HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FLAREX safely and effectively. See full prescribing information for FLAREX.

FLAREX® (fluorometholone acetate ophthalmic suspension) 0.1% for topical ophthalmic use
Initial U.S. Approval: 1986

----------INDICATIONS AND USAGE----------
FLAREX is a corticosteroid indicated for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye. (1)

----------DOSAGE AND ADMINISTRATION----------
- Instill one to two drops into the conjunctival sac(s) four times daily. (2.1)
- During the initial 24 to 48 hours of treatment, the dosage may be safely increased to two drops every two hours. (2.1)
- If there is no improvement after two weeks, consult a physician. Care should be taken not to discontinue therapy prematurely. (2.2)

----------DOSAGE FORMS AND STRENGTHS----------
Ophthalmic suspension: 0.1%. (3)

----------CONTRAINDICATIONS----------
- FLAREX is contraindicated in most viral diseases of the cornea and conjunctiva, including herpes simplex keratitis, vaccinia, and varicella, and in mycobacterial infection of the eye and fungal diseases of ocular structures. (4.1)
- Hypersensitivity to any component of FLAREX. (4.2)

----------WARNINGS AND PRECAUTIONS----------
- Intraocular Pressure (IOP) Increase: Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity, and fields of vision. If FLAREX is used for 10 days or longer, IOP should be monitored. (5.1)
- Cataracts: Use of corticosteroids may result in posterior subcapsular cataract formation. (5.2)
- Delayed Healing: The use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation. (5.3)
- Corneal and Scleral Melting: In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. (5.4)
- Bacterial Infections: Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated. (5.5)
- Viral Infections: Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). (5.6)
- Fungal Infections: Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. (5.7)

----------ADVERSE REACTIONS----------
The most common adverse reactions are possible development of glaucoma with optic nerve damage, defects in visual acuity and fields of vision, cataract formation, secondary ocular infection following suppression of host response, and delayed corneal wound healing. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Harrow Eye, LLC at 833-4HARROW(427769) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 9/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

FLAREX is indicated for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage and Administration

Instill one to two drops 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 there is no improvement after two weeks, consult a physician. Care should be taken not to discontinue therapy prematurely.

Shake well before use.

2.2 Prescribing Guidelines

The initial prescription and renewal of the medication order beyond one bottle should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and, where appropriate, fluorescein staining.

If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

Not more than one bottle should be prescribed initially, and the prescription should not be refilled without further evaluation.

3 DOSAGE FORMS AND STRENGTHS

Ophthalmic suspension containing fluorometholone acetate 0.1% (1 mg/mL).

4 CONTRAINDICATIONS

4.1 Viral, Mycobacterial, and Fungal Infections

FLAREX is 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 steroid.

4.2. Hypersensitivity

FLAREX is contraindicated in patients with hypersensitivity to any component of FLAREX.

5 WARNINGS AND PRECAUTIONS

5.1 Intraocular Pressure (IOP) Increase

Prolonged use of corticosteroids may result in the development of glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. FLAREX is used for 10 days or longer, IOP should be routinely monitored.

5.2 Cataracts

The use of corticosteroids may result in posterior subcapsular cataract formation.

5.3 Delayed Healing

The use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation.

5.4 Corneal and Scleral Melting

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 of the globe.

5.5 Bacterial Infections

Prolonged use of corticosteroids may suppress the host immune response and thus increase the hazard of secondary ocular infections. Acute purulent or parasitic infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated.

5.6 Viral Infections

Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended..

5.7 Fungal Infections

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.

5.8 Temporary Blurred Vision

Vision may be temporarily blurred following dosing with FLAREX. Exercise care in operating machinery or driving a motor vehicle.

5.9 Risk of Contamination

Do not touch the dropper tip of the bottle to the eye, eyelids, or any surface, as this may contaminate the ophthalmic suspension.

5.10 Contact Lens Use

FLAREX contains benzalkonium chloride, an antimicrobial preservative, that may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of FLAREX but may be reinserted 15 minutes after instillation.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Intraocular Pressure (IOP) Increase *[see Warnings and Precautions (5.1)]*
- Cataracts *[see Warnings and Precautions (5.2)]*
- Delayed Healing *[see Warnings and Precautions (5.3)]*
- Corneal and Scleral Melting *[see Warnings and Precautions (5.4)]*
- Bacterial Infections *[see Warnings and Precautions (5. 5.5)]*
- Viral Infections *[see Warnings and Precautions (5.6)]*
- Fungal Infections *[see Warnings and Precautions (5.7)]*

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of FLAREX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Dysgeusia.

The following additional adverse reactions have been reported: Cushing's syndrome and adrenal suppression may occur after very frequent use of topical ophthalmic corticosteroids, particularly in very young children.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well controlled studies of fluorometholone in pregnant women to inform a drug-associated risk. Fluorometholone should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

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 to 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.

8.2 Lactation

Risk Summary

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 is administered to a nursing patient. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for FLAREX and any potential adverse effects on the breastfed child from FLAREX.

8.4 Pediatric Use

The safety and effectiveness of FLAREX have not been established in pediatric patients.

8.5 Geriatric Use

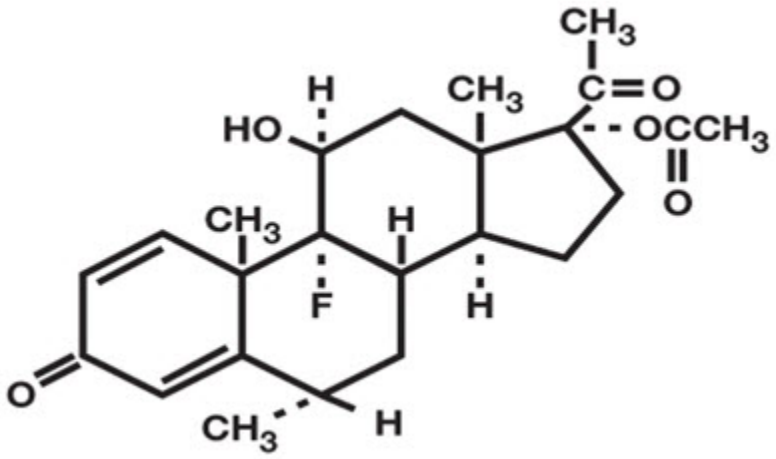
No overall differences in safety or effectiveness have been observed between elderly and younger patients.

11 DESCRIPTION

FLAREX (fluorometholone acetate ophthalmic suspension) 0.1% is a corticosteroid prepared as a sterile ophthalmic suspension for topical ophthalmic use. The pH of the suspension is approximately 7.3, with an osmolality of approximately 300 mOsm/kg.

The active ingredient, fluorometholone acetate, is a white to creamy white powder with a chemical formula of $C_{24}H_{31}FO_5$ and a molecular weight of 418.5 g/mol. 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 of FLAREX contains:

Active Ingredient: fluorometholone acetate 0.1% (1 mg/mL)

Preservative: benzalkonium chloride (0.01%)

Inactive Ingredients: sodium chloride, monobasic sodium phosphate, edetate disodium, hydroxyethyl cellulose, tyloxapol, hydrochloric acid and/or sodium hydroxide (to adjust pH), and purified water.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

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 (IOP) in susceptible individuals. In a small study, FLAREX demonstrated a significantly longer average time to produce a rise in IOP 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 IOP occurred within three days.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential, mutagenic potential, or impairment of fertility of fluorometholone.

16 HOW SUPPLIED/STORAGE AND HANDLING

FLAREX (fluorometholone acetate ophthalmic suspension) 0.1% is supplied in white low-density polyethylene (LDPE) bottles, with natural LDPE dispensing plugs and pink polypropylene closures.

NDC 82667-010-01 – 5 mL in 8 mL bottle

Storage
Store upright between 2°C to 25°C (36°F to 77°F). After opening, FLAREX can be used until the expiration date on the bottle.

Protect from freezing.

Shake well before use.

17 PATIENT COUNSELING INFORMATION

Temporary Blurred Vision
Advise patients that vision may be temporarily blurred following dosing with FLAREX. Advise patients to exercise care in operating machinery or driving a motor vehicle *[see Warnings and Precautions (5.8)].*

Risk of Contamination
Instruct patients to not touch dropper tip to the eye, eyelids, or any surface, as this may contaminate the ophthalmic suspension *[see Warnings and Precautions (5.9)]*.

Contact Lens Use
Advise patients to remove contact lenses during instillation of FLAREX. Contact lenses may be reinserted 15 minutes after instillation *[see Warnings and Precautions (5.10)].*

Manufactured for:
Harrow Eye, LLC™
Nashville, TN 37215
USA