PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MINIMS® PREDNISOLONE SODIUM PHOSPHATE 0,5 %

Eye drops, solution in single-dose container

Read all of this leaflet carefully before you start using MINIMS® Prednisolone Sodium Phosphate

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MINIMS® Prednisolone Sodium Phosphate has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MINIMS® Prednisolone Sodium Phosphate eye drops are and what they are used for
2. What you need to know before you use MINIMS® Prednisolone Sodium Phosphate eye drops
3. How to use MINIMS® Prednisolone Sodium Phosphate eye drops
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1. What MINIMS® Prednisolone Sodium Phosphate eye drops are and what they are used for

MINIMS® Prednisolone Sodium Phosphate contains a corticosteroid.

It is used to treat inflamed (red and painful) eyes for which the inflammation is not caused by an infection.

2. What you need to know before you use MINIMS® Prednisolone Sodium Phosphate eye drops

Do not use MINIMS® Prednisolone Sodium Phosphate if:

- you are hypersensitive (allergic) to prednisolone or any of the other ingredients of MINIMS® Prednisolone Sodium Phosphate (listed in section 6).
- you have an eye infection.
- you have high pressure inside the eye or you are at risk of developing glaucoma. Your doctor will have checked for this.

Take special care with MINIMS® Prednisolone Sodium Phosphate:

You may experience systemic effects of steroids following the use of MINIMS® Prednisolone Sodium Phosphate eye drops, but this is unlikely due to the reduced absorption of topical eye drops.

Children

In children, long term continuous use of MINIMS® Prednisolone Sodium Phosphate eye drops should be avoided. Check with your doctor if your child has been using this medicine for a long time. Your doctor or eye specialist may decide to prescribe an alternative.

Other medicines and MINIMS® Prednisolone Sodium Phosphate

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

MINIMS® Prednisolone Sodium Phosphate can increase the effects of:

- medicine used to treat epilepsy (barbiturates),
- medicine used to help you sleep or to relieve anxiety (sedative hypnotics), or
- medicine used to treat depression (tricyclic antidepressants).

MINIMS® Prednisolone Sodium Phosphate can decrease the effects of:

- medicines such as anticholinesterases (indicated for reduced intestinal movement and for myasthenia gravis),
- medicines used to treat infection of the eye caused by a virus, or
- medicines similar to aspirin called salicylates (indicated for inflammation, pain, fever and blood thinning).

Some medicines may increase the effects of MINIMS® Prednisolone Sodium Phosphate and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy, breastfeeding and fertility

The use of MINIMS® Prednisolone Sodium Phosphate eye drops during pregnancy and breastfeeding should be avoided.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machines

You may experience blurred vision when you instill MINIMS® Prednisolone Sodium Phosphate into your eye. Wait until your vision clears before driving or using machinery.

MINIMS® Prednisolone Sodium Phosphate contains sodium dihydrogen phosphate dihydrate

This medicine contains 0,07 mg phosphates in each drop which is equivalent to 1,83 mg/ml. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use MINIMS® Prednisolone Sodium Phosphate eye drops

Do not share medicines prescribed for you with any other person.

Always use MINIMS® Prednisolone Sodium Phosphate exactly as your doctor or pharmacist has told you. Check with our doctor or pharmacist if you are not sure.

The drops are for single use only and provided in single use Minims units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

Dosage

Adults: The normal dose is 1 or 2 drops as directed by your doctor.

Children: The dose will be decided by your doctor or eye specialist.

MINIMS® Prednisolone Sodium Phosphate eye drops should not be used for more than one week except under strict supervision.

Method of administration

Make sure you follow these instructions carefully:

1. Wash your hands.

2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue. Twist and pull the cap to separate from the Minims body.
4. Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid. Make sure the dropper does not touch any parts of your eye.
5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye if necessary, then throw away the Minims unit, even if some solution remains.

If you use more MINIMS® Prednisolone Sodium Phosphate than you should

An overdose is very unlikely to occur. If you suddenly feel unwell after using the drops, of if someone accidentally swallowed the eye drops, consult your doctor, eye specialist or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use MINIMS® Prednisolone Sodium Phosphate

You should instill the missed dose as soon as you remember, unless it is nearly time for the next dose, but you should not instill a double dose to make up for a missed dose.

4. Possible side effects

MINIMS® Prednisolone Sodium Phosphate can have side effects.

Not all side effects reported for MINIMS® Prednisolone Sodium Phosphate are included in this leaflet. Should your general health worsen or if you experience any untoward effects while

using MINIMS® Prednisolone Sodium Phosphate eye drops, please consult your health care provider for advice.

Long term, frequent use of MINIMS® Prednisolone Sodium Phosphate eye drops can lead to:

- an increase of the pressure inside the eye,
- ulcers on the clear layer at the front of the eye (cornea),
- reduced visual function,
- an increased susceptibility to infection, or
- clouding of the lens in the eye (cataract).

In very rare cases, some patients with severe damage to the clear layer at the font of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

Consult your doctor if you notice any changes in your eyesight.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

You can also report side effects directly to the company, using the following e-mail address: PV-SouthAfrica@bauschhealth.com

By reporting side effects, you can help provide more information on the safety of MINIMS® Prednisolone Sodium Phosphate.

5. How to store MINIMS® Prednisolone Sodium Phosphate

- Store all medicines out of reach of children.
- Store in a refrigerator between 2 – 8 °C
- Protect from light.
- Keep the units in the outer carton.
- Do not freeze.
- Do not use after the expiry date stated on the carton or unit.
- Discard each Minims unit after single use.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MINIMS® Prednisolone Sodium Phosphate contains

- The active substance is prednisolone sodium phosphate.
- Each dispensing unit of 0,5 ml contains 2,5 mg prednisolone sodium phosphate (0,5 % *m/v*)
- The other ingredients are disodium edetate, sodium chloride, sodium dihydrogen phosphate, sodium hydroxide (for pH adjustment) and purified water.

What MINIMS® Prednisolone Sodium Phosphate looks like and contents of the pack

MINIMS® Prednisolone Sodium Phosphate is an eye drops solution in a single-dose container. The eye drops are a clear, colourless solution, practically free from visible particulate matter. 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.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is available on the company website, www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.