1. NAME OF THE MEDICINAL PRODUCT

1% ECONOPRED® PLUS

(Prednisolone Acetate)
Sterile Ophthalmic Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ECONOPRED® Plus suspension (Prednisolone Acetate) in an adrenocortical steroid product prepared as sterile ophthalmic suspension.
Each ml contains:
Active: Prednisolone Acetate 1.0%.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Eye drops, suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.

4.2 Posology and method of 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.

- The initial prescription and renewal of the medication order 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 re-evaluated.

- The dosing of ECONOPRED Plus suspension 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.

Pediatric Use: Safety and effectiveness in children have not been established.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Herpes simplex keratitis.

• Vaccinia, varicella, and other viral infection of cornea or conjunctiva.
• Mycobacterial ocular infections.
• Fungal diseases of ocular structures.
• Acute untreated bacterial infections.

4.4 Special warnings and precautions for use

• Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

• 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. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections.

• Systemic corticosteroid side-effects may occur after intensive or long-term continuous ophthalmic corticosteroid therapy in predisposed patients, including children and patients treated with CYP3A4 inhibitors (e.g. ritonavir and cobicistat).

• If product is used for 10 days or longer, intraocular pressure should be routinely monitored. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure checked frequently.

• Since ECONOPRED Plus contains no antimicrobial, if Infection is present, appropriate measures must be taken to counter the organisms involved.

• In paediatric patients, the risk of corticosteroid-induced ocular hypertension may be greater in children and may occur earlier in adults.

• Corticosteroids may reduce resistance to and aid in the establishment of bacterial, fungal or viral infections and mask the clinical signs of infection.

• 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 effective in mustard gas keratitis and Sjogren's keratoconjunctivitis.

- Fungal infection should be suspected in patients with persistent corneal ulceration. If fungal infection occurs, corticosteroids therapy should be discontinued.

- Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids.

- 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 (See section 4.5). The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

- The wearing of contact lenses is discouraged during treatment of an ocular inflammation. Econopred Plus Eye Drops, 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 ECONOPRED Plus and wait at least 15 minutes before reinsertion.

- 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.

4.5. 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 (See section 4.4.)

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.

4.6 Fertility, pregnancy and lactation

<u>Fertility</u>

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

<u>Pregnancy</u>

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.

ECONOPRED® Plus suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Breast-feeding

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.

4.7 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.

4.8 Undesirable effects

The following adverse reactions have been reported during clinical studies with ophthalmic prednisolone-containing products 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, photophobia, vision blurred, foreign body sensation in eyes
Gastrointestinal	Nausea
Nervous system	dizziness, headache, dysgeusia

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

Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticoidism after use of topical steroids.

Corticosteroid-containing preparations have also been reported to cause acute anterior uveitis, defects in the visual fields and perforation of the globe. Conjunctivitis, corneal ulcers, conjunctival hyperemia and loss of accommodation have occasionally been reported following local use of corticosteroid.

4.9. 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 or tube.

5. PHARMACOLOGICAL PROPERTIES
Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the 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 A_2 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 phospholipase A_2.

Corticosteroids are capable of producing a rise in intraocular pressure.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Benzalkonium chloride, Glycerin, Polysorbate 80, Hypromellose, Edetate Disodium, Dried Sodium Phosphate, Sodium hydroxide and/or Citric Acid and purified water.

6.2 Incompatibilities
Not applicable

6.3 Special precautions for storage
STORAGE: Store at 46° - 75°F (8° - 24°C) in an upright position.
Keep bottle tightly closed when not in use.
Keep out of the reach of children.

6.4 Nature and content of container
5 ml in plastic DROPTAINER® dispenser

6.5 Special precautions for disposal
No special requirement

6.6 Manufacturer

See folding box

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