SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name: PREDFLAM OPHTHALMIC SUSPENSION 5 ML

Generic Name: Prednisolone Acetate

Pharmaceutical Dosage Form : Ophthalmic Suspension (sterile)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL sterile ophthalmic suspension contains Prednisolone acetate 50.00 mg.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Ophthalmic Suspension (sterile).

Off-white color suspension in 5 mL round ivory color plastic dropper bottle with plug and cap.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis, edema and inflammation. Also indicated in the treatment of corneal injury from chemical, radiation, thermal burns or penetration of foreign bodies.

4.2 Posology and method of administration

Shake well before use.

Instill 1 drop into the conjunctival sac two to four times daily. During the initial 24 to 48 hours, the dosing frequency may be increased if necessary. Care should be taken not to discontinue therapy prematurely.

4.3 Contraindications

Prednisolone Acetate ophthalmic suspension is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia and varicella and also in mycobacterial infection of the eye and fungal

diseases of ocular structures. It is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation.

4.4 Special warnings and special precautions for use

If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated. As fungal infections of the cornea are particularly prone to develop coincidentally with long term local corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. If this product is used for 10 days or longer, intraocular pressure should be monitored.

4.5 Interaction with other FPPs and other forms of interaction

Specific drug interaction studies have not been conducted with Prednisolone Acetate USP 1% ophthalmic suspension.

4.6 Fertility, pregnancy and lactation

There are no adequate and well controlled studies in pregnant women. Prednisolone Acetate USP 1% ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. So, this drug should be used nursing mother if the potential benefit justifies the potential risk to the fetus.

4.7 Effects on ability to drive and use machines

It is suggested to consult with the doctor or pharmacist.

4.8 Undesirable effects

Adverse reactions include, elevation of intraocular pressure (IOP) with possible development of glaucoma, infrequent optic nerve damage, posterior subcapsular cataract formation and delayed wound healing.

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.

4.9 Overdose

Over dosage will not ordinarily cause acute problems. If accidentally ingested, drink fluids to dilute.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids

ATC-code: S02BA03

Mechanism of action

Prednisolone Acetate is a corticosteroid that, on the basis of weight, has 3 to 5 times the anti-inflammatory potency of Hydrocortisone. Corticosteroids inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, and fibroblast proliferation, deposition of collagen and scar formation associated with inflammation.

Prednisolone Acetate is 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 release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

5.2 Pharmacokinetic properties

Following IM administration of 2 mg, peak plasma concentrations were similar to after oral (i.e. 1 0µg/ml) but are reached within 20 minutes. Haloperidol is rapidly distributed throughout the body. Haloperidol is extensively metabolized by oxidative dealkylation. Metabolites are ultimately conjugated with glycine.

5.3 Preclinical safety data

Haloperidol has been shown to block the cardiac hERG channel in several published studies in vitro. In a number of in vivo studies, intravenous administration of haloperidol in some animal models has caused significant QTc prolongation at doses around 0.3

mg/kg, producing Cmax plasma levels at least 7 to 14 times higher than the therapeutic plasma concentrations of 1 to 10 ng/ml that were effective in the majority of patients in clinical studies. These intravenous doses, which prolonged QTc, did not cause arrhythmias. In some animal studies, higher intravenous haloperidol doses of 1 mg/kg or greater caused QTc prolongation and/or ventricular arrhythmias at Cmax plasma levels at least 38 to 137 times higher than the therapeutic plasma concentrations that were effective in the majority of patients in clinical studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride Solution, 50%
Disodium Edetate
Hypromellose (Methocel E4M)
Polysorbate 80 (Tween 80)
Boric Acid
Sodium Chloride (For Sterile)
Sodium Metabisulphite
Sodium Citrate (For Sterile)
Water for Injections

6.2 Incompatibilities

The product is stable up to the mentioned shelf life. So, it can be assured that there is no incompatibility with active and excipients.

6.3 Shelf life

Two (2) years from the date of manufacturing when it is kept in original pack.

6.4 Special precautions for storage

Store below 30°C. Keep in a dry place. Protect from direct sunlight, heat & moisture. Keep out of reach of children.

6.5 Nature and contents of container

5 ml round Ivory color plastic dropper bottle with plug & cap.
The packaging material i.e container & plug material is Low Density Polyethylene(LDPE) and cap material is the combination of Low Density Polyethylene (LDPE) & High Density Polyethylene (HDPE).

6.6 Special precautions for disposal and other handling

During use of the dropper, do not touch the dropper tip to surfaces since this may contaminate the solution. After one month of opening do not use the medicine of dropper. Dispose the empty container in waste bin.

7. MARKETING AUTHORISATION HOLDER

GENERAL Pharmaceuticals Ltd. (Unit: 2)
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8. MARKETING AUTHORISATION NUMBER(S)

05573/07703/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17-12-2020

10. DATE OF REVISION OF THE TEXT

03-08-2023