

Bausch & Lomb

Minims® Prednisolone Sodium Phosphate 0.5%w/v

Eye Drops, Solution

Prednisolone sodium phosphate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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 your eye drops
3. How to use your eye drops
4. Possible side effects
5. How to store your eye drops
6. Contents of the pack and other information

1. What Minims® Prednisolone Sodium Phosphate eye drops are and what are they used for

Minims® Prednisolone Sodium Phosphate contains a corticosteroid. It is used to treat inflamed eyes (red and painful) for which the inflammation is not caused by an infection. The part of the eye affected

will vary depending on the cause of the inflammation.

Your doctor may sometimes prescribe other drugs at the same time to make sure that the inflammation is treated effectively.

This medicine is indicated for children, adults and the elderly.

2. What you need to know before you use your eye drops

Do not use these drops if:

- you are allergic to the active substance (prednisolone) or any of the other ingredients of this medicine (listed in section 6).
- you have high pressure inside the eye or you are at risk of developing glaucoma. Your doctor will have checked for this.
- you have an eye infection.
- it is intended for long term continuous therapy in children (at the discretion of the physician).

Warning and precautions

Contact your doctor if you experience blurred vision or other visual disturbances.

Children

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

Other medicines and your eye drops

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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)
- 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 (a muscle weakening disease).
- medicines used to treat infection of the eye caused by a virus.
- 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, breast-feeding and fertility

Tell your doctor or eye specialist, he/she may decide to use these drops or to prescribe you an alternative.

Contact lenses

Your doctor will ask you to remove your contact lenses prior to the administration of the drops. There is no information on the effect of this product on contact lenses. Therefore do not wear contact lenses until the effects of the drops have completely worn off.

Driving and using machines

As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

Minims® Prednisolone Sodium Phosphate contains sodium dihydrogen phosphate dihydrate.

This medicine contains 0.07 mg phosphates in each drop which is equivalent to 1.83mg/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 your eye drops

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your 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

- The normal adult dose is 1 to 2 drops in one or both eyes as often as directed by your doctor.
- The dose for children will be decided by the doctor or eye specialist.

Method of administration

If you are putting the eye drops in yourself, then 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 cap to separate from the Minims body (Diagram 1).
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 your eyes get worse or are not better after a few weeks of using the eye drops, see your doctor or eye specialist or pharmacist.

This medicine should not be used for long term and frequent use without talking to your doctor or pharmacist.

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, tell your doctor or eye specialist or contact the nearest emergency department immediately.

If you forget to use Minims® Prednisolone Sodium Phosphate, you should take the missed dose as soon as you remember, unless it is nearly time for the next dose, but you should not take a double dose to make up for a missed dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

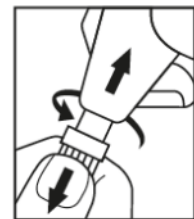


Diagram 1

Most people who are treated with these eye drops do not suffer from any side effects.

- Long term, frequent use of corticosteroids can lead to clouding of the lens in the eye (cataract) or to an increase of the pressure inside the eye.
- In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.
- With a frequency not known blurred vision may occur.

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

If any of the side effects gets serious, please seek immediate medical attention. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom

Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your eye drops

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP".

The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. Store in original package in order to protect from light.

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment.

6. Contents of the pack and other information

What your eye drops contain

- The active substance is prednisolone sodium phosphate.

Each Minims unit contains approximately 0.5 ml eye drops solution of prednisolone sodium phosphate 0.5% w/v (2.5 mg).

- The other ingredients are disodium edetate, sodium dihydrogen phosphate dihydrate, sodium chloride, sodium hydroxide solution (for pH adjustment) and purified water.

This medicine does not contain a preservative as it is a sterile single use unit.

What your eye drops look like and contents of the pack

The eye drops are a clear, colourless solution. Each carton contains 20 units.

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Marketing Authorisation Numbers:

Minims® Prednisolone Sodium Phosphate 0.5% w/v :
PL 03468/0079 (UK) ; PA23259/019/001 (Ireland)

This leaflet was last revised in: June 2022.