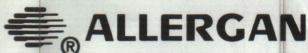


# Pred Mild®

(prednisolone acetate 0,12%)  
Sterile ophthalmic suspension



## DESCRIPTION

### Contains:

prednisolone acetate ..... 0,12%  
with: benzalkonium chloride 0,004%, polysorbate 80, boric acid, sodium citrate, sodium bisulfite, 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

Mild to moderate non-infectious allergic and inflammatory disorders of the lid, conjunctiva, cornea and sclera (including chemical and thermal burns).

## CONTRAINDICATIONS

Acute untreated purulent ocular infections, acute superficial herpes simplex (dendritic keratitis), vaccinia, varicella and most other viral diseases of the cornea and conjunctiva, ocular tuberculosis, and fungal diseases of the eye, and sensitivity of any components of the formulation.

## WARNINGS

1. In those diseases causing thinning of the cornea, perforation has been reported with the use of topical steroids.
2. This product contains Benzalkonium chloride as a preservative:
  - May cause eye irritation.
  - Avoid contact with soft contact lenses.
  - Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.
3. Since PRED MILD contains no antimicrobial, if infection is present appropriate measures must be taken to counteract the organisms involved.
4. Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids.
5. Use of steroid medication in the presence of stromal herpes simplex 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.
7. Use of topical corticosteroids may cause increased intraocular pressure in certain individuals. This may result in damage to the optic nerve with defects in the visual fields. It is advisable that the intraocular pressure be checked frequently.
8. **Use in Pregnancy** – Safety of intensive or protracted use of topical steroids during pregnancy has not been substantiated.

## PRECAUTIONS

Posterior subcapsular cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids.

Patients with histories of herpes simplex keratitis should be treated with caution.

## 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, and perforation of the globe when used in conditions where there is thinning of the cornea or sclera. Systemic side effects may occur with extensive use of steroids.

## 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 25°C ; protect from freezing. On prescription only. Keep out of the reach of children. **Shake well before use.**


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## (THIS IS A MEDICAMENT)

- Medicament is a product which affects 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.
- Do not repeat the same prescription without consulting your doctor.

**Keep medicament out of reach of children**

**Council of Arab Health Ministers  
Union of Arab Pharmacists**

 **ALLERGAN**

Westport, Co Mayo, Ireland

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