

Prednisolone Acetate 1%
Ophthalmic Suspension

Composition:

Cortisol® Ophthalmic Suspension: Each ml contains Prednisolone Acetate USP 10 mg.

Preservative : Sodium Perborate

Pharmacology:

Prednisolone is thought to act by the induction of phospholipase A2 inhibitory proteins, which control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid.

Indications:

Allergic conjunctivitis, acne rosacea, superficial keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis. It is also used in treating post-operative pain and inflammation after cataract surgery as well as uveitis.

Dosage and administration:

Instill 1 drop in the eye(s) four times daily. In cases of bacterial infections, concomitant use of anti-infective agents is mandatory.

In post-operative condition: Instill 1 drop in the operated eye(s) 4 times daily for 28 days. In uveitis: Instill 1 drop in the affected eye(s) 8 times daily for 42 days.

Contraindications:

Prednisolone Acetate Ophthalmic Suspension is contraindicated in most viral diseases of the cornea and conjunctiva.

Warnings:

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.

Precautions:

If this medication is used for 10 days or longer, intraocular pressure should be monitored. **Side effects:**

Elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage & posterior subcapsular cataract formation.

Pregnancy:

Prednisolone Acetate ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:

Due to 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.

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use:

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Storage:

- Store below 30°C temperature.
- Do not use longer than 30 days after first opening.
- Shake well before use.
- Keep out of the reach of children.

Packing

Cortisol® Ophthalmic Suspension: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.





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