5. Product Information

5.1. Prescribing Information (Summary of Product Characteristics)

1. Name of the Medicinal Product:
LUMEPRED (Prednisolone Acetate Ophthalmic Suspension USP)

2. Qualitative and Quantitative Composition:

a) Qualitative Composition

Product Name: LUMEPRED

Generic Name: Prednisolone Acetate Ophthalmic Suspension USP

Label Claim: Each mL contains:

Prednisolone Acetate USP……..1.0% w/v
Benzalkonium Chloride solution USP
(A preservative)…….0.02% v/v
Sterile Aqueous vehicle…….q.s.

3. Pharmaceutical Form
Ophthalmic Suspension
Description: A white colour suspension

4. Clinical Particulars

4.1 Therapeutic indications
For short-term treatment of steroid-responsive inflammatory conditions of the eye, after excluding the presence of viral, fungal and bacterial pathogens in adults.

4.2 Posology and method of administration
Adults:
One to two drops instilled into the conjunctival sac two to four times daily. 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.

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Paediatric population
The safety and efficacy in paediatric population have not yet been established.
No posology can be recommended.

Method of administration
Route of administration is by ocular instillation.
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.
Shake well before use.

4.3 Contraindications
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.

4.4 Special warnings and precautions for use

Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids. It contains no antimicrobial agent. 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.

Fungal infections of the cornea have been reported coincidentally with long-term steroid application and fungal invasion may be suspected in any persistent corneal ulceration where a steroid has been used, or is in use.
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.

The preservative, benzalkonium chloride, may be absorbed by and cause discoloration of soft contact lenses. Patients wearing soft contact lenses should be instructed to remove contact lenses prior to administration of the solution and wait at least 15 minutes after instilling before reinserting soft contact lenses.
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. This may result in glaucoma with damage to the optic nerve with resultant defects in visual acuity and visual fields. Steroids should be used with caution in the presence of glaucoma. It is advisable that intraocular pressure be checked frequently during treatment.

Eye drops containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for intraocular pressure.

Posterior subscapular cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids.
The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.
Systemic adverse events may occur with extensive use of topical steroids; punctual occlusion may be recommended.

The possibility of adrenal suppression should be considered with prolonged, frequent, use of high dose topical steroids, particularly in infants and children.
To prevent eye injury or contamination, care should be taken to avoid touching the bottle tip to the eye or to any other surface.

<u>Visual disturbance</u>
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised.

4.5 Interaction with other medicinal product and other forms of interaction

None known.

Co-treatment with CYP3A inhibitors, including 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.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

There is inadequate evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such defects in the human foetus. Therefore this product should be used with caution during pregnancy only if the potential benefit outweighs the potential risk to the foetus.

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.

4.7 Effects on ability to drive and use machines

Prednisolone Acetate Ophthalmic Suspension may cause short-lasting blurring of vision upon instillation. If affected, the patient should not use machinery/electric tools or drive until vision has returned to normal.

4.8 Undesirable effects

The following undesirable effects have been reported following its use.

Frequency categories: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from available data).

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	Pruritis, Rash

4.9 Overdose

There is no clinical experience of overdosage. Acute overdosage is unlikely to occur via the ophthalmic route.

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: corticosteroids, ATC code: S01BA04.

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.

5.2 Pharmacokinetic Properties

Prednisolone acetate has been shown 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.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies on the acute toxic potential of Prednisolone Acetate Ophthalmic Suspension.

6.0 Pharmaceutical particulars

6.1 List of Excipients

Benzalkonium chloride Solution USP, Boric acid USP, Sodium citrate USP, Polysorbate-80 USP, Sodium meta bisulphite USP, Disodium Edetate (EDTA)

USP, Glycerin USP, PVPK 30 (Povidone) USP, Hypromellose USP, Hydrochloric acid USP, Water for Injection USP.

6.2 Incompatibilities

None known

6.3 Shelf life

24 months from the date of manufacturing.
Use the suspension within one month after opening the vial.

6.4 Special precautions for storage

Store below 30ºC. Protect from light. Do not refrigerate or freeze.

6.5 Nature and contents of container

1x10 ml LDPE vial packed in unit carton along with pack insert.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Tighten the cap on the nozzle as shown.
The spike in the cap will pierce the tip of the vial.
Dispense drops with gentle pressure.
Replace the cap after every use.
Keep out of reach of children.
Shake well before use.

7. Marketing Authorization Holder

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8. Marketing Authorization Number(s)

TAN 22 HM 0364

9. Date of first authorization/renewal of the authorization

21/09/2022

10. Date of revision of the text

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