1.6.1

Prescribing Information (Summary of Product Characteristics)

1.6.1.1 Name of the medicinal Product

Prednisolone Acetate Ophthalmic Suspension USP 1% w/v

1.6.1.1.1 strength

1% w/v

1.6.1.1.2 Pharmaceutical Form

Ophthalmic Suspension

1.6.1.2 Qualitative and Quantitative Composition

1.6.1.2.1 Qualitative declaration

Prednisolone Acetate USP

1.6.1.2.2 Quantitative declaration

Sr. No.	Ingredients	Specification	Standard Quantity (% w/v)	Reason for Inclusion
1.	Prednisolone Acetate (Micronized & Sterile)	USP	1.000	Corticosteroid
2.	Polysorbate-80 (Tween-80)	BP	0.100	Surfactant
3.	Boric Acid (AR Grade)	BP	1.200	Antimicrobial Agent
4.	Disodium Edetate (Inj.)	BP	0.010	Chelating Agent
5.	Hypromellose (HPMC 5 CPS)	BP	0.300	Viscosity Increasing Agent
6.	Sodium Dihydrogen Phosphate Dihydrate	BP	0.250	Buffering Agent
7.	Sodium Metabisulfite	BP	0.200	Antioxidant
8.	Sodium Chloride (Inj. Grade)	BP	0.150	Tonicity Agent
9.	Benzalkonium Chloride Solution	BP	0.012% v/v	Antimicrobial Preservative

10.	Sodium Citrate	BP	1.000	Buffering Agent
11.	Water for Injections	BP	Q.S.	Vehicle

1.6.1.3 Pharmaceutical Form

Ophthalmological or Topical corticosteroids, ATC code: S01BA04

White color suspension filled in bottle.

1.6.1.4 Clinical Particulars

1.6.1.4.1 Therapeutic Indications

Prednisolone Acetate Ophthalmic Suspension 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.

1.6.1.4.2 Posology and Method of Administration

Method of administration: For topical ocular use only. 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.

Use in 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.

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

Directions for Use: Do not allow the tip of the container to touch the eye or areas around the eye. 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.

1.6.1.4.3 Contraindications

It is contraindicated in patient with known hypersensitivity to prednisolone or to any of excipients. 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.

1.6.1.4.4 Special Warnings and Special Precautions for Use

Not for injection or oral use, only for topical use.

Patients should be advised not to wear a contact lens if their eye is red. Instillation of eye drops may cause transient blurring of vision or other visual disturbances which may affect the ability to drive or use machines. The patient must wait until vision clears before driving or operate machine if blurred vision is experienced.

Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids. If infection is present, appropriate measures must be taken to counteract the infective organisms. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections. Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal or scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation. Use of intraocular steroids may prolong the course and may exacerbate the severity of many viral infections on the eye (including herpes simplex). Patients with a history of herpes simplex keratitis should be treated with caution. Use of steroid medication in the presence of stromal herpes simplex requires caution and should be followed by frequent, mandatory, slit-lamp microscopy. Prolonged use of topical corticosteroids may

cause an increase in intraocular pressure in certain individuals. Patients 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. It is advisable that intraocular pressure be checked frequently during treatment with prednisolone acetate ophthalmic suspension.

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.

Pregnancy: It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether topical administration of Prednisolone aceate 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.

Excipients with known effect: It 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.

1.6.1.4.5 Interaction with other medicinal products and other forms of interaction

None known. 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.

1.6.1.4.6 Fertility, Pregnancy and Lactation

Pregnancy: It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether topical administration of Prednisolone aceate 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.

1.6.1.4.7 Effects on ability To Drive and use Machines

Not Applicable.

1.6.1.4.8 Undesirable Effects

Immune system disorders; Not known: Hypersensitivity, Urticaria. Nervous system disorders; Not known: Headache. Eye disorders; Not known: Intraocular pressure increased* Cataract (including subcapsular)* Eye penetration (scleral or corneal perforation)* Foreign body sensation. Ocular infection (including bacterial*, fungal*, and viral* infections) Ocular stinging Eye irritation Eye pain Ocular hyperemia Vision blurred*/Visual impairment Mydriasis. Gastrointestinal disorders: Not known: Dysgeusia. Skin and subcutaneous tissue disorders; Not known: Pruritus, Rash. Systemic: extensive topical use of corticosteroids may lead to systemic side effects*.

1.6.1.4.9 Overdose

Overdosage will not ordinarily cause acute problems. If accidentally ingested, drink fluids to dilute.

1.6.1.5 Pharmacological Properties

1.6.1.5.1 Pharmacodynamics Properties

Prednisolone acetate is a synthetic adrenocorticoid with the general properties of prednisolone. Adrenocorticoids diffuse across cell membranes to complex with cytoplasmic receptors and subsequently stimulate synthesis of enzymes with anti-inflammatory effects. Glucocorticoids inhibit the oedema, fibrin deposition, capillary dilation and phagocytic migration of the acute inflammatory response as well as capillary proliferation, deposition of collagen and scar formation. Prednisolone acetate has, on a weight to weight basis, a potency three to five times that of hydrocortisone.

1.6.1.5.2 Pharmacokinetic Properties

Following topical ocular administration, prednisolone acetate was shown to have low systemic exposure to penetrate rapidly the cornea after topical application of a suspension preparation. Aqueous humour Tmax occurs between 30 and 45 minutes after installation. The half-life of prednisolone acetate in human aqueous humour is approximately 30 minutes.

1.6.1.5.3 Preclinical Safety Data

Not Applicable.

1.6.1.6 Pharmaceutical Particulars

1.6.1.6.1 List of Excipients

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

1.6.1.6.2 Incompatibilities

Not applicable.

1.6.1.6.3 Shelf Life

24 months

1.6.1.6.4 Special Precautions for Storage

Do not store above 30°C. Protect from light. Do not freeze.

1.6.1.6.5 Nature and Contents of Container

White color suspension filled in 10 ml sterile non transparent plastic dropper bottle with white plastic cap and plastic nozzle. Such 1 bottle is packed in the printed carton with packing insert.

1.6.1.6.6 Special precaution for disposal and other handling

No special requirements for disposal.

1.6.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.6.1.7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Phone: +91-079-41078096
Telefax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

1.6.1.7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Phone: +91-079-41078096
Telefax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

1.6.1.8 Marketing Authorization Number

To be included after obtaining first registration.

1.6.1.9 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

1.6.1.10 **Date of Revision of the Text**

January, 2023

1.6.1.11 Dosimetry (If Applicable)

Not Applicable

1.6.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable