Viscone Eye Drops 0.1% " Simphar "

-Antiinflammatory Ophtalmologic Agents -

Viscone eye drops is a topical cortisteroids anti-inflammatory product for ophthalmic use. Cortisteroids are capable of producing a rise in intraocular pressure. In clinical studies of doccumented steroid-responders, flurometholone demonstrated a significantly longer average time to produce a rise in intraocular pressure than dexamethasone phosphate.

Composition: Each mL contains:

Fluorometholone......1.00mg

Other ingredients:

Partially hydrolyzed polyvinyl alcohol, Sodium phosphate dibasic heptahydrate, Sodium phosphate monobasic, Sodium chloride, EDTA-2Na, Benzalkonium chloride, Polysorbate 80, Water for injection

Indications:

Viscone eye drops is indicated for the treatment of corticoster oidresponsive inflammation of the palpelbral and bulbar conjunctiva, cornea and anterior segment of the globe.

Dosage and Administration:

Instill one or two drops of solution into the conjunctival sac two to four times daily. During the initial 24 to 48 hours the dosage may be increased to one application every four hours.

Care should be taken not to discontinue therapy prematurely.

Warnings:

- Use in the treatment of Herpes simplex requires great caution.
- This drug is not effective in the treatment of Sjogren's keratoconjunctivitis.
- Prolonged use may result in glaucoma, damage to the optic nerve, defects in visual acuity and visual field, cataract formation.
- In acute purulent infection of the eye, infection appears to be enhanced with the presence of steroids.
- In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with the use of topical steroids. It is advis able that the intraocular pressure be checked frequently.

Adverse Reactions:

Glaucoma with optic nerve damage, visual acuity and visual field defects; cataract formation; secondary ocular infection following suppression of host response; and perforation of the globe may occur.

Contraindications:

Viscone eye drops is contraindicated in most viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis, vaccinia, varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures, viscone eye drops is also contraindicated in individuals with known or suspected hypersensitivity to any ingredients of this preparation and to other corticosteroids.

Precautions:

If signs and symptoms fail to improve after two days, or pain persists longer than 48 hours, the patient should be advised to discontinue use of the medication and consult a physician.

The safety and effectiveness in children below the age of two years have not been established.

Storage: Store at room temperature. Keep all drugs out of reach of children.

Directed by a physician before taking this product.

Package: Supplied in plastic bottle in less than 100mL.

DOH-PM-043184 GMP G-6805

