For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Senzpred™

Eye Drops

Prednisolone Acetate Ophthalmic Suspension USP

COMPOSITION:

Prednisolone Acetate IP ..... 1% w/v
Benzalkonium Chloride Solution IP .....0.02% v/v
(as preservative)
Water for Injections IP.....q.s.

Prednisolone acetate 1 % Sterile ophthalmic suspension

Description: Prednisolone acetate 1 % sterile ophthalmic suspension is a topical anti inflammatory agent for ophthalmic use.

Contains: Active predinsolone acetate (micro fine suspension) 1.0 %.

Clinical Pharmacology: Predinsolone acetate is a glucocorticoid that on the basis of weight, has 3 to 5 times the anti-inflammatory potency of hydrocortisone. Glucocorticoids inhibit the edema, fibrin deposition, capillary dilation and phagocytic migration of the acute inflammatory response as well as capillary proliferation, deposition of collagen and scar formation.

Indication and Usage: Prednisolone acetate is indicated for the treatment of steroid-responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

Contraindication: Prednisolone acetate is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), and also in mycobacterial infection of the eye and fungal diseases of ocular structures. Prednisolone acetate suspension is also contraindicated in individual with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

Warnings: Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve defects in visual acuity and fields of vision and in posterior sub capsular cataract formation. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections.

Various ocular diseases and long - term use of topical corticosteroids have been known to cause corneal and sclera thinning. Use of topical corticosteroids in the, presence of thin cornea or sclera tissue may lead to perforation. Acute purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroids medication.

If this product is used for 10 days or longer intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently.

The use of steroids after cataract surgery may delay healing and increase

the incidence of bleb formation.

Use of ocular steroids may prolong the course of infections of the eye (including herpes simplex). Employment of a corticosteroids medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended. Corticosteroids are not effective in mustard gas keratitis and sjogren's keratoconjunctivitis.

Precautions: General: The initial prescription and renewal of the medication order beyond 20 milliliters should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and where appropriate fluorescein staining. 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 corticosteroids applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate. If this product is used for 10 days or longer, intraocular pressure should be monitored.

Information for patients: If inflammation or pain persists longer than 48 hours or becomes aggravated the patient should be advised to discontinue use of the medication and consult a physician.

This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the bottle tip to eyelids or to any other surface. The use of this bottle by more than one person may spread the infection. Keep bottle tightly closed when not in use and keep out of reach of children.

Carcinogenesis, autogenesis, impairment of fertility: No studies have been conducted in animals or in humans to evaluate the potential of these effects.

Pregnancy Category C: Prednisolone has been shown to be teratogenic in mice when given in doses 1 -10 times the human dose. There are no adequate well controlled studies in pregnant women. Prednisolone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether topical ophthalmic medication of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroids production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from Prednisolone, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric use: Safety and effectiveness in pediatric patients have not been established.

Adverse Reactions: Adverse reactions include in decreasing order of frequency, elevation of intra ocular pressure (IOP) with possible

development of glaucoma and infrequent optic nerve damage, posterior sub capsular cataract formation, and delayed wound healing. Although systemic effects are extremely uncommon there have been rare occurences of systemic hypercorticoidism after use of topical steroids.

Corticosteroids – 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 developments of secondary ocular infection (bacterial, fungal and viral) have occurred. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term application of steroid. 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 Prednisolone acetate suspension. Other adverse events reported with the use of Prednisolone acetate suspension include : visual disturbance (blurry vision) and allergic reactions.

Overdosage: Overdosage will not cause acute problems. If accidentally ingested, drink fluids to dilute.

Dosage and Administration: Shake well before use. Instill one to two drops in conjunctival sac two to four times daily. During the initial 24 to 48 hours; the dosing may be increased if necessary. Care should be taken not to discontinue therapy. If signs and symptoms fail to improve within 2 days the patient should be re-evaluated.

STORAGE:
Keep in a cool place. Use the suspension within one month after opening the container protect form light.

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

SHAKE WELL BEFORE USE

PRESENTATION:

SENZPRED is a sterile suspension supplied in plastic opaque dropper bottle with a cap, containing 10ml of the suspension.

Directions for use:

Turn the tamper proof cap anti-clockwise to break the seal.
Remove the cap, dispense drops with gentle pressure.
Replace the cap immediately after every use.

Manufactured in INDIA by :
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