EVSUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
Hydrocortisone acetate 1 % w/v ophthalmic suspension
Hydrolin

2. Qualitative and quantitative composition
Each mL of suspension contains 10 mg of hydrocortisone acetate.

Excipient with known effect
Each mL of suspension **also** contains 0.1 mg of benzalkonium chloride (see section 4.4).

For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Suspension.

White to off-white suspension.

4. Clinical particulars

4.1 Therapeutic indications
Hydrocortisone is indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of corticosteroid use in certain infective conjunctivitis is accepted to obtain a diminution in oedema and inflammation. It is also indicated in chronic anterior uveitis and corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies.

4.2 Posology and method of administration

Posology
Shake the suspension well prior to use. Avoid contamination of the preparation container. Depending on the severity of the condition, instil 1 or 2 drops into the affected eye(s) every 3–4 hours, or more frequently, as necessary. The usual duration of treatment is as directed by the physician.

Method of administration
Topical use. Apply topically to the eye(s) as an ophthalmic suspension.

4.3 Contraindications
Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, eyelid, fingers, or any other surface.

The use of hydrocortisone acetate by more than one person may spread infection.
Patients should also be instructed that ocular products if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated products.

Hydrocortisone acetate should never be directly introduced into the anterior chamber of the eye.

Prolonged use of corticosteroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. Prolonged use may suppress the host's immune response.

Corticosteroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently.

Corticosteroids after cataract surgery may delay healing and increase the incidence of filtering blebs.

Use of the ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Great caution is required in the treatment of herpes simplex with corticosteroid medication, frequent slit lamp microscopy is recommended.

Excipients
This medicine contains **benzalkonium chloride**. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been studied. Precaution should be taken when hydrocortisone acetate is used with other ophthalmic preparations.

4.6 Fertility, pregnancy and breastfeeding

Pregnancy
There is inadequate evidence of safety in human pregnancy. Hydrocortisone acetate ophthalmic Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

4.7 Effects on the ability to drive and use machines
The medication has no or negligible influence on the ability to drive or use machinery. Temporarily blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs, the patient must wait until the vision is clear before driving or using machines.

4.8 Undesirable effects
The reactions due to the corticosteroid in decreasing order of frequency are elevation of intraocular pressure (IOP) with possible development of glaucoma, infrequent optic nerve damage, posterior subcapsular cataract formation and delayed wound healing.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Adverse Drug Reaction (ADR)/ Serious Adverse Event (SAE) electronic form linked to the MCAZ database using the following link: https://primaryreporting.who-umc.org/ZW.

4.9 Overdose
No instance of toxic overdose has been observed with hydrocortisone acetate.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacological classification: 19.2 Ophthalmic medicines: Corticosteroids.

Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to a reduction in the vascular component of the inflammatory response, suppression of migration of polymorphonuclear leukocytes, and reversal of increased capillary permeability. The vasoconstrictor action of hydrocortisone may also contribute to its anti-inflammatory activity.

5.2 Pharmacokinetic properties
It is rapidly absorbed following topical administration, metabolised in the liver and most body tissues before being excreted in the urine. Biological half-life is approximately 100 minutes and it is 90% bound to plasma protein. Hydrocortisone is absorbed through the skin, particularly in denuded areas.

5.3 Preclinical safety data
Prolonged repeated administration of hydrocortisone via the systemic route in animals reduced body weight gain and increased neoglucogenesis and hyperglycaemia, thymolysis and ocular hypertension.

6. Pharmaceutical particulars

6.1 List of excipients
Disodium edetate
Sodium metabisulfite
Glycerol
Polysorbate
Benzalkonium chloride
Purified water
Boric acid
Water injection

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months.

6.4 Special precautions for storage
Store below 30°C.

6.5 Nature and contents of the container
The suspension is packed in a sterile non-transparent LDPE bottle with a separate open transparent LDPE nozzle and a polystyrene spiked cap.

Fill volume: 10 ml.
Pack size: 1 bottle per carton.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT
Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal.-Kalol
Dist.- Gandhinagar, Gujarat State
India

8. MANUFACTURER
Lincoln Pharmaceuticals Limited
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9. REGISTRATION DETAILS
Zimbabwe registration number: 2024/19.2.1/6579
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