

Inflamase® Mild 1/8%
(PREDNISOLONE SODIUM PHOSPHATE)
OPHTHALMIC SOLUTION

Inflamase® Forte 1%
(PREDNISOLONE SODIUM PHOSPHATE)
OPHTHALMIC SOLUTION

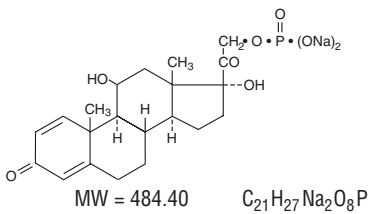
DESCRIPTION: INFLAMASE MILD and INFLAMASE FORTE (prednisolone sodium phosphate) ophthalmic solutions are sterile solutions for ophthalmic administration having the following compositions:

INFLAMASE MILD
Prednisolone Sodium Phosphate 1.25 mg/mL
(adrenocortical steroid/anti-inflammatory)
(equivalent to Prednisolone Phosphate 1.1 mg/mL)

INFLAMASE FORTE
Prednisolone Sodium Phosphate 10 mg/mL
(adrenocortical steroid/anti-inflammatory)
(equivalent to Prednisolone Phosphate 9.1 mg/mL)

in buffered, isotonic solutions containing sodium biphosphate, sodium phosphate anhydrous, sodium chloride, edetate disodium and purified water; preserved with benzalkonium chloride 0.1 mg/mL.

The chemical name for prednisolone sodium phosphate is Pregna-1,4-diene-3,20-dione,11,17-dihydroxy-21-(phosphonoxy)-, disodium salt,(11 β)-, which has the following chemical structure:



CLINICAL PHARMACOLOGY: Prednisolone sodium phosphate causes inhibition of the inflammatory response to inciting agents of a mechanical, chemical or immunological nature. No generally accepted explanation of this steroid property has been advanced.

INDICATIONS AND USAGE: INFLAMASE MILD and INFLAMASE FORTE Ophthalmic Solutions are indicated for the treatment of the following conditions: 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.

INFLAMASE FORTE Ophthalmic Solution is recommended for moderate to severe inflammations, particularly when unusually rapid control is desired. In stubborn cases of anterior segment eye disease, systemic adrenocortical hormone therapy may be required. When the deeper ocular structures are involved, systemic therapy is necessary.

CONTRAINDICATIONS: The use of these preparations is contraindicated in the presence of acute superficial herpes simplex keratitis, fungal diseases of the ocular structures, acute infectious stages of vaccinia, varicella and most other viral diseases of the cornea and conjunctiva, tuberculosis of the eye and hypersensitivity to a component of this preparation.

The use of these preparations is always contraindicated after uncomplicated removal of a superficial corneal foreign body.

WARNINGS: NOT FOR INJECTION INTO THE EYE - FOR TOPICAL USE ONLY. Employment of steroid medication in the treatment of herpes simplex keratitis involving the stroma requires great caution; frequent slit lamp microscopy is mandatory.

Prolonged use may result in elevated intraocular pressure and/or glaucoma, damage to the optic nerve, defects in visual acuity and fields of vision, posterior subcapsular cataract formation, or may result in secondary ocular infections. Viral, bacterial and fungal infections of the cornea may be exacerbated by the application of steroids. In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with the use of topical steroids. Acute purulent untreated infection of the eye may be masked or activity enhanced by the presence of steroid medication.

These drugs are not effective in mustard gas keratitis and Sjögren's keratoconjunctivitis.

Inflamase®
(PREDNISOLONE SODIUM PHOSPHATE) OPHTHALMIC SOLUTION
(Continued)

If irritation persists or develops, the patient should be advised to discontinue use and consult prescribing physician.

PRECAUTIONS: General: As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid applications, fungus 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.

Pregnancy: Teratogenic Effects: Pregnancy Category C: Animal reproductive studies have not been conducted with prednisolone sodium phosphate. It is also 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 effect of prednisolone sodium phosphate on the later growth, development and functional maturation of the child is 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: The following adverse reactions have been reported: glaucoma with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infections from pathogens including herpes simplex and fungi, and perforation of the globe.

Rarely, filtering blebs have been reported when topical steroids have been used following cataract surgery.

Rarely, stinging or burning may occur.

DOSAGE AND ADMINISTRATION: Depending on the severity of inflammation, instill one or two drops of solution into the conjunctival sac up to every hour during the day and every two hours during the night as necessary as initial therapy.

When a favorable response is observed, reduce dosage to one drop every four hours.

Later, 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. Relapses, more common in chronic active lesions than in self-limiting conditions, usually respond to retreatment.

HOW SUPPLIED:

- 3 mL plastic squeeze bottle with dropper tip.
 - INFLAMASE MILD NDC 58768-875-99
 - 1/8% (Prednisolone Sodium Phosphate)
 - INFLAMASE FORTE NDC 58768-877-99
 - 1% (Prednisolone Sodium Phosphate)
- 5 mL plastic squeeze bottle with dropper tip.
 - INFLAMASE MILD NDC 58768-875-05
 - INFLAMASE FORTE NDC 58768-877-05
- 10 mL plastic squeeze bottle with dropper tip.
 - INFLAMASE MILD NDC 58768-875-10
 - INFLAMASE FORTE NDC 58768-877-10
- 15 mL plastic squeeze bottle with dropper tip.
 - INFLAMASE FORTE NDC 58768-877-15

To be dispensed only in original, unopened container.

STORE BETWEEN 59°- 77° F (15°- 25° C).

Protect from light. Keep out of the reach of children.

CAUTION: Federal (U.S.) law prohibits dispensing without prescription.

Mfd. by OMJ Pharmaceuticals, Inc.,
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