

Fluorometholone 0.1% & Tetrahydrozoline HCl 0.025% Ophthalmic Suspension

#### Composition:

**AFM-T Ophthalmic Suspension:** Each ml contains Fluorometholone USP 1 mg and Tetrahydrozoline HCl USP 0.25 mg.

Preservative: Benzalkonium Chloride Solution BP 0.01%.

Vehicle: Polyvinyl Alcohol USP 1.4%.

### Pharmacology:

Fluorometholone is thought to act by the induction of phospholipase A<sub>2</sub> 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. On the other hand, Tetrahydrozoline is an alpha agonist which constricts the conjunctival blood vessels and thereby relieves the redness of the eye.

#### Indications:

AFM-T Ophthalmic Suspension is indicated in acute allergy, noninfectious conjunctivitis & keratitis, severe swelling & hyperaemia, noninfectious inflammation of the anterior segment of the eye (including anterior uveitis, episcleritis & scleritis) and post-operative conditions.

### Dosage & administration:

Instill 1 drop into the conjunctival sac 2-3 times daily. The dose may be increased for severe and adult patient to 1 drop hourly for first one to two days.

#### **Contraindications:**

It is contraindicated in infectious conjunctivitis or keratitis, injuries or ulcerous processes of the cornea, glaucoma, diseases associated with stromal damage of the cornea or sclera & dry eyes.

# Side-effects:

Mild burning sensation, reversible increase in intraocular pressure, reactive hyperemia, cataract & corneal defects, glaucoma, systemic effects (chronic use).

## **Precautions:**

Avoid prolonged use. This preparation should be used after a careful risk benefit evaluation in case of patients with severe blood circulation diseases, metabolic disturbances, under treatment with MAOIs & other potentially hypertensive drugs, history of cataract, herpes simplex infection, rhinitis sicca.

# Use in pregnancy & lactation:

There are no adequate and well-controlled studies of Fluorometholone & Tetrahydrozoline in pregnancy or while breast-feeding. Therefore, this combination should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.

# Use in children:

Safety & effectiveness in children below 2 years of age 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.
- Shake well before use.
- Keep out of the reach of children.

## Packing:

**AFM-T Ophthalmic Suspension:** Each LDPE dropper bottle contains 5 ml sterile eye drops.



