

NEW ZEALAND DATA SHEET

1. PRODUCT NAME

PRED FORTE® 1.0% w/v ophthalmic suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Prednisolone acetate 1.0% w/v (microfine suspension)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A topical anti-inflammatory ophthalmic suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PRED FORTE® is indicated for the treatment of steroid-responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

4.2 Dose and method of administration

Shake well before using.

Instil 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 **Special warnings and precautions for use**).

Use in Children

Safety and effectiveness in paediatric patients have not been established.

Use in the Elderly:

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

4.3 Contraindications

PRED FORTE® suspension is contraindicated in:

- most viral diseases of the cornea and conjunctiva including superficial or epithelial herpes simplex keratitis (dendritic keratitis), vaccinia and varicella,
- mycobacterial infection such as tuberculosis of the eye,
- fungal diseases of ocular structures,
- individuals with known or suspected hypersensitivity to the active substance or to any of the excipients listed in section 6.1 and to other corticosteroids.

4.4 Special warnings and precautions for use

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.

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 Sjogren's keratoconjunctivitis.

Precautions:

General: The initial prescription and renewal of the medication order beyond 20 mL of PRED FORTE[®] 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**).

The possibility of adrenal suppression should be considered with prolonged, frequent, use of high dose topical steroid, particularly in infants and children.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, consider evaluating for possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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 eye injury or 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 the bottle tightly closed when not in use. Keep out of the reach of children.

Use with Contact Lenses:

The preservative in PRED FORTE[®], benzalkonium chloride, may be absorbed by and cause discoloration of soft contact lenses. Patients wearing soft contact lenses should be instructed to remove contact lenses prior to administration of the suspension and wait at least 15 minutes after instilling PRED FORTE[®] before reinserting soft contact lenses.

4.5 Interactions with other medicines and other forms of interactions

Although the systemic exposure is expected to be low with topical ophthalmic corticosteroid administration, co-treatment with CYP3A inhibitors may increase the risk of systemic corticosteroid-related side-effects.

4.6 Fertility, pregnancy and lactation

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 foetus or the newborn infant.

There are no adequate and well controlled studies in pregnant women. PRED FORTE[®] should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

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.

4.7 Effects on ability to drive and use machines

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.

4.8 Undesirable effects

Immune system disorders:

Hypersensitivity, urticaria

Nervous system disorders:

Dysgeusia, headache

Eye disorders:

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.

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 steroid. The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used (see **Special warnings and precautions for use**).

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

Eye irritation, eye pain, ocular hyperemia and foreign body sensation have also been reported.

Skin and subcutaneous tissue disorders:

Pruritus, rash

General disorders and administration site conditions:

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

Reporting of suspected adverse reaction:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare

professionals are asked to report any suspected adverse reactions
<https://nzphvc.otago.ac.nz/reporting/>.

4.9 Overdose

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

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

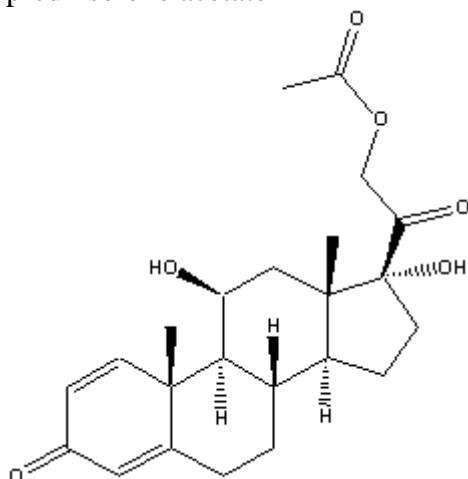
5. PHARMACOLOGICAL PROPERTIES

Chemical Name:

11 β , 17, 21-trihydroxypregna-1,4-diene-3,20-dione 21-acetate

Structural Formula:

prednisolone acetate



5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Corticosteroid

Mechanism of action:

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

5.2 Preclinical safety data

Carcinogenesis, Mutagenesis, Impairment of Fertility:

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Preservative:

benzalkonium chloride

Inactives:

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

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

Discard unused solution four weeks after opening.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

PRED FORTE® 1.0% ophthalmic suspension is supplied sterile in plastic dropper bottles in the following size: 5 mL dropper bottle.

6.6 Special precautions for disposal

No special requirements for disposal

7. MEDICINE SCHEDULE

Prescription only

8. SPONSOR

Allergan New Zealand Limited
Cnr Manu Tapu Drive & Joseph Hammond Place
Auckland International Airport
Mangere, Auckland
New Zealand

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9. DATE OF FIRST APPROVAL

July 1975

10. DATE OF REVISION OF TEXT

December 2017

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SUMMARY TABLE OF CHANGES

| Sections changed | Summary of new information |
|-------------------------|--|
| | All headings amended to align to Medsafe's updated DS requirements and sections within the Data Sheet have been moved under the appropriate headings in line with Medsafe's updated DS requirements. |
| | Minor editorial changes, including typographical and grammatical amendments, implemented throughout the DS to ensure legibility of this document. |
| 4.3 | Amended the contraindication relating to hypersensitivity in line with Medsafe's requirements. |
| 4.4 | Addition of precaution in with CCDS v5.0 |
| 4.5 | Addition of Interactions with other medicines in line with CCDS v4.0 and v5.0 |
| 4.8 | MedDRA SOC headings added and adverse events moved under the appropriate MedDRA SOC in line with CCDS v4.0, 5.0 and Medsafe's updated DS requirements. Addition of adverse events in line with Company Core Data Sheet. Addition of information relating to "Reporting of suspected adverse reactions" in line with Medsafe's updated DS requirements. |
| 4.9 | Addition of information relating to the management of overdose in line with Medsafe's updated DS requirements. |
| 5.1 | Addition of Pharmacotherapeutic group in line with Medsafe's updated DS requirements. |
| 6.2 | Additional information included in line with Medsafe's updated DS requirements. |
| 6.3 | Additional information included in line with Medsafe's updated DS requirements. |
| 6.6 | Additional information included in line with Medsafe's updated DS requirements. |
| 9 | Addition of Date of First Approval of PRED FORTE® in line with Medsafe's updated DS requirements. |