

1.6.1

Prescribing Information (Summary of Product Characteristics)

Module-1 Administrative Information and Product Information

1.6.1.1 Name of the medicinal Product

Dexamethasone Sodium Phosphate Ophthalmic Solution USP 0.1% w/v

1.6.1.1.1 strength

0.1 % w/v

1.6.1.1.2 Pharmaceutical Form

Ophthalmic Drops

1.6.1.2 Qualitative and Quantitative Composition

1.6.1.2.1 Qualitative declaration

Dexamethasone Sodium Phosphate USP

1.6.1.2.2 Quantitative declaration

Sr. No.	Ingredients Chemical Name	Specification	Standard Quantity (w/v)	Reason for Inclusion
01	Dexamethasone Sodium Phosphate Eq.to Dexamethasone Phosphate (A)	USP	0.11 % Eq. to 0.1 %	Glucocorticoid
02	Disodium Edetate	BP	0.100 %	Chelating Agent
03	Sodium Dihydrogen Phosphate Dihydrate	BP	0.300 %	Buffering Agent
04	Anhydrous Disodium Hydrogen Phosphate	BP	3.200 %	Buffering Agent
05	Sodium Metabisulphite	BP	0.500 %	Antioxidant
06.	Creatinine	USP-NF	0.200 %	Stabilizer
07	Benzalkonium Chloride Solution	BP	0.02 %	Preservative
08	Water for Injection	BP	Q.S.	Vehicle

1.6.1.3 Pharmaceutical Form

Ophthalmic Drops

Clear Colourless solution.

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1.6.1.4 Clinical Particulars**1.6.1.4.1 Therapeutic Indications**

Vernal conjunctivitis, allergic blepharitis and conjunctivitis, nonspecific keratitis, superficial punctate keratitis, disciform keratitis (provided the corneal surface is intact). Affect ion of the anterior uvea, such as acute or chronic iritis and iridocyclitis (with exception of tuberculous forms), scleritis and episcleritis, sympathetic ophthalmia.

1.6.1.4.2 Posology and Method of Administration

Eye: Instil one or two drops of solution into the conjunctival sac every hour during the day and every two hours during the night as initial therapy. When a favorable response is observed, reduce dosage to one drop every four hours. Later, further reduction in dosage to one drop three or four times daily may suffice to control symptoms.

Ear: Instil 3-4 drops into the aural canal 2-3 times a day; reduce dose gradually once a favorable response is obtained. Alternately, may pack the aural canal with a gauze wick saturated with the solution; remove from the ear after 12-24 hours. Repeat as necessary.

Method of Administration: Ophthalmic Administration

1.6.1.4.3 Contraindications

Injuries and ulcerations of the cornea, in particular those of bacterial or viral origin (herpes simplex and herpes zoster), purulent infections of the conjunctiva and eyelids, tuberculosis, mycoses and glaucoma.

1.6.1.4.4 Special Warnings and Special Precautions for Use

As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations cannot be excluded, regular ophthalmological examination is required.

Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an ex tended period in patients with extensive ocular surface disease.

1.6.1.4.5 Interaction with other medicinal products and other forms of interaction

There are no known significant interactions.

1.6.1.4.6 Fertility, Pregnancy and Lactation

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Pregnancy: Pregnancy Category C. There are no adequate or well-controlled studies in pregnant women. Studies in animals have shown that topically applied steroids can be absorbed systemically and can cause abnormalities of foetal development in pregnant animals. Although the relevance of these findings to human beings has not been established, the use Dexamethasone Sodium Phosphate ophthalmic solution during pregnancy should be avoided.

Lactation: It is not known whether dexamethasone is excreted in human milk; caution should be exercised when Dexamethasone Sodium Phosphate ophthalmic solution is administered to a nursing woman.

1.6.1.4.7 Effects on ability To Drive and use Machines

Not Applicable

1.6.1.4.8 Undesirable Effects

The local use of dexamethasone over a prolonged period may lead in some cases to secondary glaucoma and the development of complicated cataract. To be used, therefore, under strict medical supervision.

1.6.1.4.9 Overdose

If a rise of intraocular pressure occurs, the treatment has to be discontinued.

1.6.1.5 Pharmacological Properties

Dexamethasone is one of the most potent corticosteroids; it is 5-14 times more potent than prednisolone and 25 - 75 times more potent than cortisone and hydrocortisone of paramount importance with regard to local therapy is the fact that Dexamethasone is over 2000 times more soluble than hydrocortisone or prednisolone.

1.6.1.5.1 Preclinical Safety Data

Not Applicable.

1.6.1.6 Pharmaceutical Particulars

1.6.1.6.1 List of Excipients

Disodium Edetate BP

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Sodium Dihydrogen Phosphate Dihydrate BP

Anhydrous Disodium Hydrogen Phosphate BP

Sodium Metabisulphite BP

Creatinine USP-NF

Benzalkonium Chloride Solution BP

Water for injection BP

1.6.1.6.2 Incompatibilities

Not applicable.

1.6.1.6.3 Shelf Life

36 months

1.6.1.6.4 Special Precautions for Storage

Store below 30°C. Protect from light. Do not freeze.

1.6.1.6.5 Nature and Contents of Container

A clear colourless solution filled in 10 ml Plastic Dropper Bottle. Such 1 labelled Bottle is packed in Printed carton with Packing Insert.

1.6.1.6.6 Special precaution for disposal and other handling

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

Use the solution within 28 days after opening of the container.

Keep the medicine out of reach of children.

Not for injection.

External use only.

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.



Module-1 Administrative Information and Product Information

Fax: +91-79-41078062

Email:

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ncolnphar

ma.com

Website:

www.linc

olnpharm

a.com

1.6.1.7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited

11, Trimul Estate,

Khatraj, Taluka:

Kalol, District:

Gandhinagar

Gujarat, India.

Telephone no.: +91-79-41078096

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ncolnphar

ma.com

Website:

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olnpharm

a.com

1.6.1.8 Marketing Authorization Number

To be included after obtaining first registration.

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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

1.6.1.11 Dosimetry (If Applicable)

Not Applicable

1.6.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)