

Flucort® Sterile ophthalmic suspension
Fluorometholone 0.1%

COMPOSITION:

Each ml contains Fluorometholone USP 1 mg.

ACTIONS:

Inhibition of the inflammatory response to inciting agents of mechanical, chemical or immunological nature. 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. Arachidonic acid is released from membrane phospholipids by phospholipase-A₂. Adreno-corticosteroids and their derivatives are capable of producing a rise in intraocular pressure.

INDICATIONS:

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

DOSAGE AND ADMINISTRATION:

1 to 2 drops instilled into the conjunctival sac 2 to 4 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:

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:

Use of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Prolonged use may cause increased intraocular pressure in susceptible individuals resulting in glaucoma, with damage to the optic nerve, defects in visual acuity and field of vision; posterior subcapsular cataract formation; or may aid in the establishment of secondary ocular infections from fungi or viruses liberated from ocular tissues.

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.

Acute purulent untreated infection of the eye may be masked or activity enhanced by presence of steroid medication.

Safety and effectiveness have not been demonstrated in children of the age group 2 years or below.

USE IN PREGNANCY:

Safety of the use of topical steroids during pregnancy has not been established.

PRECAUTIONS:

As fungal infections of the cornea are particularly prone to develop coincidentally with long term local steroid applications, fungal invasion must be suspected in any persistent corneal ulcer-intraocular pressure should be checked frequently.

ADVERSE REACTIONS:

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

PACKING:

Each plastic dropper bottle contains 5 ml sterile ophthalmic suspension.

Manufactured by:
Gaeo Pharmaceuticals
(G. A. Company Ltd.)
Dhaka, Bangladesh