CLEAN PROFESSIONAL INFORMATION

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME AND DOSAGE FORM

PRED FORTE Sterile Eye Suspension

COMPOSITION

PRED FORTE Sterile Eye Suspension contains: Prednisolone acetate 10 mg/ml

Preservative: Benzalkonium chloride 0,004 % m/v

Excipients included in the formulation: Boric acid, disodium edetate, hypromellose, sodium chloride, sodium citrate dihydrate, sodium metabisulphite, polysorbate 80, purified water.

PHARMACOLOGICAL CLASSIFICATION

A 15.2 Ophthalmic preparations with corticosteroids.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Prednisolone acetate is a synthetic corticosteroid with anti-inflammatory properties. Prednisolone acetate has, on a weight to weight basis, an anti-inflammatory potency three to five times that of hydrocortisone.

Pharmacokinetic properties

The pharmacokinetic profile following topical ocular administration of 1 % prednisolone acetate has been evaluated in human volunteers undergoing cataract surgery; peak concentration of prednisolone in aqueous humour was found to occur within two hours after

instillation, and the half-life in aqueous humour was estimated to be approximately 30 minutes.

Prednisolone is mainly metabolised in the liver. After intravenous administration of 14C-prednisolone, greater than 90 % of the administered radioactivity was excreted in the urine, and approximately 10 - 30 % of the dose was excreted unchanged in urine.

INDICATIONS

For steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye globe.

CONTRA-INDICATIONS

Acute, untreated purulent ocular infections, superficial herpes simplex (dendritic keratitis), vaccinia, varicella and other viral diseases of the cornea and conjunctiva, mycobacterial infection of the eye, fungal diseases of the ocular structures, and hypersensitivity to any components of the formulation.

WARNINGS AND SPECIAL PRECAUTIONS

PRED FORTE, should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for intraocular pressure.

PRED FORTE contains benzalkonium chloride as a preservative, which is an irritant to the eye and could cause discolouration of soft (hydrophilic) contact lenses. The patient should avoid contact with contact lenses and therefore be instructed to remove them before PRED FORTE is used and then wait for at least 15 minutes before reinsertion. PRED FORTE should not be administered while wearing soft (hydrophilic) contact lenses.

As the possibility of adverse effects on the corneal permeability and danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved preparations cannot be excluded, regular ophthalmological examination is required.

Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease

PRED FORTE contains sodium metabisulphite, a sulphite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes. Sulphite sensitivity is seen more frequently in asthmatic patients.

Posterior subcapsular cataract formation has been reported after prolonged use of the topical ophthalmic corticosteroids.

In those diseases causing thinning of the cornea or sclera, perforation has been reported with the use of PRED FORTE.

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

Use of intraocular steroids may prolong the course and may exacerbate the severity of many viral infections on the eye (including herpes simplex). Patients with histories of herpes simplex should be treated with caution. Use of PRED FORTE in the presence of stromal herpes simplex requires caution and should be followed by frequent mandatory slit-lamp microscopy.

Acute purulent infections of the eye may be masked or enhanced by the use of PRED FORTE.

As fungal infections of the cornea have been reported coincidentally with long-term PRED FORTE applications, fungal invasion may be suspected in any persistent corneal ulceration where PRED FORTE has been used or is in use. Fungal cultures should be taken when appropriate.

Use of PRED FORTE may cause increased intraocular pressure. This may result in damage to the optic nerve with defects in the visual fields. PRED FORTE should be used with caution in the presence of glaucoma. It is advisable that the intraocular pressure be checked frequently. Because of the possibility of inducing corneal abscess, fungal keratopathy or glaucoma, the patient should be referred to an ophthalmologist if the eye has not responded within 48 hours.

Since PRED FORTE is not an anti-infective, if infection is present, appropriate measures must be taken to counteract the organism involved.

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

To prevent eye injury or contamination, care should be taken to avoid touching the bottle to the eye or to any other surface. The use of the same bottle by more than one person may spread infection.

Systemic adverse events may occur with the use of PRED FORTE. The possibility of adrenal suppression should be considered with prolonged, frequent use of high doses of PRED FORTE, particularly in infants and children. Punctal occlusion may be recommended (see ‘DOSAGE AND DIRECTIONS FOR USE’).

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.

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.

INTERACTIONS

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

PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

PRED FORTE, should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for intraocular pressure (see 'WARNINGS AND SPECIAL PRECAUTIONS').

Adults: 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 increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely (i.e. not to stop PRED FORTE abruptly or taper off too quickly). Shake well before using.

Treatment should not exceed 10 days without reassessment.

Safety and efficacy in paediatric patients have not been established.

To reduce possible systemic absorption, it may be recommended that the lacrimal sac be compressed at the medial canthus (punctal occlusion) for 1 minute. This should be performed immediately following the instillation of each drop (see 'WARNINGS AND SPECIAL PRECAUTIONS').

SIDE EFFECTS

The following side effects have been reported following use of PRED FORTE (frequencies unknown):

Immune system disorders

Hypersensitivity, urticaria

Nervous system disorders

Headache

Eye disorders

Increased intraocular pressure*, cataract (including subcapsular)*, eye penetration (scleral or corneal perforation)*, ocular infection (including fungal eye infection*, viral eye infection*, bacterial eye infection*), ocular stinging, ocular hyperaemia, eye irritation, eye pain, blurred vision / visual disturbance, mydriasis, foreign body sensation

Gastrointestinal disorders

Dysgeusia

Skin and subcutaneous tissue disorders

Pruritus, rash

Systemic: extensive topical use of corticosteroids may lead to systemic side effects*.

* Refer to 'WARNINGS AND SPECIAL PRECAUTIONS' for further information.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Healthcare professionals, patients and caregivers are also asked to report any suspected adverse reaction to AbbVie (Pty) Ltd via this e-mail address: MEAPV@abbvie.com

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

There is no clinical experience of overdosage. Acute overdosage is unlikely to occur via the ophthalmic route.

If accidentally ingested, patients should be advised to drink fluids to dilute. Refer to 'SIDE EFFECTS' listed above.

IDENTIFICATION

Dense, white microfine suspension.

PRESENTATION

PRED FORTE Sterile Eye Suspension is supplied in sterile plastic dropper bottles containing 5 ml suspension. For topical use only, under supervision of a medical practitioner.

STORAGE INSTRUCTIONS

Store at or below 25 ºC. Do not freeze. Do not use more than 30 days after opening.

Store upright. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

J/15.2/77

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION OF THE PACKAGE INSERT

Date of registration: 23 December 1976

Date of most recently revised professional information as approved by SAHPRA :21 April 2023