

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist
- In this leaflet, Predsol-N Drops for Eye & Ear. 0.5% w/v Solution will be called Predsol-N Drops.

In this leaflet:

1. What Predsol-N Drops are for
2. Before you use Predsol-N Drops
3. How to use Predsol-N Drops
4. Possible side effects
5. How to store Predsol-N Drops
6. Further information.

1. What Predsol-N Drops are for

Predsol-N Drops contains Prednisolone sodium phosphate. This belongs to a group of medicines called corticosteroids which can reduce inflammation (redness, itching and soreness).

Predsol-N Drops also contain neomycin sulphate which is an “aminoglycoside antibiotic.” This prevents bacterial infections from developing.

Predsol-N Drops are used to reduce inflammation in the eye or ear when there may also be a risk of bacterial infection. Predsol-N Drops are used after your doctor has confirmed that the inflammation is not due to a fungal or viral infection.

2. Before you use Predsol-N Drops

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.

Do not use Predsol-N Drops if:

- You are allergic to Prednisolone
- You are allergic to any of the other ingredients of Predsol-N Drops (see section 6)
- You have an infection in the eye, or it is producing pus and is sticky
- You have ulcers in your eye (shingles)
- You have glaucoma (increased pressure in the eye)
- You have a perforated ear drum.

If any of the above applies to you talk to your doctor or pharmacist.

Check with your doctor before using Predsol-N Drops if:

- You have been treated with Predsol-N or similar corticosteroid drops recently. Do not have repeated or prolonged treatment without regular check-ups from your doctor
- If you have an open wound near to your eye or ear
- You wear soft contact lenses (see warnings about the ingredients below).

Taking other medicines

Tell your doctor if you are taking any other medicine, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor or pharmacist for advice before using Predsol-N Drops.

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

Driving and using machines

Predsol-N 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 the ingredients in Predsol-N Drops

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.

3. How to use Predsol-N Drops

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 Predsol-N 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 Predsol-N Drops for the first time. Wash and dry your hands. Do not breathe on or touch the dropper nozzle.

Eyes

- The usual 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 usual 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 Predsol-N Drops than you should

If you accidentally use too much Predsol-N 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.

If you forget to use Predsol-N

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

If you stop using Predsol-N Drops

Do not stop using Predsol-N Drops without first talking to your doctor.

If you have been using Predsol-N 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 about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Predsol-N Drops can cause side effects, although not everybody gets them. These may include:

Effects on your eyes

- 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

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

- Irritation
- Burning
- Stinging
- Itching
- Redness.

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

5. How to store Predsol-N Drops

Keep out of the reach and sight of children.

Do not use Predsol-N Drops after the expiry date on the label. Do not use for longer than 28 days after the seal on the bottle has been broken.

Store Predsol-N Drops below 25°C and in the original carton to protect it from light.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. Further information

What Predsol-N Drops contains

There are two active substances in this medicine: Prednisolone sodium phosphate (0.5 %) and Neomycin sulphate (0.5 %).

The other ingredients are benzalkonium chloride, disodium edentate, polyethylene glycol, sodium formate, anhydrous sodium sulphate, disodium hydrogen phosphate anhydrous, sodium acid phosphate, sodium hydroxide, phosphoric acid, purified water.

What Predsol-N Drops looks like

Predsol-N Drops is clear, colourless solution. It comes in 5 ml or 10 ml plastic bottles with a built-in nozzle and a tamper-evident plastic cap.

Marketing Authorisation Holder

UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK

Manufacturer

Recipharm Limited, Vale of Bardsley, Ashton-under-Lyne, OL7 9RR, UK

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If this leaflet is difficult to see or read or you would like it in a different format, please contact

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