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# PRED FORTE®

prednisolone acetate 1%
sterile ophthalmic suspension

## DESCRIPTION

Each mL contains: prednisolone acetate 10 mg with: benzalkonium chloride 0.06 mg, polysorbate 80, boric acid, sodium citrate, sodium chloride, edetate disodium, hydroxypropyl methylcellulose and purified water.

## ACTIONS

Prednisolone acetate is a glucocorticoid that, on the basis of weight, has 3 to 5 times the anti-inflammatory potency of hydrocortisone. Glucocorticoids inhibit the edema, fibrin deposition, capillary dilatation and phagocytic migration of the acute inflammatory response as well as capillary proliferation, deposition of collagen and scar formation.

## INDICATIONS

For steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

## CONTRAINDICATIONS

Most viral diseases of the cornea and conjunctiva, including , superficial (or epithelial) herpes simplex keratitis (dendritic keratitis), vaccinia, varicella Mycobacterial infection of the eye fungal diseases of ocular structures. Hypersensitivity to the active substance or to any of the excipients of the formulation.

## WARNINGS

1. In those diseases causing thinning of the cornea, perforation has been reported with the use of topical steroids. Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal or scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.
2. Since PRED FORTE® contains no antimicrobial, if infection is present appropriate measures must be taken to counteract the organisms involved.
3. Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids. Prolonged use may suppress the host immune response in ocular tissues and thus increase the possibility of secondary ocular infections.
4. Eye drops containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision with regular checks of intra-ocular pressure (IOP).
5. Use of intraocular steroids may prolong the course and may exacerbate the severity of many viral infections on the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex virus requires caution and should be followed by frequent mandatory slit-lamp microscopy.
6. As fungal infections of the cornea have been reported coincidentally with long-term local steroid applications, fungal invasion may be suspected in any persistent corneal ulceration where a steroid has been used, or is in use. Fungal cultures should be taken when appropriate.
7. Use of topical corticosteroids may cause increased intraocular pressure in certain individuals. This may result in glaucoma with damage to the optic nerve with defects in the visual fields. It is advisable that the intraocular pressure be checked frequently, particularly in patients with a history or presence of glaucoma.
8. Systemic adverse events may occur with extensive use of topical steroids; punctal occlusion may be recommended.
9. The possibility of adrenal suppression should be considered with prolonged, frequent, use of high dose topical steroids, particularly in infants and children.
10. PRED FORTE® contains benzalkonium chloride, which is irritant to the eye and could cause discoloration of soft (hydrophilic) contact lenses. The patient should avoid contact with contact lenses and therefore be instructed to remove them before PRED FORTE® is used and then wait for at least 15 minutes before reinsertion.
11. To prevent eye injury or contamination, care should be taken to avoid touching the bottle tip to the eye or to any other surface. The use of the bottle or tube by more than one person may spread infection. Keep bottle or tube tightly closed when not in use. Keep out of the reach of children.
12. 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, consider evaluating for 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.
13. **Use in Pregnancy -** Safety of intensive or protracted use of topical steroids during pregnancy has not been substantiated. PRED FORTE® should be used with caution during pregnancy only if the potential benefit outweighs the potential risk to the fetus. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development.
14. **Nursing Mothers -** It is not known whether topical administration could result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when PRED FORTE® is administered to a nursing woman taking into consideration the importance of the drug to the mother.
15. **Use in Children -** Safety and effectiveness of corticosteroids in children below the age of two years has not been established.
16. **Geriatric Use** No overall differences in safety or effectiveness have been observed between elderly and younger patients.
17. **Effects on Ability to Drive and Use Machines -** Upon instillation, patients may experience transient blurred vision which may impair the ability to drive or use machinery. If affected, patients should not drive or use machinery until their vision has cleared.
18. Drug Interactions: Although the systemic exposure is expected to be low with topical ophthalmic corticosteroid administration, co-treatment with CYP3A inhibitors may increase the risk of systemic corticosteroid-related side-effects.

## PRECAUTIONS

Posterior subcapsular cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids, or may aid in the establishment of secondary ocular infections from fungi or viruses liberated from ocular tissue, or by suppression of the host immune response. Acute anterior uveitis may occur in susceptible individuals. The use of steroids after cataract surgery may delay healing and increase the incidence of filtering blebs. If signs of hypersensitivity or other serious reactions occur, discontinue use of this preparation. Cross-sensitivity among corticosteroids has been demonstrated (see **ADVERSE REACTIONS**).

## ADVERSE REACTIONS

Increased intraocular pressure, with optic nerve damage, defects in the visual fields. Also posterior subcapsular cataract formation, secondary ocular infections from fungi or viruses liberated from ocular tissues, perforation of the globe when used in conditions where there is thinning of the cornea or sclera, and delayed wound healing. Corticosteroid-containing preparations can also cause acute anterior uveitis or perforation of the globe. Mydriasis, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids. Systemic side effects may occur with extensive use of steroids. There have been rare occurrences of systemic hypercorticoidism after use of topical steroids.

The following adverse reactions have been identified during post approval use of PRED FORTE®. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

*Immune system disorders:* Hypersensitivity, Urticaria.

*Nervous system disorders:* Headache.

*Eye disorders:* Cataract subcapsular, Eye irritation, Eye pain, Eye penetration (scleral or corneal perforation), Foreign body sensation, Intraocular pressure increased, Mydriasis, Ocular hyperemia, Ocular infection (including bacterial, fungal, and viral infections), Vision blurred/Visual disturbance, Eyelid ptosis.

*Gastrointestinal disorders:* Dysgeusia.

*Skin and subcutaneous tissue disorders:* Pruritus, Rash.

## OVERDOSE

There is no clinical experience of overdosage. Acute overdosage is unlikely to occur via the ophthalmic route. Oral overdosage will not ordinarily cause acute problems: if accidentally ingested, patients should be advised to drink fluids to dilute.

## PHARMACOKINETIC

Following a single 30-µL ocular topical dose of 1% prednisolone acetate suspension into rabbit eyes, prednisolone acetate was rapidly absorbed into aqueous humor, vitreous humor, and plasma, with peak aqueous humor concentrations (Cmax) occurring within 1 hour. In aqueous humor and vitreous humor, prednisolone acetate was extensively converted into prednisolone and in plasma to prednisolone and prednisone. The prednisolone concentrations in vitreous humor were much lower than those in aqueous humor. There was minimal absorption into the contralateral (undosed) eye following administration of 1% prednisolone acetate suspension.

### Preclinical Safety Data

In rabbit eyes, no toxic effects were observed after application of approximately 6 mg prednisolone acetate per day over 20 days as a 1% suspension. Also, no toxic effects were observed after a single oral administration of 500 mg/kg in rats.

## DOSAGE AND ADMINISTRATION

1 to 2 drops instilled into the conjunctival sac two to four times daily. During the initial 24 to 48 hours the dosage may be safely increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

## HOW SUPPLIED

As a sterile suspension in 5 mL and 10 mL plastic dropper bottles.

**Note:** Do not store above 30°C. Discard unused contents 4 weeks after opening. Protect from freezing. Store upright. On prescription only. Keep out of the reach of children. **Shake well before use.**



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