CONSUMER INFORMATION

[Pr]PRED FORTE®

Prednisolone acetate 1.0%

Sterile ophthalmic suspension

Corticosteroid

ABOUT THIS MEDICATION

What the medication is used for:

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

What it does:

PRED FORTE® 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.

When it should not be used:

Do not use **PRED FORTE®**:

- if you have most viral diseases of the cornea and conjunctiva, including superficial (or epithelial) herpes simplex keratitis (dendritic keratitis), vaccinia and varicella
- if you have mycobacterial infection of the eye or fungal diseases of the eye
- if you have hypersensitivity to any component of the product

What the medicinal ingredient is:

Prednisolone acetate

What the important nonmedicinal ingredients are:

Benzalkonium chloride 0.004% (as preservative), boric acid, edetate disodium, hydroxypropyl methylcellulose, polysorbate 80, purified water, sodium bisulfite, sodium chloride and sodium citrate.

What dosage forms it comes in:

PRED FORTE® ophthalmic suspension, prednisolone acetate 1.0%, w/v

A sterile suspension in 5 and 10 mL plastic dropper bottles – on prescription only.

WARNINGS AND PRECAUTIONS

PRED FORTE® contains sodium bisulfite, 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.

Since **PRED FORTE®** contains no antimicrobial, if infection is present, appropriate measures must be taken to counteract the organisms involved.

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.

Potential Effects of Prolonged Use

Prolonged use of topical corticosteroids may increase intraocular pressure in susceptible individuals, resulting in glaucoma, with damage to the optic nerve, defects in the visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma; intraocular pressure be checked frequently

Prolonged use may result in posterior subcapsular cataract formation.

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

Eye drops containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for intraocular pressure.

Corneal and Scleral Thinning

Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.

Masking Acute Purulent Infections

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

Secondary Ocular Infections

Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections.

As fungal infections of the cornea are particularly prone to develop 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. Fungal cultures should be taken when appropriate.

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

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

BEFORE you use **PRED FORTE®**, talk to your doctor or pharmacist if:

- if you are pregnant as safety of the use of topical steroids during pregnancy has not been established. There are no adequate and well controlled studies in pregnant women, therefore this product should be used with caution during pregnancy only if the potential benefit outweighs the potential risk to the fetus. Administration of corticosteroids to pregnant animals has been associated with abnormalities of fetal development.
- if you are breastfeeding as it is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Therefore, use is not recommended in women breast feeding infants.

There are no adequate and well controlled studies in pediatric patients.

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

INTERACTIONS WITH THIS MEDICATION

Interactions with this medication have not been studied.

PROPER USE OF THIS MEDICATION

Usual dose:
Shake well before using. Apply 1 to 2 drops into the conjunctival sac two to four times daily. During the initial 24 to 48 hours, the dosing frequency may be safely increased if necessary. Care should be taken not to discontinue therapy prematurely.

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.

Follow the following steps to help you use **PRED FORTE®** properly:

1. Wash your hands. Tilt your head back and look at the ceiling.

2. Gently pull down the lower eyelid to create a small pocket.

3. Turn the bottle upside down and squeeze it gently to release one drop into each eye that needs treatment.

4. Let go of the lower lid, and close your eye for 30 seconds.

If a drop misses your eye, try again.

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 solution and wait at least 15 minutes after instilling **PRED FORTE®** before reinserting soft contact lenses.

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 the bottle by more than one person may spread infection. Keep bottle or tube tightly closed when not in use.

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

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Increased intraocular pressure, with optic nerve damage and defects in the visual fields.

Also posterior subcapsular cataract formation, secondary ocular infections from fungi or viruses liberated from ocular tissues, perforation of the globe when used in conditions where there is thinning of the cornea or sclera, and delayed wound healing.

Systemic side effects may occur with extensive use of steroids.

The following adverse reactions have been identified during post approval use of **PRED FORTE®**. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune system disorders: Hypersensitivity, Urticaria
Nervous system disorders: Headache
Eye disorders: Cataract subcapsular, Eye irritation, Eye penetration (scleral or corneal perforation), Foreign body sensation, Intraocular pressure increased, Mydriasis, Ocular hyperemia, Ocular infection (including bacterial, fungal, and viral infections), Vision blurred/Visual disturbance
Gastrointestinal disorders: Dysgeusia
Skin and subcutaneous tissue disorders: Pruritus, Rash

HOW TO STORE IT

Keep out of reach of children.

PRED FORTE® should be stored at 15º to 25ºC. Protect from freezing. Store in an upright position.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

  Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Allergan Inc., at: 1-800-668-6424

This leaflet was prepared by Allergan Inc.

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