1. Name of the medicinal Product

Betamethasone sodium phosphate and Neomycin sulfate eye drops- BETA-N

2. Qualitative and Quantitative Composition

Qualitative declaration

Betamethasone sodium phosphate BP and Neomycin sulfate USP

Quantitative declaration

Excipients with known effect

Benzalkonium chloride solution 0.04% v/v

Sodium Dihydrogen Phosphate Dihydrate 0.15% w/v

For full list of Excipients, see section 6.1.

3. Pharmaceutical Form

Ophthalmic solution

Distribution category POM

A clear colourless to pale yellow colour solution.

4. Clinical Particulars

1. Therapeutic Indications

Betamethasone sodium Phosphate and Neomycin Sulfate Eye Drops is indicated for the short- term treatment of steroid responsive inflammatory conditions of the eye when prophylactic antibiotic treatment is also required, after excluding the presence of viral and fungal disease.

2. ***Posology and Method of Administration***

For topical ophthalmic use only. Not for injection

The frequency of dosing depends on the clinical response. If there is no clinical response within 7 days of treatment, the drops should be discontinued.

In adults & children, 1 or 2 drops applied to each affected eye up to six times daily up to 7 days depending on clinical response. If there is no clinical response within 7 days of treatment, the drops should be discontinued. Treatment should be the lowest effective dose for the shortest possible time.

Normally, it should not be given for more than 7 days, unless under expert supervision. After more prolonged treatment (over 6 to 8 weeks), the drops should be withdrawn slowly to avoid relapse.

3. Contraindications

In patient with history of hypersensitivity to betamethasone, neomycin or any excipient of the preparation.

Bacterial, viral, fungal, tuberculous or purulent conditions of the eye. Use is contra indicated if glaucoma is present, or where herpetic keratitis (e.g. dendritic ulcer) is considered a possibility. Use of topical steroids in the latter condition can lead to an extension of the ulcer and marked visual deterioration.

4. Special warnings and precautions for use

Topical corticosteroids should never be given for an undiagnosed red eye as inappropriate use is potentially blinding. Long-term intensive topical use may lead to systemic effects.

If there is no clinical response within 7 days of treatment, the drops should be discontinued.

Prolonged use may lead to the risk of adrenal suppression in infants.

Treatment with corticosteroid preparations should not be repeated or prolonged without regular review to exclude raised intraocular pressure, cataract formation or unsuspected infections.

High dose topical aminoglycoside antibiotics treatment to small children or infants may cause irreversible, partial or total deafness when given systemically or when applied topically to open wounds or damaged skin. This effect is dose related and is enhanced by renal or hepatic impairment.

Pregnancy and lactation

Safety for use in pregnancy and lactation has not been established. However, neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal ototoxicity, thus use of it is not recommended in pregnancy or lactation. It should only be used when considered essential by physician and only if the anticipated benefit outweighs the potential risk.

Excipients with specified warning

This medicine contains 0.04% v/v benzalkonium chloride in each dose. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Contact lenses should be removed before using this medicine and reinserted 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially in patients with dry eyes or disorders of the cornea. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

This medicine contains 0.15% w/v phosphates in each dose. In patients suffering from severe damage to the cornea, phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

5. Interaction with other medicinal products and other forms of interaction

Betamethasone & Neomycin Eye Drops contain benzalkonium chloride as a preservative, therefore should not be used to treat patients who wear soft contact lenses. 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.

6. Pregnancy and Lactation

Safety for use in pregnancy and lactation has not been established. However, neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal ototoxicity, thus use of it is not recommended in pregnancy or lactation. It should only be used when considered essential by physician and only if the anticipated benefit outweighs the potential risk.

7. ***Effects on ability to Drive and use Machines***

May cause transient blurring of vision on instillation. Patients should be warned not to drive or operate hazardous machinery unless vision is clear.

8. Undesirable effect

Delayed type Hypersensitivity reactions, usually of the delayed type, may occur leading to irritation, burning, stinging, itching and dermatitis.

Topical corticosteroid use may result in corneal ulceration, increased intraocular pressure leading to optic nerve damage, reduced visual acuity and visual field defects. Intensive or prolonged use of topical corticosteroids may lead to formation of posterior subcapsular cataracts.

In those diseases causing thinning of the cornea or sclera, corticosteroid therapy may result in thinning of the globe leading to perforation.

Mydriasis, ptosis, epithelial punctate keratitis and glaucoma have also been reported following ophthalmic use of corticosteroids. Very rarely, corneal calcification with use of phosphate containing eye drops. Very rarely may happen (corneal calcification) in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

Neomycin occasionally causes skin sensitization.

9. Overdose

Long-term intensive topical use may lead to systemic effects.

Treatment with higher than recommended doses may result in significant adrenal suppression. If there is evidence of hire commended doses being used, then additional systemic corticoste should be considered during periods of stress or elective surgery.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Pharmacotherapeutic Group: Ophthalmological, Corticosteroids and Antiinfective in combination, Betamethasone and anti- infective, ATC Code: S03CA06

Betamethasone is a glucocorticoid and it is a synthetic analog of prednisolone which is more Potent (five to seven fold) greater systemic anti-inflammatory activity than prednisolone. Glucocorticoid which has topical anti-inflammatory activity. It Stabilizes lysosomal neutrophils and prevents their degranulation, inhibits synthesis of lipoxygenase products and prostaglandins, activates anti-inflammatory genes, and inhibits various cytokines.

The presence of neomycin should prevent the development of bacterial infection. It interferes with bacterial protein synthesis by binding to 30S ribosomal subunit, causing misreading of genetic code. Inaccurate peptide sequence then forms in protein chain, causing bacterial death.

5.2 Pharmacokinetic Properties

Betamethasone sodium phosphate: Based on data of penetration of topically applied betamethasone sodium phosphate into human aqueous humor. Absorption of topically applied betamethasone sodium phosphate into the aqueous humour of human subjects undergoing routine intraocular surgery was greatest in the interval 91-120 minutes following topical administration (mean peak concentration = 7.7 ng/ml). At twelve hours post instillation the mean concentration of Betamethasone was 2.5 ng/ml and detectable levels were recorded in the aqueous humour 24 hours after application (mean concentration 0.4 ng/ml).

Neomycin sulfate: Absorption through skin is limited. Topical application of neomycin in petrolatum does not result in detectable drug concentrations in either serum or urine.

5.3 Preclinical Safety Data

Non stated.

6. Pharmaceutical Particulars

6.1 List of Excipients

Macrogols (Polyethylene Glycol 400)
Disodium Edetate (Inj.)
Sodium Formate
Sodium Dihydrogen Phosphate Dihydrate
Anhydrous Disodium Hydrogen Phosphate
Anhydrous Sodium Sulfate
Benzalkonium chloride solution
Sodium Hydroxide
Phosphoric Acid
Water for injections

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 Months

Use the solution within 28 days after opening the container.

6.4 Special Precautions for Storage

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

6.5 Nature and contents of container

A clear colourless to pale yellow colour solution filled in 10 ml non-transparent plastic dropper bottle with white cap. Such a bottle packed in printed carton with package insert.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal. Kalol,
Dist. Gandhinagar,
Gujarat, India.
Phone: +91-079-49135000
Email: khatraj@lincolnpharma.com
Website: www.lincolnpharma.com

7.2 Name and Address of Manufacturing Site(s)

Lincoln Parenteral Limited
11, Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
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Email: khatraj@lincolnpharma.com
Website: www.lincolnpharma.com

8 Marketing Authorization Number

TAN 22 HM 0179

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

04th May, 2022

10 Date of Revision of the Text