

# Metholone Sterile Eye Drops

Fluorometholone USP 0.1%

## Composition:

Each ml of Metholone Eye Drops contains Fluorometholone USP 1 mg.

## Description:

Fluorometholone is a synthetic corticosteroid with an excellent anti-inflammatory action with no significant influence on the intraocular pressure. In comparison with other corticosteroids, Fluorometholone is more rapidly degraded in tissue and therefore has less effect on the intraocular pressure. The anti-inflammatory activity of Fluorometholone is at least 40 times stronger than that of Hydrocortisone. The corticosteroids are 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 which is released from membrane phospholipids by phospholipase A2. Fluorometholone inhibits the edema, fibrin deposition, capillary dilation, leukocyte migration, phagocytic activity, capillary proliferation, fibroblast proliferation, deposition of collagen and scar formation associated with inflammation.

## Indications:

Metholone Eye Drops is indicated for the treatment of corticosteroid-responsive inflammatory conditions including:

- Acute and chronic non-infectious conjunctivitis and keratitis of allergic origin.
- Non-infectious inflammation of the anterior chamber of the eye (including anterior uveitis, episcleritis and scleritis).
- Post-operative irritative conditions after strabismus, cataract and glaucoma surgery.

## Dosage & Administration:

1 drop 2-4 times daily in the conjunctival sac(s). During the first 24-48 hours, the dosage may be safely increased to 1 drop hourly. The dosing of Fluorometholone eye drops may be reduced, but care should be taken not to discontinue therapy prematurely. In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of applications.

## 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, dry eyes, especially keratoconjunctivitis sicca, glaucoma & hypersensitivity to the constituents of this medication.

## Side-effects:

Elevation of intraocular pressure with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, secondary ocular infection from pathogens liberated from ocular tissues, loss of visual acuity or defects in fields of vision, delayed wound healing and perforation of the globe where there is thinning of the cornea or sclera.

Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticism after use of topical steroids. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids. Other adverse events reported with the use of Fluorometholone drops include: allergic reactions, visual disturbance (blurry vision) and taste perversion.

## Use in Pregnancy and Lactation:

It is a drug of pregnancy category-C. Safety of the use of topical steroids during pregnancy and lactation has not been established.

## Use in Children:

Safety and effectiveness in infants below the age of 2 years have not yet been established.

## Precaution & Warning:

Corticosteroids may mask, activate or aggravate an infection of the eye. 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.

## Drug Interaction:

No information is available.

## Storage:

- Store in a cool, dry place and protected from light.
- Close the dropper immediately after use.
- Do not use for longer than one month after first opening.
- Keep out of the reach of children.

## How Supplied:

Plastic dropper bottle containing 5 ml sterile eye drops.

Manufactured by :



**KEMIKO PHARMACEUTICALS LTD.**

Bangladesh