



# Fluomet™

Fluorometholone 0.1%

Sterile Ophthalmic Suspension

## Description

Fluomet is a sterile ophthalmic suspension containing Fluorometholone - a corticosteroid for topical administration to the eyes.

## Composition

Each ml Fluomet ophthalmic suspension contains:

Active Substance: Fluorometholone USP 1 mg

Preservative: Benzalkonium Chloride 0.1 mg

## Clinical Pharmacology

Fluorometholone is a corticosteroid with an excellent anti-inflammatory action with no significant influence on the intraocular pressure. The anti-inflammatory activity of Fluorometholone is at least 40 times stronger than that of Hydrocortisone.

Corticosteroids are thought to act by the introduction of phospholipase A<sub>2</sub> inhibitory proteins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandin and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A<sub>2</sub>. In comparison with other corticosteroids Fluorometholone is more rapidly degraded in tissue and therefore has less effect on the intraocular pressure. The immunosuppressive action of Fluorometholone is less pronounced than that of Dexamethasone.

## Indications and Uses

Fluomet ophthalmic suspension is indicated for the treatment of

- ▶ 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 and Administration

1 drop 2-4 times daily in the conjunctival sac(s).

During the first 24-48 hours the dosage can be increased to 1 drop hourly.

## Contraindications

- ▶ Hypersensitivity to any ingredient of the formulation.
- ▶ Infectious conjunctivitis or keratitis.
- ▶ Injuries and ulcerous processes of cornea, especially infections caused by virus, bacteria and fungi.
- ▶ Dry eyes, especially keratoconjunctivitis sicca.
- ▶ Glaucoma.

## Precautions

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. Do not touch dropper tip to any surface as this may contaminate this preparation.

## Side Effects

Elevation of intraocular pressure (IOP) with possible development of glaucoma and optic nerve damage, loss of visual acuity or defects in fields of vision, posterior subcapsular cataract formation and delayed wound healing. The following adverse reactions may also occur - secondary ocular infection from pathogens liberated from ocular tissues and perforation of the globe where there is thinning of the cornea or sclera.

## Use in Pregnancy & Lactation

Animal experiments with Fluorometholone have shown adverse effect on the fetus. However, Fluorometholone ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

## Drug Interactions

Specific drug interaction studies have not been conducted with Fluorometholone ophthalmic suspension.

## Overdosage

Overdose through local administration is not known and not likely.

## Pharmaceutical Precautions

Store at room temperature, protect from light and freezing. It is desirable that the contents should not be used more than one month after first opening of the bottle.

## Commercial Pack

A sterile suspension in 5 ml plastic dropper bottle.

Manufactured by :



**POPULAR PHARMACEUTICALS LTD.**

TONGI, GAZIPUR, BANGLADESH