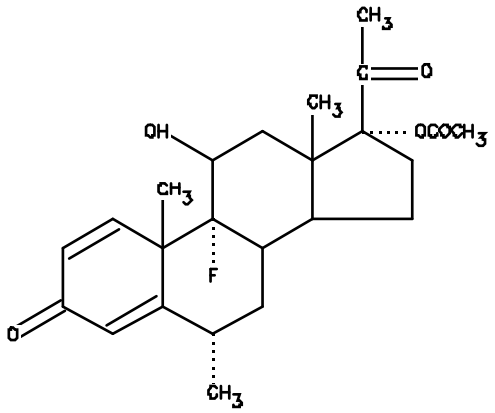
PRODUCT INFORMATION

NAME OF THE MEDICINE

FLAREX ®EYE DROPS 0.1%
Fluorometholone Acetate Ophthalmic Suspension

DESCRIPTION

Fluorometholone acetate, a corticosteroid, 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 9α-fluoro-11ß-17α dihydroxy-6α-methyl pregna-1, 4-diene-3, 20-dione 17-acetate. The chemical structure of fluorometholone acetate is presented below:



Each mL contains fluorometholone acetate 1 mg (0.1%), benzalkonium chloride, sodium biphosphate, tyloxapol, disodium edetate, sodium chloride, hyetellose, hydrochloric acid/sodium hydroxide to adjust pH, purified water.

PHARMACOLOGY

Corticosteroids suppress the inflammatory response to a variety of agents. Clinical studies demonstrate that fluorometholone acetate is significantly more efficacious than fluorometholone for the treatment of external ocular inflammation. Corticosteroids cause a rise in intraocular pressure in susceptible individuals. In clinical studies, Fluorometholone Acetate Ophthalmic Suspension was demonstrated to raise intraocular pressure more slowly but ultimately to the same extent as dexamethasone phosphate.

INDICATIONS

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

-Acute, untreated bacterial infections
-Mycobacterial ocular infections
-Herpes simplex keratitis
-Vaccinia, varicella and most other viral diseases of the cornea and conjunctiva
-Tuberculosis of the eye
-Fungal diseases of ocular structures
-Acute untreated infections
-Hypersensitivity to the constituents of this medication.

PRECAUTIONS

Employment of steroid medication in the treatment of stromal keratitis or uveitis caused by herpes simplex requires great caution; periodic slit lamp microscopy is essential. Prolonged use may result in ocular hypertension and/or glaucoma, damage to the optic nerve, defects in visual acuity and visual field, posterior subcapsular cataract formation and/or may aid in the establishment of secondary ocular infections from pathogens due to suppression of host responses.

Acute infections of the eye may be masked or exacerbated by the presence of steroid medications. In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with the chronic use of topical steroids.

It is advisable that the intraocular pressure be checked frequently. This is especially important in paediatric patients, as the risk of corticosteroid induced ocular hypertension may be greater in children and may occur earlier than in adults. FLAREX is not approved for use in paediatric patients. The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).

Topical ophthalmic corticosteroids may slow corneal wound healing. Topical NSAIDs are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. (See INTERACTIONS WITH OTHER MEDICINES).

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 and corticosteroid therapy should be discontinued if fungal infection occurs.

Effects on Fertility
There is no data regarding the effects of FLAREX on male or female fertility.

Use in Pregnancy
Category B3

There are no or limited amount of data from the use of FLAREX Eye Drops in pregnant women. FLAREX Eye Drops is not recommended during pregnancy and in women of childbearing potential not using contraception.

Animal reproduction studies have not been conducted with Fluorometholone Acetate Ophthalmic Suspension. Animal studies with corticosteroids have shown reproductive toxicity. It is also not known whether Fluorometholone Acetate Ophthalmic Suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. However, other steroids have been found to be teratogenic. Fluorometholone Acetate Ophthalmic Suspension should be given to a pregnant woman only if clearly needed.

Use in Lactation
It is not known whether this drug and its metabolites are excreted in human milk. Systemic corticosteroids are excreted into human milk. A risk to the suckling child cannot be excluded. Because of the potential for serious adverse reactions in nursing infants from fluorometholone, use only when considered essential by the physician.

Paediatric Use
Safety and effectiveness in children have not been established.
It is advisable that the intraocular pressure be checked frequently. This is especially important in paediatric patients, as the risk of corticosteroid induced ocular hypertension may be greater in children and may occur earlier than in adults. FLAREX is not approved for use in paediatric patients.

Contact Lenses
No contact lenses should be worn under FLAREX treatment. Additionally, this product contains benzalkonium chloride which may cause irritation and is known to discolour soft contact lenses.

Effects on Ability to Drive and Use Machines
Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until vision clears before driving or using machinery.

INTERACTIONS WITH OTHER MEDICINES

Concomitant use of topical steroids and topical NSAIDs may increase the potential for corneal healing problems.

ADVERSE EFFECTS

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.

Post Marketing Experience
The following adverse reactions have been reported following use of fluorometholone topical ophthalmic preparations. Frequencies cannot be estimated from the available data. Adverse reactions are presented in order of decreasing seriousness.

Eye Disorders
Intraocular pressure increased, vision blurred, eye pain, ocular discomfort, foreign body sensation in eyes, eye irritation, ocular hyperaemia, lacrimation increased.

Gastrointestinal Disorders
Dysgeusia.

DOSAGE AND ADMINISTRATION

One to two 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 two hours. Care should be taken not to discontinue therapy prematurely.

OVERDOSAGE

An ocular overdose of FLAREX Eye Drops is not likely to be associated with toxicity. Accidental ingestion is also unlikely to be associated with toxicity. Treatment of suspected ingestion should be symptomatic and supportive.

In Australia, contact the Poisons Information Centre on 13 11 26 for advice on management.

PRESENTATION AND STORAGE CONDITIONS

As a sterile ophthalmic suspension in 5 mL and 10 mL DROP-TAINER™ dispensers. Store below 25°C.

Shake well before use.

NAME AND ADDRESS OF THE SPONSOR

Novartis Pharmaceuticals Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
Macquarie Park NSW 2113

POISON SCHEDULE OF THE MEDICINE

Prescription Only Medicine (Schedule 4)

DATE OF FIRST INCLUSION IN THE ARTG

15 October 1991

DATE OF MOST RECENT AMENDMENT

5 July 2017

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