

## Summary of Product Characteristics

Name of the medicinal Product

Hydrocortisone Acetate Ophthalmic Suspension

**1. Qualitative and Quantitative Composition**

**1.1. Qualitative declaration**

Hydrocortisone Acetate USP

**1.2. Quantitative declaration**

<b>Sr. No</b>	<b>Ingredients</b>	<b>Standard Quantity (% w/v)</b>
01	Hydrocortisone Acetate (Micronized & Sterile	2.000

**2. Pharmaceutical Form**

Eye Drops

A white to off white coloured suspension

### **3. Clinical Particulars**

#### **3.1. Therapeutic Indications**

Ocular corticosteroids are 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 edema and inflammation. It is also indicated in chronic anterior uveitis and corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies.

#### **3.2. Posology and Method of Administration**

Apply topically to the eye(s) as an ophthalmic suspension. Not for injection in to eye. Shake suspension well prior to use. Avoid contamination of the preparation container. For Topical administration to the eye only. Depending on the severity of condition,

Hydrocortisone acetate ophthalmic Suspension Instill 1 or 2 drops into affected eye(s) every 3-4 hours, or more frequently, as necessary. Usual duration of treatment is as directed by physician.

#### **3.3. Contraindications**

In patients with known hypersensitivity to hydrocortisone acetate or any of the excipients.

#### **3.4. Special Warnings and Special 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 ophthalmic Suspension 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 ophthalmic Suspension 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 in posterior subcapsular cataract formation. Prolonged use may suppress the host 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 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.

### **3.5. Interaction with other medicinal products and other forms of interaction**

Precaution should be taken when hydrocortisone acetate ophthalmic Suspension used with other topical ophthalmic preparations.

### **3.6. Fertility, Pregnancy and Lactation**

Pregnancy and Lactation: Hydrocortisone acetate ophthalmic Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

### **3.7. Effects on ability To Drive and use Machines**

No Known

### **3.8. Undesirable Effects**

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

### **3.9. Overdose**

No instance of toxic overdose has been observed with Hydrocortisone Acetate Ophthalmic Suspension.

## **4. Pharmacological Properties**

### **4.1. Pharmacodynamics Properties**

Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to 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.

#### **4.2. Pharmacokinetic Properties**

It is rapidly absorbed following topical administration, metabolised in 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.

#### **4.3. Preclinical Safety Data**

Not Known

### **5. Pharmaceutical Particulars**

#### **5.1. List of Excipients**

Boric Acid BP (AR Grade)

Disodium Edetate BP

Sodium Metabisulfite BP

Glycerol BP (Glycerin)

Polysorbate-80 BP (Tween-80)

Benzalkonium Chloride Solution BP

Sodium Citrate BP

Water for injection BP

#### **5.2. Incompatibilities**

Not applicable.

#### **5.3. Shelf Life**

24 months

Use the solution within 28 days after opening the container.

#### **5.4. Special Precautions for Storage**

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

#### **5.5. Nature and Contents of Container**

A white to off white coloured suspension is filled in 10 ml Non sterile Dropper Bottle.

Such 1 Dropper Bottle is packed in Printed Carton with Packing Insert.

**5.6. Special precaution for disposal and other handling**

Any unused product or waste material should be disposed of in accordance with local requirements.

**6. Marketing Authorization Holder And Manufacturing Site Addresses**

**6.1. Name and Address of Marketing Authorization Holder**

Lincoln Pharmaceuticals Limited  
Trimul Estate, Khatraj, Tal. Kalol,  
Dist. Gandhinagar,  
Gujarat, India.  
Phone: +91-02764-665000, 305000  
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Email: [khatraj@lincolnpharma.com](mailto:khatraj@lincolnpharma.com)  
Website: [www.lincolnpharma.com](http://www.lincolnpharma.com)

**6.2. Name and Address of manufacturing site(s)**

Lincoln Parenteral Limited  
11, Trimul Estate, Khatraj, Taluka: Kalol,  
District: Gandhinagar Gujarat, India.  
Telephone no.: +91-02764-665000  
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Email: [khatraj@lincolnpharma.com](mailto:khatraj@lincolnpharma.com)  
Website: [www.lincolnpharma.com](http://www.lincolnpharma.com)

**7. Marketing Authorization Number**

TAN 22 HM 0287

**8. Date of First <Registration> / Renewal of The <Registration>**

19<sup>th</sup> July, 2022

**9. Date of Revision of the Text**

