

SUMMARY OF PRODUCT CHARACTERISTICS

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1. Name of drug product

Tolon Eye Drops

2. Qualitative and quantitative compositions

Each mL contains 1mg of fluorometholone

3. Pharmaceutical Form

White suspension in a transparent plastic container.

4. Clinical particulars

4.1 Therapeutic indications

Tolon Eye Drops is indicated for corticosteroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.

4.2 Posology and method of administration

Posology

Paediatric population

The safety and efficacy in children aged 2 years or less has not been established.

Elderly population

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Method of administration

Tolon Eye Drops is for topical ophthalmic use only. Shake FML Liquifilm suspension well before use.

Topically as drops into the conjunctival sac.

1-2 drops instilled into the conjunctival sac 2-4 times daily. During the first 24 to 48 hours of treatment, the dose may be safely increased to 2 drops at one hour intervals.

The treatment should not be withdrawn too early.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Tolon Eye Drops is contraindicated in active viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, as well as mycobacterial and untreated bacterial infection of the eye and fungal diseases of ocular structures.

4.4 Special warnings and precautions for use

Eye drops containing corticosteroids should not be used for longer than a week except under an eye specialist's careful surveillance combined with regular measurement of intraocular pressure.

Prolonged use of corticosteroids may result in elevated intraocular pressure (IOP) with possible development of glaucoma and infrequent damage to the optic nerve, defects in visual acuity and fields of vision, posterior subcapsular cataract formation, and delayed wound healing. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently.

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

Use of intraocular steroids may prolong the course and may exacerbate the severity of many viral infections on the eye (including herpes simplex). Use of a corticosteroid medication in the treatment of the patients with a history of herpes simplex keratitis requires great caution. Frequent slit lamp microscopy is recommended, in severe cases once a day.

To prevent eye injury or contamination, care should be taken to avoid touching the applicator tip to the eye or to any other surface. The use of the bottle by more than one person may spread infection.

Tolon Eye Drops contains benzalkonium chloride which is irritant to the eye and could cause discoloration of soft contact lenses. Avoid contact with soft contact lenses. Remove contact lenses before FML is used and wait for at least 15 minutes before reinsertion.

Concomitant ocular medication should be administered 5 minutes prior to the instillation of Tolon Eye Drops.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of fluorometholone in pregnant women. Studies in animals have shown reproductive toxicity.

Tolon Eye Drops is not recommended during pregnancy.

Lactation

It is unknown whether fluorometholone is excreted in human milk.

Tolon Eye Drops should not be used during breast-feeding.

It is not known whether Sodium Cromoglicate is excreted in human milk. Therefore caution should be exercised when the eye drops are administered to nursing mothers.

4.7 Effects on ability to drive and use machines

Tolon Eye Drops has no influence on the ability to drive and use machines. However, instillation of any eye drop could result in transient blurring of vision. If this occurs, the patient should wait for the blurring to subside before driving or operating machinery.

4.8 Overdose

Overdosage by the topical ophthalmic route will not ordinarily cause acute problems.

If accidental overdosage occurs in the eye, the eye should be flushed with water or normal saline. If accidentally ingested, the patient should drink fluids to dilute.

5. Adverse reactions

Adverse reactions include, in decreasing order of frequency, elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior

subcapsular cataract formation, and delayed wound healing.

Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticism after use of topical dermatologic steroids applied to the skin.

Corticosteroid-containing preparations have also been reported to cause acute anterior uveitis and perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids.

The development of secondary ocular infection (bacterial, fungal and viral) has occurred. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids. The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used

Transient burning and stinging upon instillation and other minor symptoms of ocular irritation have been reported with the use of fluorometholone suspension.

Other adverse events reported with the use of fluorometholone include: allergic reactions; foreign body sensation; erythema of eyelid; eyelid edema/eye swelling; eye discharge; eye pain; eye pruritus; lacrimation increased; rash; taste perversion; visual disturbance (blurry vision); and visual field defect.

6. Pharmaceutical particulars

6.1 List of excipients

Hydroxyethylcellulose NF

Benzalkonium chloride KP

Disodium Edetate Hydrate KP

Sodium chloride KP

Anhydrous dibasic sodium phosphate USP

Monobasic sodium phosphate monohydrate USP

Polysorbate 80 KP

Sodium hydroxide KP

Water for injection KP

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

3 years from manufacturing date

6.4 Special precaution for storage

Preserve in tight containers. Store at room temperature not exceeding 30°C.

6.5 Nature and contents of container

Tolon Eye Drops is filled in low-density polyethylene (LDPE) bottles sealed with half-clear low-density polyethylene (LDPE) dropper applicators and opaque high-density polyethylene (HDPE) tamper-proof screw caps.

7. Marketing authorization holder

SAMCHUNDANG CO., LTD

Address : SamChunDang Pharmaceutical Co., Ltd. 351, Hyoryeong-ro, Seocho-gu, Seoul, Korea

8. Marketing authorization number

Not applicable

9. Date of first authorization / renewal of authorization

Not applicable

10. Date of revision of the text

December 29, 2017