PREDAMIA

Sterile Ophthalmic Suspension

Composition:
Each 1ml of **PREDAMIA** ophthalmic suspension contains 10mg Prednisolone acetate, and Benzalkonium chloride 0.006% and Boric acid 1% as preservative

Excipient:
polysorbate 80, Sodium citrate dihydrate, Sodium Chloride, Disodium Edetate, Hydroxypropylmethylcellulose, purified water QS to 5ml.

Mechanism of action:
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.
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 release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.
Corticosteroids are capable of producing a rise in intraocular pressure.

Pharmacokinetic properties:
Prednisolone acetate has been shown to penetrate rapidly the cornea after topical application of a suspension. Aqueous humour T_{max} occurs between 30 and 45 minutes after installation. The half-life of prednisolone acetate in human aqueous humour is approximately 30 minutes.

Indications:
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, cyclitis, selected infective 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.

Contraindications:
PREDAMIA ophthalmic suspension is contraindicated in most viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia,varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures, it is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

Warning & precautions:
- Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation.
- Suppress the host immune response and thus increase the hazard of secondary ocular infections.
- Corneal or scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.
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- Acute purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication.
- If this product is used for 10 days or longer, intraocular pressure (IOP) 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. IOP 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.
- If signs and symptoms fail to improve after two days, the patient should be reevaluated.
- Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use.

Side effects:
- Elevation of IOP with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, and delayed wound healing, in decreasing order of frequency.
- Rare occurrences of systemic hypercorticoidism.
- Cause acute anterior uveitis and perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodation and ptosis.
- The development of secondary ocular infection (bacterial, fungal and viral) ,fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroid.
- Cushing's syndrome and adrenal suppression may occur after very frequent use of ophthalmic prednisolone, particularly in very young children.

Pregnancy & lactation:
Pregnancy: **PREDAMIA** ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Lactation: 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.

Effects on ability to drive and use machines:
May cause short-lasting blurring of vision upon instillation. If affected, the patient should not use machinery/electric tools or drive until vision has returned to normal.

Dosage & administration:
- Two drops topically in the affected eye 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 dosing of **PREDAMIA** ophthalmic 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.

Information for patients:
- Shake well before use.
- 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.

Storage conditions:
- Store at temperature not exceeding 25°C, in an upright position, protected from freezing, out of reach of children.
- Discard the content after 28 days from the container first opening.

Packaging:
PREDAMIA ophthalmic suspension is supplied in polyethylene bottle 5ml with dropper and a leaflet, tightly sealed with a polyethylene closer, within a carton box.

Produced by MIAMED Pharmaceutical Industries –Damascus countryside –Syria

This is a medicament
- A medicament is a product but unlike any other products.
- A medicament is a product which affect your health, and its consumption contrary to instructions is dangerous for you.
- follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
Keep medicaments out of reach of children

Council of Arab Health Ministers Arab pharmacist Association

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PKG-260/01