

# AFM

Fluorometholone Acetate 0.1%  
Ophthalmic Suspension

**Composition :**

**AFM Ophthalmic Suspension :** Each ml contains Fluorometholone Acetate USP 1 mg.

**Preservative :** Sodium Borate BP 0.02%.

**Vehicle :** Hydroxyethyl Cellulose USP-NF 0.35%

**Pharmacology :**

Fluorometholone is thought to act by the induction of phospholipase A2 inhibitory proteins which control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid.

**Indications :**

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

**Dosage and Administration :**

1 drop instilled into the conjunctival sac 2-4 times daily. During the initial 24 to 48 hours the dosage may be safely increased to 2 drops every hourly. Care should be taken not to discontinue therapy prematurely.

**Side-effects :**

Elevation of intraocular pressure with possible development of glaucoma and frequent optic nerve damage, posterior subcapsular cataract formation, secondary ocular infection from pathogens liberated from ocular tissues, perforation of the globe and delayed wound healing.

**Contraindications :**

Acute superficial herpes simplex keratitis, fungal diseases of ocular structures, vaccinia, varicella and most other viral diseases of the cornea and conjunctiva, tuberculosis of the eye, hypersensitivity to the constituents of this medication.

**Warnings :**

1. If sensitivity or other untoward reactions occur, discontinue the medication.
2. As fungal infections of the cornea have been reported coincidentally with long-term local steroid applications, fungal invasion may be suspected in any persistent corneal ulceration where a steroid has been used, or is in use, over a prolonged period of time.
3. 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.
4. Acute purulent untreated infections of the eye may be masked, enhanced, or activated by the presence of steroid medication. Secondary ocular infection may occur from pathogens liberated from ocular tissues.
5. Use of steroid medication in the treatment of patients with a history of herpes simplex requires great caution, frequent slit-lamp microscopy is required.
6. Reports in the literature indicate that posterior subcapsular lenticular opacities have occurred after heavy or prolonged use of topical ophthalmic corticosteroids.
7. Prolonged use of topical steroids may increase intraocular pressure. Although currently available data indicate that intraocular pressure rise is generally not a problem with patients being treated with Fluorometholone Acetate 0.1%, their intraocular pressure should be checked periodically.

**Use in pregnancy and lactation :** Safety of the use of topical steroids during pregnancy and lactation have not been established.

**Use in children :** Safety and effectiveness in children below the age of 2 years have not been established.

**Storage :**

- ◆ Store below 30°C temperature in a dry place, protect from light.
- ◆ Do not use longer than 30 days after first opening.
- ◆ Keep out of the reach of children.

**Packing :**

**AFM Ophthalmic Suspension :** Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.



Manufactured by:  
**ARISTOPHARMA LTD.**  
GAZIPUR, BANGLADESH

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