PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

MINIMS® PREDNISOLONE SODIUM PHOSPHATE 0,5 %

Eye drops, solution in single-dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sterile preservative-free solution containing 2,5 mg prednisolone sodium phosphate per dispensing unit of 0,5 ml (0,5 % *m/v*) as the active ingredient.

Excipients with known effect:

Sodium dihydrogen phosphate dihydrate (0,07 mg phosphates in each drop, equivalent to 1,83 mg/ml)

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution in single-dose container

A clear, colourless solution, practically free from visible particulate matter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

MINIMS® Prednisolone Sodium Phosphate is administered locally for non-infected inflammatory conditions of the outer eye and anterior segment.

4.2 Posology and method of administration

Adults: One or two drops to be instilled as directed.

Children: at the discretion of the ophthalmologist.

Each Minims unit should be discarded after single use.

Prednisolone should not be used for more than one week except under strict supervision.

4.3 Contraindications

- Hypersensitivity to prednisolone sodium phosphate or to any of the ingredients of MINIMS® Prednisolone Sodium Phosphate (see **6.1 List of excipients**).
- MINIMS® Prednisolone Sodium Phosphate is contra-indicated in viral, fungal, tuberculous, and other bacterial infections, or in ulcerated eyes.
- MINIMS® Prednisolone Sodium Phosphate should not be used in patients with glaucoma as prolonged use can cause intra-ocular pressure to rise.

4.4 Special warnings and precautions for use

The systemic effects of steroids are possible following the use of MINIMS® Prednisolone Sodium Phosphate, but are however unlikely due to the reduced absorption of topical eye drops.

Paediatric use

In children, long term continuous use should be avoided due to possible adrenal suppression.

4.5 Interaction with other medicines and other forms of interaction

Corticosteroids such as contained in MINIMS® Prednisolone Sodium Phosphate are known to increase the effects of barbiturates, sedative hypnotics and tricyclic antidepressants.

In addition, they may decrease the effects of anticholinesterases, antiviral eye preparations and salicylates.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit

outweighs the increased risk of systemic corticosteroid side-effects in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, pregnancy and lactation

Topical administration of corticosteroids to pregnant animals can cause foetal abnormalities, although the relevance of this finding to human being has not been established. The use of MINIMS® Prednisolone Sodium Phosphate during pregnancy and lactation should be avoided.

4.8 Undesirable effects

Prolonged use of MINIMS® Prednisolone Sodium Phosphate causes increased intra-ocular pressure, corneal ulcers, and reduced visual function, as well as increased susceptibility to infection.

Prolonged treatment with MINIMS® Prednisolone Sodium Phosphate in high dosage may be associated with subcapsular cataract.

Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patient with significantly damaged corneas.

Reporting of suspected adverse reactions

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

Suspected adverse reactions may also be reported directly to the Holder of the Certificate of registration using the following e-mail address: PV-SouthAfrica@bauschhealth.com

4.9 Overdose

See sections 4.4 Special warnings and precautions for use and 4.8 Undesirable effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 15.2 Ophthalmic preparations with corticosteroids.

Prednisolone is a synthetic corticosteroid with anti-inflammatory effects.

5.2 Pharmacokinetic properties

Prednisolone has an oral availability of 82 ± 13 %. Prednisolone has a urinary excretion of 26 ± 9 % and additional 3 ± 2 % is excreted as prednisone. The extent of binding to plasma proteins is dependent on concentration over the range encountered. Approximately 90 – 95 % is bound in plasma. The clearance of prednisolone is 10 ± 0,16 mℓ/min/kg and increases as protein binding is saturated and with increasing dose. The volume of distribution is 0,42 ± 0,11 L/kg and increases with dose due to saturable protein binding. The half-life of prednisolone is 2,2 ± 0,5 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate, sodium chloride, sodium dihydrogen phosphate, sodium hydroxide (for pH adjustment) and purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

30 months

6.4 Special precautions for storage

Store between 2 and 8 °C.

Protect from strong light. Store in carton.

DO NOT FREEZE.

6.5 Nature and contents of container

MINIMS® Prednisolone Sodium Phosphate eye drops are provided in a sealed conical shaped polypropylene tube (unit), fitted with a polypropylene twist and pull-of cap. Each unit contains approximately 0,5 ml of solution.

Each unit is individually overwrapped in a polypropylene/paper sachet. The sachets are packed in cartons of 20 units.

6.6 Special precautions for disposal

Each MINIMS® unit should be discarded after single use.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

P/15.2/212

9 DATE OF FIRST AUTHORISATION

3 December 1982

10 DATE OF REVISION OF THE TEXT

28 April 2021