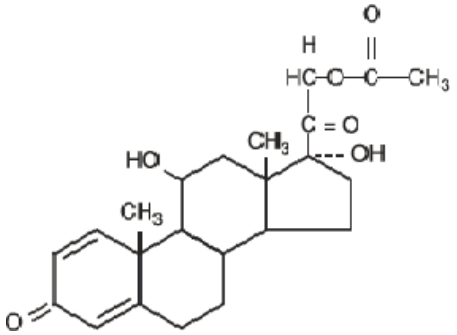
PREDNISOLONE
acetate

ECONOPRED™ PLUS

10 mg/mL (1%)
Sterile Ophthalmic Suspension

Anti-inflammatory

DESCRIPTION:
PREDNISOLONE acetate (ECONOPRED™ PLUS) 10mg/mL Sterile Ophthalmic Suspension is an adrenocortical steroid product prepared as sterile ophthalmic suspension. The active ingredient is represented by the chemical structure:



Established name: Prednisolone Acetate
Chemical name: Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-,(11ß)-.

Each mL contains:
Active: Prednisolone Acetate 10 mg.
Preservative: Benzalkonium Chloride 0.1 mg.
Vehicle: Hypromellose
Inactives: Dibasic Sodium Phosphate (anhydrous), Polysorbate 80, Edetate Disodium, Glycerin, Citric Acid (monohydrate) and/or Sodium Hydroxide (to adjust pH) Purified Water.

CLINICAL PHARMACOLOGY:
Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation.
There is no generally accepted explanation for the mechanism of action of ocular corticosteroids. However, corticosteroids are 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 the release of their common precursor arachidonic acid. Arachidonic acid is released from the membrane phospholipids by phospholipase A2.
Corticosteroids are capable of producing a rise in intraocular pressure.

INDICATIONS AND USAGE:
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, cystitis, selected infective conjunctivitides, when the inherent

hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies.

PREDNISOLONE acetate (ECONOPRED™ PLUS) 10mg/mL Sterile Ophthalmic Suspension is for the treatment of conditions for which corticosteroid therapy is indicated except adrenocortical-deficiency states.

CONTRAINDICATIONS:
Prednisolone acetate is contraindicated in most viral diseases of the cornea and conjunctiva including herpes simplex keratitis, vaccinia, varicella and other viral infection of cornea or conjunctiva, mycobacterial ocular infections, fungal diseases of ocular structures and acute untreated bacterial infections. Prednisolone acetate is also contraindicated in individuals with known or suspected hypersensitivity to the active substance or to any of the excipients.

WARNINGS:
Prolonged use of ophthalmic corticosteroids may result in ocular hypertension and/or glaucoma, which may lead to optic nerve damage, visual field defects, reduced visual acuity and posterior subcapsular cataract formation. In patients receiving prolonged ophthalmic corticosteroid therapy, intraocular pressure should be checked routinely and frequently. This is especially important in paediatric patients, as the risk of corticosteroid-induced ocular hypertension may be greater in children and may occur earlier than in adults. PREDNISOLONE acetate (ECONOPRED™ PLUS) 10mg/mL Sterile Ophthalmic Suspension is not approved for use in paediatric patients. The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).
Systemic corticosteroid side-effects may occur after intensive or long-term continuous ophthalmic corticosteroid therapy in predisposed patients, including patients treated with CYP3A4 inhibitors (e.g. ritonavir and cobicistat).
In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids.
Corticosteroids may reduce resistance to and aid in the establishment of bacterial, fungal or viral infections and mask the clinical signs of infection.
Fungal infection should be suspected in patients with persistent corneal ulceration. If fungal infection occurs, corticosteroids therapy should be discontinued.
Topical ophthalmic corticosteroids may slow corneal wound healing. Topical NSAIDs are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
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 and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid 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.
The wearing of contact lenses is discouraged during treatment of an ocular inflammation. PREDNISOLONE acetate (ECONOPRED™ PLUS) 10mg/mL Sterile Ophthalmic Suspension contains benzalkonium chloride which may cause irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. In case patients are allowed to wear contact lenses, they must be instructed to remove contact lenses prior to application of PREDNISOLONE acetate (ECONOPRED™ PLUS) 10mg/mL Sterile Ophthalmic Suspension and wait at least 15 minutes before reinsertion.

PRECAUTIONS:
General:
The initial prescription and renewal of the medication 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 two days, the patient should be reevaluated.
As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application, 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 (SEE WARNINGS).

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 infection. Keep bottle tightly closed when not in use. Keep out of reach of children.

Interaction with other medicinal products and other forms of interaction

Concomitant use of topical steroids and topical NSAIDs may increase the potential for corneal healing problems.
Co-treatment with CYP3A4 inhibitors, including ritonavir and cobicistat, may increase systemic exposure resulting in increased risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

FERTILITY, PREGNANCY AND LACTATION:

Fertility

Studies have not been performed to evaluate the effect of topical ocular administration of prednisolone on human fertility.

Pregnancy

Teratogenic effects: Prednisolone has been shown to be teratogenic in mice when given in doses 1-10 times the human dose. Dexamethasone, hydrocortisone and prednisolone were ocularly applied to both the eyes of pregnant mice five times per day on days 10 through 13 of gestation. A significant increase in the incidence of cleft palate was observed in the fetuses of the treated mice. There are no adequate and well controlled studies in pregnant women. Prednisolone acetate should be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
There are no or limited amount of data from the use of ophthalmic prednisolone in pregnant women. Animal studies with prednisolone have shown reproductive toxicity.

Breast-feeding

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from prednisolone acetate, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Prednisolone/ metabolites are excreted in human milk following systemic administration. It is unknown whether prednisolone/metabolites are excreted in human milk following topical ocular administration.

Pediatric Use:

Safety and effectiveness in children have not been established.

Effects on ability to drive and use machines

Temporary blurred vision or other visual disturbances after use of eye preparations may affect the ability to drive or use machines. If blurred vision occurs after administration, the patient must wait until the vision clears before driving or using machinery.

UNDESIRABLE EFFECTS:

The following adverse reactions have been reported during clinical studies with PREDNISOLONE acetate (ECONOPRED™ PLUS) 10mg/mL Sterile Ophthalmic Suspension and are classified according to the subsequent convention: very common (≥ 1/10), common (≥ 1/100 to <1/10),

uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) and very rare (<1/10,000). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	MedDRA Preferred Term (v. 16.0)
Eye disorders	*Common:* ophthalmic medication residue *Uncommon:* intraocular pressure increased, ocular discomfort, ocular hyperaemia

Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data.

System Organ Classification	MedDRA Preferred Term (v. 16.0)
Eye disorders	Keratitis, mydriasis, ptosis, vision blurred, photophobia, foreign body sensation in eyes
Gastrointestinal	Nausea
Nervous system	Dizziness, dysgeusia, headache

DOSAGE AND ADMINISTRATION:
SHAKE WELL BEFORE USING.
Two drops topically in the eye(s) four times daily. In cases of bacterial infections, concomitant use of anti-infective agents is mandatory. Care should be taken not to discontinue therapy prematurely. If signs and symptoms fail to improve after two days, the patient should be reevaluated (see PRECAUTIONS).
The dosing of Prednisolone acetate may be reduced, but care should be taken not to discontinue therapy prematurely. In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of applications.

OVERDOSE:
Due to the characteristics of this preparation, no toxic effects are to be expected with an ocular overdose of this product, nor in the event of an accidental ingestion of the contents of one bottle.

AVAILABILITY:
Plastic Droptainer x 5 mL (Box of 1's)

STORAGE:
Store upright at temperatures not exceeding 25°C. SHAKE WELL BEFORE USING.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
The patient is advised to seek IMMEDIATE medical attention at the first sign of adverse drug reaction.

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