ASHFORD LABORATORIES LIMITED

SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product:

1.1 Product Name : DEXOPTIC-N Eye Drops
(Dexamethasone Sodium Phosphate and Neomycin Sulfate Ophthalmic Solution USP)

1.2 Strength: Neomycin Sulfate 0.5%, Dexamethasone Sodium Phosphate 0.1%

1.3 Pharmaceutical Dosage Form: Ophthalmic Solution (Eye Drops)

2-Quality and Quantitative Composition:

Each mL contains: Neomycin Sulfate ……. 5 mg
Dexamethasone Sodium Phosphate… 1 mg

3-Pharmaceutical Form: Ophthalmic solution (Eye Drops)

4-Clinical Particulars:

4.1 Therapeutic indications:

Used in many disorders of the anterior segment of the eye due to or complicated by infection, as in vernal, allergic and non-purulent conjunctivitis; keratitis of different forms; iritis, cyclitis; and in superficial and chemical burns of the cornea.

4.2 Posology and method of administration:

Instill 1 to 2 drops topically in the conjunctival sac every hour during the day and every two hours at night. When improvements occur, the dosage may be reduced to one drop 3-4 times daily.

4.3 Contraindications:

Dexoptic-N Eye Drops is contraindicated in tuberculous, fungal and most viral lesions of the eyes. Also in those patients who have shown hypersensitivity to any of its components.

4.4 Special warning and precautions for use

Prolonged use may result in posterior sub capsular cataract formation and glaucoma with optic nerve damage. Monitor intraocular pressure. Perforation has been known to occur in patients with diseases causing thinning of the cornea. Safety in intensive or prolonged use of topical steroids during pregnancy has not been substantiated. Extensive use may lead to systemic side effects.

4.5 Interaction with other medicinal products and other forms of interactions.

No drug interaction or incompatibility has been known.

4.6 Pregnancy and Lactation

None known

4.7 Effects of the ability to drive and use machines

None known

4.8 Undesirable Effects

Neomycin is a common cutaneous sensitiser. Articles in the current literature indicate an increase in the prevalence of persons allergic to neomycin. Cease usage if adverse reactions persist and consult your doctor.

4.9 Overdose and special antidotes

None known

5-Pharmacological Properties:

Neomycin in DEXOPTIC-N is a topical antibiotic used topically in the treatment of infections of the skin, ear, and eye due to susceptible staphylococci and other organisms.

Neomycin is often used topically in combination with another antibacterial agent such as bacitracin, colistin, gramicidin, or polymyxin B. Such combination have been used topically in the eye in the treatment of acanthamoeba keratitis and before ophthalmic surgery for infection prophylaxis.

Ref.: Martindale 31st edition, p. 254

CORTICOSTEROID PORTION OF DEXOPTIC-N

Dexamethasone in DEXOPTIC-N is absorbed from sites of local application which are the conjunctival sacs. When treatment is prolonged, the absorption may be sufficient to cause systemic effects including adrenocortical suppression.

The corticosteroid in DEXOPTIC-N acts by inhibition of inflammatory responses to inciting agents of mechanical, chemical or immunological nature.

Inflammation is caused by interaction of an antigen with surface anti-bodies on B cells from which cell-mediated immunity begins by the ingestion and processing of the antigen by the macrophages. The activated macrophages secrete interleukin-1 (IL-1) and tumor necrosis factor (TNF) and display the processed antigen on the cell surface together with a major histocompatibility

antigen. Both TNF and IL-1 initiate a number of processes involved in inflammation. Dexamethasone in DEXOPTIC-N cure inflammation by exerting its inhibitory effects with the release of TNF and IL-1 from the macrophages and on the release of their by-products from the activated T cells. Stubborn cases of anterior segment eye diseases may require therapy with systemic corticosteroid.

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For ophthalmic disorders or for topical application in the treatment of various skin disorders, either dexamethasone or its esters may be employed; concentrations are often expressed in terms of dexamethasone or dexamethasone phosphate and are commonly 0.5% to 0.1% for eye or ear drops and ointments and 0.1%for topical skin preparations.

Ref. Martindale 33rd edition, p. 1068

6-Pharmaceutical Particulars:

6.1 List of excipients

1. Sodium Borate NF
2. Disodium Edetate USP
3. Sodium Citrate USP
4. Sodium Metabisulfite NF
5. Creatinine USP
6. Polysorbate 80 NF
7. Phenylmercuric Nitrate NF
8. Purified Water USP

6.2 Incompatibilities: None

6.3 Shelf life:

a.) As packages for sale: **3 years**

b.) After first opening: **Discard 4 weeks from opening**

6.4 Special precautions for storage: Store at temperature 20°C – 25°C.

6.5 Nature and contents of container:

10 mL, packed in LDPE white bottle and clear plug with HDPE white cap

7-Marketing Authorization Holder : **Linkabs Pharmaceuticals Ltd.**

8-Marketing Authorization Numbers : **04-3469**

9-Date of first authorization/renewal of the authorization : **10 September 2019**

10-Date of revision of the text : --