PRENS

(Prednisolone acetate)

Sterile Ophthalmic Suspension

پریز

پریڈنی سولون ایسیٹیٹ

Composition:
Each ml contains:
Prednisolone acetate ……. 10mg
(U.S.P Specifications)
Preservative:
Benzalkonium Chloride

Actions:
Prednisolone acetate is a glucocorticoid that, on the basis of weight, has 3 to 5 times the anti inflammatory potency of hydrocortisone. Glucocorticoid inhibits the edema, fibrin deposition, capillary dilatation and phagocytic migration of the acute inflammatory response as well as capillary proliferation, deposition of collagen and scar formation.

Indications:
For steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

Dosage and administration:
Instill 1 to 2 drops into the conjunctival sac 2 to 4 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. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluatd.

Contraindications:
Acute untreated purulent ocular infections, acute superficial herpes simplex (dendritic keratitis), vaccinia, varicella and most other viral diseases of the cornea and conjunctiva, ocular tuberculosis and fungal diseases of the eye, and sensitivity to any components of the formulation.

Precautions and warnings:
1. In those diseases causing thinning of the cornea, perforation has been reported with the use of topical steroids. Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal or scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.
2. Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids. Prolonged use may suppress the host immune response in ocular tissues and thus increase the possibility of secondary ocular infections.
3. Use of steroid medication in the treatment of patients with a history of herpes simplex requires caution and should be followed by frequent mandatory slit-lamp microscopy.
4. Use of topical corticosteroids may cause increased intra ocular pressure in certain individuals. This may result in glaucoma with damage to the optic nerve with defects in the visual fields. It is advisable that the intra ocular pressure be checked frequently, particularly in patients with a history or presence of glaucoma.
5. **Use in Pregnancy**: Safety of intensive or protracted use of topical steroids during pregnancy has not been substantiated.
6. **Nursing Mothers:** It is not known whether topical administration could result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when Prens is administered to a nursing woman taking into consideration the importance of the drug to the mother.
7. **Use in children:** Safety and effectiveness of corticosteroids in children below the age of two years has not been established.

Posterior subcapsullar cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids. Acute anterior uveitis may occur in susceptible individuals. The use of steroids after cataract surgery may delay healing and increase the incidence of filtering blebs. If signs of hypersensitivity or other serious reactions occur, discontinue use of this preparation. Cross-sensitivity among corticosteroids has been demonstrated.

Adverse Reactions:
Increased intra ocular pressure, with optic nerve damage, defects in the visual fields. Also posterior subcapsullar cataract formation, secondary ocular infections from fungi or viruses liberated from ocular tissues, perforation of the globe when used in conditions where there is thinning of the cornea or sclera and delayed wound healing. Corticosteroid-containing preparations can also cause acute anterior uveitis or perforations of the globe. Mydriasis, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids. Systemic side effects may occur with extensive use of steroids.

How Supplied:
As 5ml sterile ophthalmic suspension in plastic dropper bottles.

Storage and Instructions:
Store below 30°C.
Protect from heat and sunlight.
Keep out of reach of children.
Use only on medical advice.
For Ophthalmic use only.
Shake well before use.
Use within four weeks after first opening the bottle.

خوراک: ڈاکٹری ہدایات کی مطابق استعمال کریں۔
ہدایات: دوا کو دھوپ اور گرمی سے بچائیں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔
پہلی دفعہ بوتل کھولنے کے بعد دوا کو چار ہفتوں تک استعمال کیا جاسکتا ہے۔
استعمال سے پہلے اچھی طرح ہلائیں۔

Manufactured by:
Vega Pharmaceuticals (Pvt.) Ltd.
30 Km, Multan Road, Lahore, Pakistan.