Prednisolone Sodium Phosphate Ophthalmic Solution USP, 1% (Sterile)

For use only.

DESCRIPTION
Prednisolone Sodium Phosphate Ophthalmic Solution, 1%, is a sterile solution for ophthalmic administration having the following composition:

Each ml contains:
ACTIVITIES: Prednisolone Sodium Phosphate (10mg%) equivalent to 5 mg/ml, prednisolone phosphate is a buffered isotonic solution containing PHOSTEX, Bepanthenol, Miconazole Nitrate, Sodium Chloride, Sodium Hydroxide, Hydrochloric Acid, and Purified Water. Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust the pH (6.2 - 8.2).

The chemical name for prednisolone sodium phosphate is progesterone 1,4-diene-3,20-dione, 11,17-dihydroxy-21 (phosphorylamino)-, diisodium salt, (11β,17α) -, which has the following structural formula:

Molecular Formula: C₂₁H₂₇Na₂O₈P
Molecular Weight: 484.39

CLINICAL PHARMACOLOGY
Prednisolone sodium phosphate causes inhibition of inflammatory response to inciting agents of mechanical, chemical, or immunological nature. For generally accepted explanation of the steroid property, advancement has been made.

INDICATIONS AND USAGE
Prednisolone Sodium Phosphate Ophthalmic Solution 1% or 1/8% is for the treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acute acute, superficial punctate keratitis, herpes simplex keratitis, iritis, cyclitis, selected uveitis conditions when the inherent hazards of steroid use are accepted to obtain an acceptable diminution of acute and inflammation, corneal injury from chemical, radiation or thermal burn, or penetration of foreign bodies.

Prednisolone Sodium Phosphate Ophthalmic Solution 1%, is recommended for moderate to severe infective conjunctivitis when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation. Monkeys 119-214 diabetic retinopathy, diabetic uveitis and anterior uveitis.

The use of this preparation is contraindicated in the presence of:
1. Acute superficial keratitis, vernal keratoconjunctivitis.
2. Acute anterior uveitis.
3. Acute viral conjunctivitis.
4. Uveitis due to infectious processes.
5. Hypersensitivity to any of the components.

CONTRAINDICATIONS
The use of this preparation is contraindicated after a complicated detachment of a superficial corneal/foreign body.

WARNINGS
NOT FOR INJECTION INTO EYE - FOR TOPICAL USE ONLY

Employment of medication in the treatment of herpes simplex keratitis involving the cornea requires great caution, frequent observation being mandatory.

Prolonged use may result in increased intraocular pressure and/or glaucoma, damage to the optic nerve, defects in visual fields with visual field defects, precipitate subcapsular cataracts, systemic therapy is necessary. When deeper ocular structures are involved, systemic therapy is necessary.

GENERAL:
Later, further reduction in dosage to one drop three to four times daily may suffice to control symptoms. If irritation persists or develops, patient should be advised to discontinue use and consult prescribing physician.

PRECAUTIONS
General:
As with all infections of the cornea, a properly designed study including long-term institutional applications, fungal invasion must be suspected in any persistent corneal ulceration where a steroid has been used or is in use.

Intraocular pressure should be checked frequently.

Information for Patients:
Do not touch dropper tip to any surface as this may contaminate the solution.

Usage in Pregnancy: Pregnancy Category C: Animal reproductive studies have not been conducted with prednisolone sodium phosphate. It is not known whether prednisolone sodium phosphate can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Prednisolone sodium phosphate should be given to a pregnant woman only if clearly needed.

The effects of prednisolone sodium phosphate on the lactation, development and functional maturation of the child are unknown.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when prednisolone sodium phosphate is administered to a nursing woman.

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

ADVERSE REACTIONS
Glaucoma with or without glaucoma, which may occur.

Rarely, stinginess, or burning may occur.

DOSAGE AND ADMINISTRATION
Depending on the severity of the inflammation, instill one or two drops of solution into the conjunctival sac up to every hour during the day and every other hour during the night as necessary to control symptoms. When a favorable response is observed, reduce dosage to one drop every four hours.

Lenses: Further reduction in dosage to one drop three to four times daily may suffice to control symptoms.

The duration of treatment will vary with the type of lesion and may extend from a few days to several weeks, according to therapeutic response. Nevertheless, more cases continue to chronic active lesions than in self-limited conditions, usually respond to reintroduction.
HOW SUPPLIED
Prednisolone Sodium Phosphate Ophthalmic Solution USP, 1% is supplied in a plastic squeeze bottle with a controlled drop tip in the following sizes:

- 5 mL bottle - NDC 24208-715-02
- 10 mL bottle - NDC 24208-715-10
- 15 mL bottle - NDC 24208-715-06

Storage:
Store between 15° - 25° C (59° - 77° F).
Protect from light. Keep tightly closed.

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.
KEEP OUT OF REACH OF CHILDREN.

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Tampa, FL 33637
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