NOVARTIS

ECONOPRED PLUS (prednisolone acetate 1%)

10mg/mL sterile ophthalmic suspension

Basic Succinct Statement

CODE: BSS RD MAR 18; APPR 25 OCT 2018

This material is only meant for Healthcare Professionals

ECONOPRED* PLUS

Important note: Before prescribing, consult full prescribing information.

Presentation: DROP-TAINER* dispenser. Each ml of suspension contains 10 mg prednisolone acetate and 0.1 mg Benzalkonium Chloride as a preservative.

Indications: Steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis 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.

Dosage and administration: 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 2 days, the patient should be re-evaluated. Dosing 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.

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

Warnings and Precautions: ♦Prolonged use of ophthalmic corticosteroids may result in ocular hypertension and/or glaucoma, with 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 for greater in children and may occur earlier than in adults. ECONOPRED* PLUS Sterile Ophthalmic Suspension is not approved use in paediatric patients. The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (eg, diabetes). ♦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). ♦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. ♦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. ♦The wearing of contact lenses is discouraged during treatment of an ocular inflammation. ECONOPRED* PLUS 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

ECONOPRED* PLUS Sterile Ophthalmic Suspension and wait at least 15 minutes before reinsertion. ♦**Ability to drive and use machines:** Temporary blurred vision or other visual disturbances after eye preparations use 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.

Adverse drug reactions: 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. ♦**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**:** keratitis, ptosis, mydriasis, vision blurred, photophobia, foreign body sensation in eyes, nausea, dizziness, headache, dysgeusia.

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