREX Ophthalmic Suspension demonstrated a significantly longer average time to produce a rise in intraocular pressure than did dexamethasone phosphate; however, the ultimate magnitude of the rise was equivalent for both drugs and in a small percentage of individuals a significant rise in intraocular pressure occurred within three days.²

INDICATIONS AND USAGE:

For steroid responsive allergic and other inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye.

CONTRAINDICATIONS:

Acute superficial herpes simplex keratitis, vaccinia, varicella and most other viral diseases of the cornea and conjunctiva; fungal diseases, tuberculosis; acute purulent untreated infections which, like other diseases caused by microorganisms, may be masked or enhanced by the presence of the steroid; and in those persons who have known hypersensitivity to any component of this preparation.

WARNINGS: FOR TOPICAL USE ONLY — NOT FOR INJECTION.

Use of steroid medication in the treatment of herpes simplex infection requires great caution. Prolonged use may result in glaucoma, damage to the optic nerve, defects in visual acuity and visual field, cataract formation, and/or may aid in the establishment of secondary ocular infections from pathogens due to suppression of host response. Acute purulent infections of the eye may be masked or

ALCON BELGIUM

PRODUKTNAAM :	Flarex 5 ml	
CODE /LAND:	34695-D	EET
AFMETING :	140 x 210 / 140 x 22 mm	
AANTAL FILMEN :	2	recto-verso
KLEUR :	zwart	
INITIALEN/DATUM :	MM	24-07-'00

exacerbated by the presence of steroid medication. In those diseases causing thinning of the cornea or sclera, intraocular pressure has been known to occur with chronic use of topical steroids. It is advisable that the intraocular pressure be checked frequently.

PRECAUTIONS:

General: Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.

Information for Patients: Do not touch dropper tip to any surface, as this may contaminate the suspension.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No studies have been conducted in animals or in humans to evaluate the possibility of these effects with fluorometholone.

Pregnancy: Fluorometholone has been shown to be embryocidal and teratogenic in rabbits when administered at low multiples of the human ocular dose. Fluorometholone was applied ocularly to rabbits daily on days 6-18 of gestation, and dose-related fetal loss and fetal abnormalities including cleft palate, deformed rib cage, anomalous limbs and neural abnormalities such as encephalocele, craniorachischisis, and spina bifida were observed. There are no adequate and well controlled studies of fluorometholone in pregnant women, and it is not known whether fluorometholone can cause fetal harm when administered to a pregnant women. Fluorometholone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemically-administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from fluorometholone, a decision should be made whether to discontinue nursing or to discontinue the drug.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS:

Glaucoma with optic nerve damage, visual acuity and visual field defects, cataract formation, secondary ocular infection following suppression of host response, and perforation of the globe may occur.

DOSAGE AND ADMINISTRATION:

SHAKE WELL BEFORE USING. One to two drops instilled into the conjunctival sac of the affected eye(s) four times daily. During the initial 24 to 48 hours the dosage may be safely increased to two drops every two hours. If no improvement occurs after two weeks, consult physician. Care should be taken not to discontinue therapy prematurely.

HOW SUPPLIED:

5 ml plastic DROP-TAINER® Dispenser.

STORAGE:

Store upright at 2°-27°C. Protect from freezing.

Keep out of reach of children.

Discard one month after opening.

references:

1. Leibowitz, H. M., et. al., Annals of Ophthalmology 1984; 16:1110.
2. Stewart, R. H., et. al., Current Eye Research 1984; 3:835.

Alcon[®]
ALCON-COUVREUR
B-2870 Puurs, (Belgium)

ALCON BELGIUM

PRODUKTNAAM :	Flarex 5 ml	
CODE /LAND :	34695-D	EET
AFMETING :	140 x 210 / 140 x 22 mm	
AANTAL FILMEN :	2	recto- verso
KLEUR :	zwart	
INITIALEN/DATUM :	MM	24-07-'00