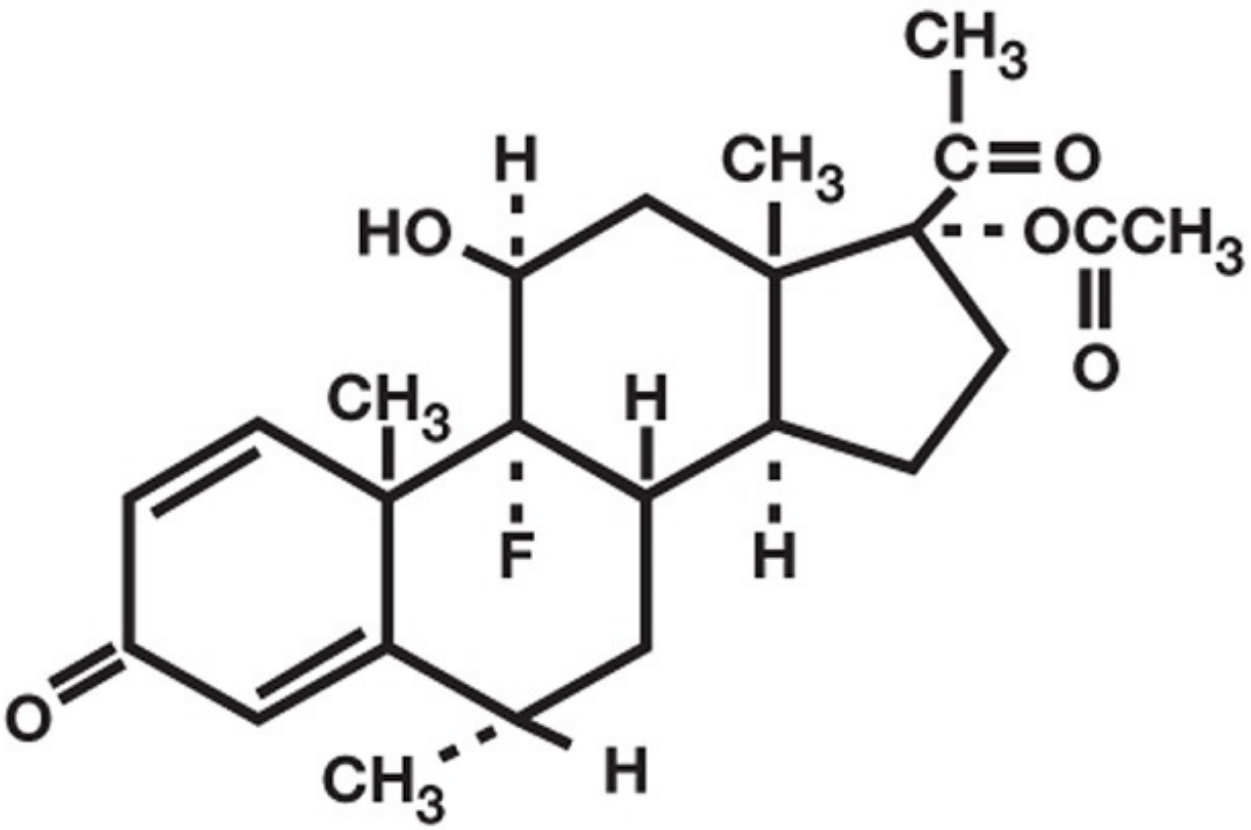
FLAREX - fluorometholone acetate suspension/ drops
Alcon Laboratories, Inc.

Flarex®
(fluorometholone acetate ophthalmic suspension) 0.1%
Sterile

DESCRIPTION

FLAREX® (fluorometholone acetate ophthalmic suspension) 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 $C_{24}H_{31}FO_5$ and a molecular weight of 418.5. Its chemical name is 9-fluoro-11$^{\beta}$, 17-dihydroxy-6$^{\alpha}$-methylpregna-1, 4-diene-3, 20-dione 17-acetate. The chemical structure of Fluorometholone Acetate is presented below:



Each mL contains: Active: fluorometholone acetate 1 mg (0.1%). **Preservative:** benzalkonium chloride 0.01%. **Inactives:** sodium chloride, monobasic sodium phosphate, edetate disodium, hydroxyethyl cellulose, tyloxapol, hydrochloric acid and/or sodium hydroxide (to adjust pH), and purified water. The pH of the suspension is approximately 7.3, with an osmolality of approximately 300 mOsm/kg.

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. Corticosteroids cause a rise in intraocular pressure in susceptible individuals. In a small study,

FLAREX (fluorometholone acetate 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.

INDICATIONS AND USAGE

FLAREX (fluorometholone acetate ophthalmic suspension) is indicated for use in the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye.

CONTRAINDICATIONS

Contraindicated in acute superficial herpes simplex keratitis, vaccinia, varicella, and most other viral diseases of cornea and conjunctiva; mycobacterial infection of the eye; fungal diseases; 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 OPHTHALMIC USE ONLY. NOT FOR INJECTION. Use in the treatment of herpes simplex infection requires great caution. Prolonged use may result in glaucoma, damage to the optic nerve, defect 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 exacerbated by presence of steroid medication. Topical ophthalmic corticosteroids may slow corneal wound healing. In those diseases causing thinning of the cornea or sclera, perforation 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. The preservative in FLAREX® (fluorometholone acetate ophthalmic suspension), benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of FLAREX (fluorometholone acetate ophthalmic suspension) but may be reinserted 15 minutes after instillation.

Patients should be advised that their vision may be temporarily blurred following dosing with FLAREX (fluorometholone acetate ophthalmic suspension). Care should be exercised in operating machinery or driving a motor vehicle.

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 woman. Fluorometholone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when FLAREX (fluorometholone acetate ophthalmic suspension), is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

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

Postmarketing Experience: The following reaction has been identified during post-marketing use of FLAREX® (fluorometholone acetate ophthalmic suspension) in clinical practice. Because reactions are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reactions, which has been chosen for inclusion due to either its seriousness, frequency of reporting, possible causal connection to FLAREX, or a combination of these factors, includes: dysgeusia.

DOSAGE AND ADMINISTRATION

Shake Well Before Using. One to two drops instilled into the conjunctival sac(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 after two weeks, consult physician. Care should be taken not to discontinue therapy prematurely.

HOW SUPPLIED

FLAREX (fluorometholone acetate ophthalmic suspension) is supplied in white low density polyethylene (LDPE) bottles, with natural LDPE dispensing plugs and pink polypropylene closures. The product is supplied as 5mL in an 8 mL bottle.

5 mL: NDC 0065-0096-05

STORAGE: Store upright between 2°-25°C (36°-77°F). Protect from freezing.

Protect from freezing.

Distributed by:

ALCON LABORATORIES, INC.

Fort Worth, Texas 76134 USA

Revised: October 2016

ALCON®

a Novartis company

9012837-0116

PRINCIPAL DISPLAY PANEL

NDC 0065-0096-05

Alcon®
a Novartis company

Flarex®
(fluorometholone acetate ophthalmic suspension) 0.1%

5 mL Sterile

Rx Only

STORAGE: Store upright between 2°-25°C (36°-77°F).

Protect from freezing.

Each mL CONTAINS:
Active: fluorometholone acetate 0.1% (1 mg).
Preservative: benzalkonium chloride 0.01%.
Inactives: sodium chloride, monobasic sodium phosphate, edetate disodium, hydroxyethyl cellulose, tyloxapol, hydrochloric acid and/or sodium hydroxide (to adjust pH), and purified water.

DOSAGE AND ADMINISTRATION:
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Alcon®

ALCON LABORATORIES, INC.
Fort Worth, Texas 76134 USA
Country of Origin: Italy
A190374-0416

LOT:

EXP.:

NDC 0065-0096-05

Alcon®

Flarex®
(fluorometholone acetate ophthalmic suspension) 0.1%

Sterile 5 mL

Rx Only

STERILE

FOR OPHTHALMIC USE ONLY

Each mL contains:

Active: fluorometholone acetate 0.1% (1 mg).
Preservative: benzalkonium chloride 0.01%.
Inactive: sodium chloride, monobasic sodium phosphate, edetate disodium, hydroxyethyl cellulose, tyloxapol, hydrochloric acid and/or sodium hydroxide (to adjust pH), and purified water.

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ALCON LABORATORIES, INC. Fort Worth, Texas 76134 USA

LOT:

EXP.:

A190371-0416

FLAREX
fluorometholone acetate suspension/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0065-0096
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FLUOROMETHOLONE ACETATE (UNII: 9I50C3I3OK) (FLUOROMETHOLONE - UNII:SV0CSG527L)	FLUOROMETHOLONE ACETATE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
TYLOXAPOL (UNII: Y27PUL9H56)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0096-05	1 in 1 CARTON	02/06/1992	
1		5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019079	02/06/1992	

Labeler - Alcon Laboratories, Inc. (008018525)

Registrant - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Research LLC		007672236	manufacture(0065-0096)

Revised: 10/2016 Alcon Laboratories, Inc.