

## DATA SHEET

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### Name of Medicine

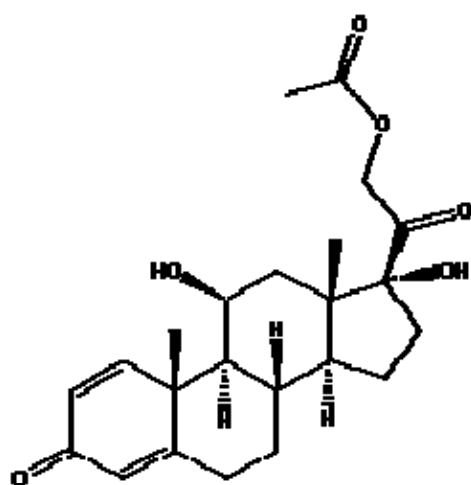
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PRED MILD<sup>®</sup> ophthalmic suspension (prednisolone acetate) 0.12% is a topical anti-inflammatory agent for ophthalmic use.

**Chemical Name:**

11 $\beta$ , 17, 21-trihydroxypregna-1,4-diene-3,20-dione 21-acetate

**Structural Formula:** prednisolone acetate



**Contains:**

**Active:** prednisolone acetate 0.12% (microfine suspension)

**Preservative:** benzalkonium chloride

**Inactives:** polysorbate 80; boric acid; sodium citrate dihydrate ; sodium metabisulfite ; sodium chloride; edetate disodium; hypromellose; sodium hydroxide, hydrochloric acid; and purified water.

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### Uses

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**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 dilation, and phagocytic migration of the acute inflammatory response, as well as capillary proliferation, deposition of collagen, and scar formation.

**Indications:**

PRED MILD<sup>®</sup> is indicated for the treatment of mild to moderate noninfectious allergic and inflammatory disorders of the lid, conjunctiva, cornea, and sclera (including chemical and thermal burns).

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**Dosage and Administration**

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**Shake well before using.** Instill one drop into the conjunctival sac two to four times daily. During the initial 24 to 48 hours, the dosing frequency may be increased if necessary. Care should be taken not to discontinue therapy prematurely.

If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated (see **Warnings and Precautions**).

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**Contraindications**

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PRED MILD<sup>®</sup> suspension is contraindicated in acute untreated purulent ocular infections, in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, in mycobacterial infection of the eye, fungal infections of ocular structures and tuberculosis of the eye. PRED MILD<sup>®</sup> suspension is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

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**Warnings and Precautions**

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**Warnings:**

Prolonged use of corticosteroids may increase intraocular pressure in susceptible individuals resulting in glaucoma with damage to the optic nerve, defects in visual acuity, and fields of vision, and in posterior subcapsular cataract formation. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections.

Since PRED MILD<sup>®</sup> contains no antimicrobial, if infection is present, appropriate measures must be taken to counteract the organisms involved.

Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.

Acute untreated purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication.

Eye drops containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision. If this product is used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Use of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.

Corticosteroids are not effective in mustard gas keratitis and Sjorgen's keratoconjunctivitis.

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

### ***Precautions:***

**General:** The initial prescription and renewal of the medication order beyond 20 milliliters of PRED MILD<sup>®</sup> should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and, where appropriate, fluorescein staining. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.

If this product is used for 10 days or longer, intraocular pressure should be monitored (see **Warnings**).

**Information for patients:** If inflammation or pain persists longer than 48 hours or becomes aggravated, the patient should be advised to discontinue use of the medication and consult a physician.

This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the bottle tip to the eye or to any other surface. The use of this bottle by more than one person may spread infection. Keep bottle tightly closed when not in use. Keep out of the reach of children.

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.

### ***Carcinogenesis, Mutagenesis, Impairment of Fertility:***

No studies have been conducted in animals or in humans to evaluate the potential of these effects.

### ***Use in Pregnancy:***

Use in pregnancy: Category C. In animal experiments, corticosteroids have been found to cause malformations of various kinds (cleft palate, skeletal malformations) and abortion. These findings do not seem to be relevant to humans. Reduced intrauterine growth and lower birth weight have been recorded in animals and humans after long-term or high dose treatment. Suppression of the adrenal cortex in the newborn baby, infants and children may occur after frequent long-term treatment with high dose topical steroids. The short-term use of corticosteroids prior to delivery for the prevention of respiratory distress syndrome, does not seem to pose a risk to the fetus or the newborn infant.

There are no adequate and well controlled studies in pregnant women. PRED MILD<sup>®</sup> should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Maternal pulmonary oedema has been reported with tocolysis and fluid overload.

### ***Use in Lactation:***

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from prednisolone, use is not recommended in women breast feeding infants.

### ***Use in Children:***

Safety and effectiveness in pediatric patients has not been established.

### ***Use in the Elderly:***

No overall differences in safety or effectiveness has been observed between elderly and young patients.

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## **Adverse Effects**

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Adverse reactions include, in decreasing order of frequency, elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, eye penetration (scleral or corneal perforation) and delayed wound healing.

Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticism after use of topical steroids.

Corticosteroid-containing preparations have also been reported to cause acute anterior uveitis and perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids.

The development of secondary ocular infection (bacterial, fungal, and viral) has occurred. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids. The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used (see **Warnings and Precautions**).

Transient burning and stinging upon instillation and other minor symptoms of ocular irritation have been reported with the use of PRED MILD<sup>®</sup> suspension. Other adverse events reported with the use of PRED MILD<sup>®</sup> suspension include: visual disturbance (blurry vision) and allergic reactions.

Urticaria, headache, dysgeusia, pruritus, and rash have also been reported.

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## **Overdosage**

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Overdosage by the topical ophthalmic route will not ordinarily cause acute problems. If accidentally ingested, drink fluids to dilute.

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## Pharmaceutical Precautions

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Discard unused solution four weeks after opening.

### ***Special Precautions for Storage***

Store at or below 25°C. Protect from freezing. For external use only. Store upright.

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## Medicine Classification

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Prescription Only

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## Package Quantities

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PRED MILD<sup>®</sup> ophthalmic suspension (prednisolone acetate) 0.12% is supplied sterile in plastic dropper bottles in the following size: 5 mL dropper bottles.

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## Name and Address

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Allergan New Zealand Limited  
Cnr Manu Tapu Drive & Joseph Hammond Place  
Auckland International Airport  
Mangere, Auckland 1  
N.Z.  
Toll free telephone: 0800 659 912

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## Date of Preparation

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9th July, 2010

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