For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Fluorometholone Acetate Ophthalmic Suspension 0.1%w/v

FLI DROPS™

For the use of Registered Medical Practitioner only

Composition

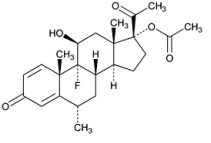
Fluorometholone Acetate USP ..... 0.1% w/v

Benzalkonium Chloride Solution USP ..... 0.02% v/v

(as preservative)

Water for Injection USP ..... q.s

Chemical Structure & Name



C24H31FO5

Pregna-1,4-diene-3,20-dione, 17-(acetyloxy)-9-fluoro-11-hydroxy-6-methyl-, (6–,11–)-. 9-Fluoro-11–,17-dihydroxy-6-–methylpregna-1,4-diene-3,20-dione, 17 acetate

Category

Pharmacotherapeutic group: ophthalmologicals; anti-inflammatory agents; corticosteroids,plain

ATC code: S01BA07

Description:

Ophthalmic Suspension.

A White to off-white color suspension.

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, 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.

Pharmacokinetic:

When tritium-labelled 0.1 % fluorometholone suspension was administered locally, the peak concentration of the radioactive substance in aqueous humour was achieved 30 minutes after administration. A rapidly forming metabolite occurred at high concentrations both in aqueous humour and corneal extracts, which

shows that fluorometholone is metabolised to a certain extent while penetrating the cornea and aqueous humour.

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.

Dosage & 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.

Method of Administration:

To prevent contamination of the dropper tip and suspension, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle.

In order to prevent the drops from being absorbed via the nasal mucosa, the nasolacrimal ducts should be held closed for 2 to 3 minutes with the fingers after administering the drops.

After cap is removed, if tamper evident snap collar is loose, remove before using the product.

If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.

Contact lenses should be removed during instillation of Fluorometholone acetate ophthalmic suspension but may be reinserted 15 minutes after instillation.

Contraindications

Fluorometholone acetate ophthalmic suspension 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 the steroid; and in those persons who have known hypersensitivity to any component of this preparation.

Warning and Precaution

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.

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

The preservative in Fluorometholone acetate ophthalmic suspension, benzalkonium chloride, may be absorbed by soft contact lenses. Benzalkonium chloride is known to discolour soft contact lenses. Contact lenses should be removed during instillation of Fluorometholone acetate ophthalmic suspension but may be reinserted 15 minutes after instillation.

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.

As with other ophthalmic medications, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs upon application, the patient must wait until the vision clears before driving or using machinery.

Interactions

No specific interaction studies were performed with Fluorometholone Acetate Ophthalmic Suspension.

Pregnancy & Lactation

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.

Lactation

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 Fluorometholone acetate ophthalmic suspension, is administered to a nursing woman.

Adverse reaction

Adverse reactions like 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.

Dysgeusia has been identified during post-marketing use of Fluorometholone acetate ophthalmic suspension in clinical practice.

Overdosage

Overdosage by the topical ophthalmic route will not ordinarily cause acute problems. If accidentaloverdosage occurs in the eye, the eye should be flushed with water or normal saline. If accidentally ingested, the patient should drink fluids to dilute. Notify your physician in such cases.

Storage

Store between 15°C - 30 °C. Protect from light

Keep out of reach of children.

Shelf life

24 Months from the date of manufacture.

Presentation

A White to off-white colour suspension filled in 5mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap in printed carton along with leaflet.

Directions for use :

Turn the tamper proof cap anti-clockwise to break the seal.

Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :

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