Fluflam®

Fluorometholone BP
Ophthalmic Suspension

DESCRIPTION

Fluflam® is a preparation of Fluorometholone ophthalmic suspension. Fluorometholone is a corticosteroid with an excellent anti-inflammatory action to inciting agents of mechanical, chemical or immunological in nature. Fluorometholone is thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2. In clinical studies on patient's eyes treated with both Dexamethasone and Fluorometholone suspensions, Fluorometholone demonstrated a lower propensity to increase intraocular pressure than did Dexamethasone. Benzalkonium Chloride 0.004% is used as preservative. Poly Vinyl Alcohol 1.4% is used as vehicle.

INDICATIONS

For steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

DOSAGE & ADMINISTRATION

Bottle should be shaken before use. 1 to 2 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 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

CONTRAINDICATIONS

Contraindicated in patients with acute superficial Herpes simplex keratitis, fungal diseases of ocular structures, vaccinia, varicella, mycobacterial infection of the eye and most other viral diseases of the cornea and conjunctiva, tuberculosis of the eye, or hypersensitivity to the constituents of this medication.

SIDE EFFECTS

Elevation of intraocular pressure with possible development of glaucoma, loss of visual acuity or defects in fields of vision, eye irritation, ocular hyperaemia, eye pain, visual disturbance, foreign body sensation, eyelid edema, blurred vision, eye discharge, eye pruritus, eye swelling, posterior subcapsular cataract formation, ulcerative keratitis, ocular infection (including bacterial fungal and viral), punctate keratitis, hypersensitivity, rash and delayed wound healing.

PRECAUTION & WARNING

Steroid medication in the treatment of patients with a history of Herpes simplex keratitis requires great caution. Eye drops contain a corticosteroid should not be used for more than 10 days except under strict supervision with regular checks for intraocular pressure. Corticosteroids may mask, activate or aggravate an infection of the eye. If no improvement is seen after a few days of application, other form of treatment should be used.

USE IN PREGNANCY & LACTATION

Pregnancy Category B3. Fluorometholone ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether ophthalmic use of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Because of the potential for serious adverse reactions in nursing infants from a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

Use in Children: Safety and effectiveness have not been demonstrated in children under 2 years of age.

PHARMACEUTICAL PRECAUTION

Store in a dry place and away from light. Keep out of reach of children. Store in an upright position. To prevent contamination of the dropper tip and suspension, care should be taken, not to touch the eyelids, surrounding areas, finger or other surfaces with the dropper tip of the bottle. The bottle should be tightly closed when not in use. Do not use after 4 weeks of first opening.

PACKAGING

Fluflam® Ophthalmic Suspension: Plastic dropper bottle containing 5 mL sterile ophthalmic suspension. Each mL contains Fluorometholone BP 1 mg.

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Manufactured by
ESKAYEF BANGLADESH LIMITED
GAZIPUR, BANGLADESH
® REGD. TRADEMARK
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