

Patient Information leaflet (PIL)

Auropred (Prednisolone Sodium Phosphate Eye Drops 0.5% w/v)

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 Prednisolone sodium Phosphate Eye drops is and what it is used for
2. What you need to know before you use Prednisolone sodium Phosphate Eye drops
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1. What Prednisolone sodium Phosphate Eye drops is and what it is used for

Prednisolone Sodium Phosphate 0.5% w/v Eye and Ear Drops, Solution (referred to as Prednisolone Sodium Phosphate drops in this leaflet) contains 0.5% w/v of Prednisolone Sodium Phosphate. It belongs to a group of medicines called corticosteroids.

Prednisolone Sodium Phosphate Drops work by reducing inflammation (redness, itching and soreness).

Prednisolone Sodium Phosphate Drops is used to treat inflammation of the eye or ear where there is no infection.

2. What you need to know before you use Prednisolone sodium Phosphate Eye drops

Do not use Prednisolone Sodium Phosphate Drops:

- if you are allergic to Prednisolone Sodium Phosphate or any of the other ingredients of this medicine (listed in section 6)
- if you have an infection in the eye, or it is producing pus and is sticky
- if you have glaucoma (increased pressure in the eye)
- if you have ulcers in your eye (shingles)
- if you have a fungal disease in your ear
- if you have a perforated ear drum.

Warnings and precautions

Important: Never use this medicine in your eye without first checking with your doctor. If it is used for the wrong condition, it could lead to blindness.

Talk to your doctor or pharmacist before using Prednisolone Sodium Phosphate Drops

- if you have been treated with Prednisolone Sodium Phosphate or similar corticosteroid drops recently. Do not have repeated or prolonged treatment without regular checkups from your doctor
- if you have tuberculosis (TB)
- if you wear soft contact lenses (see other medicines and Prednisolone Sodium Phosphate Drops below)

Systemic effects of nasal corticosteroids:

Prolonged use at high doses may cause:

- Cushing's syndrome (a hormonal disorder caused by high levels of cortisol), Cushingoid features such as facial roundness or puffiness, adrenal suppression, cataract and glaucoma.
- Rarely, a range of psychological effects including psychomotor hyperactivity (a feeling of restlessness, muscle spasms, twitches), sleep disorders, anxiety.

Children

- prolonged use may lead to the risk of adrenal suppression in infants
- growth retardation in children and adolescents
- depression or aggression (particularly in children)

Other medicines and Prednisolone Sodium Phosphate Drops

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

This medicine contains benzalkonium chloride as a preservative which may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

Benzalkonium chloride is known to discolour soft contact lenses.

Some medicines may increase the effects of Prednisolone Sodium Phosphate Drops 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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is a small risk of cleft palate or retarded growth in the foetus.

Driving and using machines

Prednisolone Sodium Phosphate Drops may cause temporary blurred vision. If this happens to you, do not drive or use machinery until your sight returns to normal.

Warnings about visual problems when using Prednisolone Sodium Phosphate Drops

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

3. How to use Prednisolone sodium Phosphate 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.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it is not, or you are not sure, ask your doctor or pharmacist.

Remember:

- Always use Prednisolone Sodium Phosphate exactly as your doctor has told you
- How often you use the drops will depend on how your body responds to the treatment.
- Use as few drops as possible for the shortest possible time.
- If there is no improvement in your symptoms after 7 days, stop using the drops and see your doctor again.

Check that the seal on the bottle is not broken before using Prednisolone Sodium Phosphate Drops for the first time. Wash and dry your hands. Do not breathe on or touch the dropper nozzle.

Eyes

- The recommended dose is 1 or 2 drops put into the eye every one or two hours
- Once the redness, itching and soreness starts to feel better, apply the drops less often.

1. Tilt your head back
2. Gently pull your lower eyelid downwards and outwards
3. Place drops in the gap between the eyelid and eye (squeeze bottle very gently if necessary)
4. Blink a few times to spread out the drops
5. Repeat for the other eye if needed.

Ears

- The recommended dose is 2 or 3 drops put into the ear every two or three hours
- Once the redness, itching and soreness starts to feel better, apply the drops less often.

1. Tilt your head to one side
2. Place drops in the ear canal (squeeze bottle gently if necessary)
3. Keep head tilted for a minute or two to let the drops soak in
4. Repeat for other ear if needed.

Medical check-ups

If you are using this medicine for your eyes and you use it for a number of weeks, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you. Your doctor will check your eyes for:

- An increase in pressure
- Cataracts
- Infection.

If you use more Prednisolone Sodium Phosphate Drops than you should

If you accidentally use too much Prednisolone Sodium Phosphate Drops it is unlikely to lead to any serious side effects. However, if you are concerned, contact your doctor or the nearest hospital casualty department.

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse.

If you forget to use Prednisolone Sodium Phosphate Drops

Do not use a double dose to make up for a forgotten dose. Simply use the next dose as planned.

If you stop using Prednisolone Sodium Phosphate Drops

Do not stop using Prednisolone Sodium Phosphate Drops without first talking to your doctor.

If you have been using Prednisolone Sodium Phosphate Drops for a long period of time (around 6 to 8 weeks), then you should stop using it gradually, to avoid the inflammation coming back.

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.

Effects on your eyes

Very rare: may affect up to 1 in 10,000 people

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.

Frequency not known (cannot be estimated from the available data)

- Ulcers on the surface of the eye (cornea). Tell your doctor if your eye becomes painful and if you have blurred vision which does not improve after a few minutes
- Increased pressure in the eye (glaucoma) which can lead to problems with your sight
- A hole in the eyeball (if you have a disease which causes thinning of the surface of the eye)
- Cataracts (clouding of the lens of the eye)
- Enlarged pupils
- Drooping of the eyelid
- Swelling and redness of the outer surface of the eye
- Blurred vision and other alterations to your sight.

Effects on the skin around your eyes

Frequency not known (cannot be estimated from the available data)

These may not appear until sometime after you have started to use the medicine.

- Irritation
- Burning
- Stinging

- Itching
- Redness

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.

5. How to store Prednisolone sodium Phosphate Eye drops

Do not store above 30°C. Do not freeze. Keep in the original container to protect from light

6. Contents of the pack and other information

5ml filled in 10ml Low density polyethylene container with HDPE cap and Nozzle.
Such 10ml is packed in a mono carton with package insert.

Marketing Authorisation Holder

Aurolab, No.1,
Sivagangai Main road,
Veerapanjan,
Madurai - 625020,
India.

Manufacturer

Aurolab, No.1,
Sivagangai Main road,
Veerapanjan,
Madurai - 625020,
India.