CLEAN PROFESSIONAL INFORMATION

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME AND DOSAGE FORM

PRED MILD Sterile Eye Suspension.

COMPOSITION

PRED MILD Sterile Eye Suspension contains: Prednisolone acetate 1,2 mg/ml

Preservative:

Benzalkonium chloride 0,004 % m/v

PHARMACOLOGICAL CLASSIFICATION

A 15.2 Ophthalmic preparations with corticosteroids.

PHARMACOLOGICAL ACTION

Prednisolone acetate is a glucocorticoid. 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.

INDICATIONS

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

CONTRA-INDICATIONS

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

WARNINGS

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.

DOSAGE AND DIRECTION FOR USE

1 to 2 drops instilled into the conjunctival sac two to four times daily. During the initial 24 to 48 hours the dosage may safely be increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely. Shake container well before using.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Posterior subcapsular cataract formation has been reported after heavy or protracted use of the topical ophthalmic corticosteroids. Patients with histories of herpes simplex should be treated with caution. In those diseases causing thinning of the cornea, perforation has been reported with the use of topical steroids. Since PRED MILD contains no antimicrobial agent, if infection is present, appropriate measures must be taken to counteract the organism involved.

Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids. Use of steroid medication in the presence of stromal herpes simplex requires caution and should be followed by frequent mandatory slit-lamp microscopy. 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. 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. Because of the possibility of inducing corneal abscess, fungal keratopathy of glaucoma, the patient should be referred to an ophthalmologist if the eye has not responded within 48 hours.

Use in pregnancy

Safety of intensive or protracted use of topical steroids during pregnancy has not been substantiated.

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

Refer to 'Side Effects and Special Precautions' listed above.

IDENTIFICATION

A milky suspension.

PRESENTATION

PRED MILD 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 °C. Do not freeze. Do not use more than 30 days after opening. KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

J/15.2/73

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

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