

**PATIENT INFORMATION LEAFLET**  
**(PREDNI) PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION USP 1%W/V**  
**[Prednisolone acetate]**

**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 physician, health care provider 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 physician, health care provider or pharmacist.

**WHAT IS IN THIS LEAFLET:**

1. What prednisolone acetate ophthalmic suspension is and what it is used for
2. Before you use prednisolone acetate ophthalmic suspension
3. How to use prednisolone acetate ophthalmic suspension
4. Possible side effects
5. How to store prednisolone acetate ophthalmic suspension
6. Further information

**1. WHAT PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION IS AND WHAT IT IS USED FOR**

It contains active ingredient prednisolone acetate is known as topical steroidal anti-inflammatory drugs. It is a sterile, preserved, aqueous ophthalmic suspension. It is used for short-term treatment of steroid-responsive inflammatory conditions of the eye (palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe) after excluding the presence of viral, fungal and bacterial pathogens in adults.

**2. BEFORE YOU USE PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION**

Do not use it if you are allergic to prednisolone acetate, benzalkonium chloride or any of the other ingredients of this medicine. If you suffer from acute untreated purulent ocular infections. Acute superficial herpes simplex (dendritic keratitis); vaccinia, varicella and most other viral diseases of the cornea and conjunctiva. Fungal diseases of the eye. Mycobacterial infection such as tuberculosis of the eye. Do not take if any of the above apply to you. If you are not sure, talk to your physician, pharmacist or nurse before having prednisolone acetate ophthalmic suspension.

**Take special care with prednisolone acetate ophthalmic suspension:**

To avoid contamination and cross-infection, avoid the use of the same bottle of medication for the treatment of infections. Contamination of the solution may occur if the dropper tip touches any surface. It may retard corneal healing.

**Warnings and Precautions:** Talk to your physician before taking prednisolone acetate ophthalmic suspension. If you have now or have had in the past. Eye ulcers or have had a disease or treatment to the eye that caused the tissue to become thin. You have glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) reported after use of systemic and topical corticosteroids and treated for raised pressure within the eye. You have had surgery for cataracts, bacterial, viral or fungal eye infections. Contact your physician if you experience blurred vision or other visual disturbances. It containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for intraocular pressure.

**Paediatric:** Not recommended because of as safety and efficacy in paediatric population have not yet been established.

**Using other medicines:** None known, it can affect or be affected by other medicines you are using, some medicines may increase the effects of prednisolone acetate ophthalmic suspension. Co-treatment with CYP3A inhibitors, including for HIV: ritonavir, 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.

**Using prednisolone acetate ophthalmic suspension with food and drink:** None

**Pregnancy and breast-feeding:** Before taking any medicine for advice consult to direction of physician. **Pregnancy:** It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Use in breast-feeding:** It is not known whether topical administration of prednisolone acetate ophthalmic suspension could result in sufficient systemic absorption to produce detectable quantities in breast milk. Therefore, use is not recommended in women breast- feeding infants.

**Driving and using machines:** There are possible side effects associated with prednisolone acetate ophthalmic suspension, such as it may cause temporary blurred vision. Do not drive and/or operate machinery until you feel well and your vision is clear.

**Important information about some of the ingredients of prednisolone acetate ophthalmic suspension** contains benzalkonium chloride BP as a preservative. It may cause eye irritation and is known to discolour soft contact lenses, therefore contact with soft contact lenses should be avoided. If you wear contact lens you should remove contact lenses prior to application and wait at least 15 minutes before putting your lenses back in. If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your physician.

### 3. HOW TO USE PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION

Always take your dose of prednisolone acetate ophthalmic suspension exactly as qualified person, like a physician or a nurse has told you, you should check with your physician, health care provider or pharmacist if you are not sure. Do not change your usual dose without talking to your physician.

**How prednisolone acetate ophthalmic suspension will be given to you:** Do not allow the tip of the container to touch the eye or areas around the eye. **Method of administration:** For Ocular Use Only. For External Use Only. Not For Injections. To reduce possible systemic absorption, it may be recommended that the lacrimal sac be compressed at the medial canthus (punctal occlusion) for 1 minute. This should be performed immediately following the instillation of each drop. **The usual recommended doses: Adult:** Instill 1 to 2 drops of prednisolone acetate ophthalmic suspension into the conjunctival sac in affected eye(s) at 2 to 4 times in day. During the initial 24 to 48 hours the dosing frequency may be safely increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

**Every time you use ophthalmic suspension:** Follow the "Instructions for Use" given as below Shake well before use.

1. Wash your hands. Open the bottle. Take special care that the tip of the dropper bottle does not touch your eye, the skin around your eye or your fingers. Tilt your head backwards and hold the bottle upside down over the eye.
2. Pull the lower eyelid downwards and look up. Hold and gently squeeze the bottle on the flattened sides of the bottle and let one drop fall into the space between the lower eyelid and the eye.

3. Turn the bottle upside down and squeeze it to release 1 or 2 drops into each eye that needs treatment.
4. Let go of the over lid and close your eye. Press your finger against the corner of eye side where your eyes meets to nose for one minutes. Repeat steps 3 to 4 with the other eye if instructed to do so by your Physician. Put the cap back on and close the bottle tightly.

Ophthalmic suspension, if handled improperly, it can become contaminated by common bacteria known to cause infections. Bacteria that can cause eye infection leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, keep the tip of the container away from contact with any surface. If you think your medication may be contaminated, or if you develop an eye infection, contact your physician immediately concerning continued use of this bottle.

**Use in children and adolescents:** Not recommended in children less than 12 years old because of safety concerns.

**If you more prednisolone acetate ophthalmic suspension than you should:** the over dosage is unlikely to occur via the ophthalmic route. If you have placed too many drops in your eye(s), wash your eye(s) with clean water. Apply your next dose at the normal time. If, by accident, anyone drinks this medicine, contact your physician straight away.

**If you forget to prednisolone acetate ophthalmic suspension:** It is important to take **prednisolone acetate ophthalmic suspension** as prescribed by your physician. If you miss a dose, use the drops as soon as possible. If it is almost time for the next dose, skip the missed dose and take the next dose at the usual time. Do not take a double dose to make up for the forgotten dose.

**If you stop using prednisolone acetate ophthalmic suspension:** If you have any further questions on the use of this product, ask your physician, health care provider or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Like all medicines, it can cause side effects, although not everybody gets them. Following less frequent adverse effects have been reported with ocular administration of prednisolone: Intraocular pressure increased cataract (including subcapsular), eye penetration (scleral or corneal perforation) foreign body sensation, headache, a feeling that something is in your eye, eye infections (bacterial, fungal or viral), mild stinging or irritation, red eye, blurred or visual impairment mydriasis, dysgeusia, urticaria, pruritus, rash or itching. **Systemic:** extensive topical use of corticosteroids may lead to systemic side effects. Stop using these drops and tell your physician immediately.

#### 5. HOW TO STORE PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light. Do Not Freeze. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Discard 28 Days after first opening. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

#### 6. FURTHER INFORMATION

What prednisolone acetate ophthalmic suspension contains: It contain active substances as Prednisolone Acetate USP. Polysorbate-80 (Tween-80) BP, boric acid (AR Grade) BP, disodium edetate (Inj.) BP, hypromellose (HPMC 5 CPS) BP, sodium dihydrogen phosphate dihydrate BP,

sodium metabisulfite BP, sodium chloride (Inj. Grade) BP, benzalkonium chloride solution BP, sodium citrate BP, water for injections BP. Pack size: White color, prednisolone acetate ophthalmic suspension filled in bottle. filled in 10 ml Plastic dropper bottle. Such 1 bottle is packed in the Printed carton with packing insert.

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