Predbon®

Ophthalmic Suspension 5mL

(Loteprednol Etabonate) 0.5% w/v

پریڈبون اوپتھیلمک سسپنشن ۵ ملی لیٹر

(لوٹیپریڈنول ایٹابونیٹ) ۰.۵ فیصد وزن/حجم

Qualitative And Quantitative Composition:
Each mL of suspension contains:
Loteprednol Etabonate 5mg
Innovator's Specification.

Description:
Predbon® is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

Clinical Pharmacology:
Mechanism of Action
Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing, corticosteroids are thought to act by induction of phospholipase A2 inhibitory protein collectively called lipoproteins.
Pharmacodynamics
Animal studies have shown that Loteprednol etabonate has a binding affinity to steroid receptors that is 4.3 times greater than dexamethasone. Loteprednol etabonate possesses a metabolically labile 17 beta-chloromethyl ester function which was designed in order to be hydrolyzed to an inactive carboxylic acid moiety.
This inactive metabolite is more hydrophilic and is thus readily eliminated from the body.
Pharmacokinetics
Absorption: Loteprednol etabonate (LE) demonstrates good ocular permeation properties as it is lipid solu-ble, allowing the agent to penetrate into cells with relative ease.
Distribution: The only data available regarding the volume of distribution of loteprednol etabonate (LE) is the volume of distribution the agent demonstrated when administered to dogs - a value of 3.7 L/kg. It has been shown, however, that the topical ocular administration of LE distributes preferentially into the cellular components of blood.
Biotransformation: Studies have demonstrated that LE (chloromethyl 17alpha-ethoxycarbonyloxy-11beta-h droxy-3-oxoandrosta-1,4-diene) is rapidly hydrolyzed at the location of its 17beta-chloromethyl ester function by paraoxonase 1 in human plasma at the site of administration at the level of the affected eye tissue to the 17beta-carboxylate PJ-91 metabolite and PJ-90 metabolite. Both metabolites are considered inactive.
Excretion: Following systemic administration to rats, loteprednol etabonate is eliminated primarily via the biliary/faecal route, with most of the dose eliminated in the form of the metabolite, PJ-90. Loteprednol etabonate was slowly hydrolyzed in liver at clearance rates of 0.21 +/- 0.04 and 2.41 +/- 0.13 ml/h/kg in the liver and plasma, respectively.
Preclinical safety data: No Preclinical safety data is availaible.

Indications:
Predbon® is indicated for the treatment of steroid responsive inflammatory condition of the palpebral con-junctiva, cornea and anterior segment of the globe as allergic conjunctivitis, acne rosacea, superficial punc-tate ketatits, herpes zoster keratitis, iritis, cyclitis, selected infective conductivities, when the inherent haz-ard of steroid use is occupied to obtain am advisable diminution in edema and inflammation.

Contraindications:
Predbon®, as with ophthalmic corticosteroids, is contraindicat-ed in most viral disease of the cornea and con-junctiva including epithelial herpes simplex keratitis, vaccinia, and varicella, and also in myocardial infection of the eye and fungal disease od ocular structures. Predbon® is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticoster-oids.

Interactions:
No interactions are available in humans.

Special Warnings And Precautions For Use:
Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infec-tions. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection. Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may

exacerbate the severity of many viral infections of the eye (including herpes simplex). The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

Use In Specific Population:

Pregnancy

Teratogenic Effects: Pregnancy Category C. Loteprednol etabonate has been shown to be embryotoxic (de-layed ossification) and teratogenic (increased incidence of meningo-cele, abnormal left common carotid artery, and limb flexures) when administered orally to rabbits during organogenesis at a dose of 3 mg/kg/day (35 times the maximum daily clinical dose), a dose which caused no maternal toxicity. The no-observed-effect-level (NOEL) for these effects was 0.5 mg/kg/day (6 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at ≥5 mg/kg/day doses, and cleft palate and umbilical hernia at ≥50 mg/kg/day) and embryotox-icity (in-creased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossifica-tion with ≥50 mg/kg/day). Treatment of rats with 0.5 mg/kg/day (6 times the maximum clinical dose) dur-ing organogenesis did not result in any reproductive toxicity.

Nursing Mothers:

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient sys-temic absorption to produce detectable quantities in human milk. Systemic steroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when Predbon® is administered to a nursing woman.

Pediatric

Use Safety and effectiveness in pediatric patients have not been established.

Adverse Reactions:

Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with infrequent optic nerve damage, visual acuity and field defects, posterior subcapsular cata-ract formation, delayed wound healing and secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Dosage And Administration:

Steroid responsive disease treatment: Apply one to two drops of Predbon® into the conjunctival sac of the affected eye(s) four of Predbon® into the conjunctival sac of affected eye(s) four times daily. During the ini-tial treatment within the first week, the dosing may be increased, upto 1 drop every hour, if necessary, care should be taken not to discontinue therapy prematurely. If sign and symptom fail to improve after two days, the patient should be re-evaluated.

Post-Operative Inflammation: Apply one to two drops of Predbon® into conjunctival sac of the operated eye(s) four times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of postoperative period.

Instructions:

Store below 30°C. Do not freeze.

For Ophthalmic Use Only

Presentation:

Predbon® Ophthalmic Suspension is packed in 5mL labeled HDPE bottle with dropper nozzle in a carton.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔ **ہدایات:** ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور گرمی سے محفوظ رکھیں۔ استعمال سے پہلے بوتل کو اچھی طرح ہلالیں۔ بوتل کھولنے کے بعد چار ہفتوں
سے زیادہ استعمال نہ کریں۔ تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ استعمال کے بعد ڈھکن کو مضبوطی سے بند کریں۔

صرف آنکھوں کے استعمال کیلئے۔

For detailed information:

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