1. Name of the Medicinal Product

1.1 Name of the Medicinal Product

Beta-N

(Betamethasone sodium phosphate and neomycin sulphate Eye/Ear Drops)

1.2. Strength

Betamethasone sodium phosphate	BP	0.1% w/v
Neomycin Sulphate	BP	0.5% w/v

1.3. Pharmaceutical Dosage Form

Ophthalmic Preparation

2. Qualitative And Quantitative Composition

Qualitative Declaration

The Beta-N Eye drop contains (Betamethasone sodium phosphate and neomycin sulphate eye/ear drops)

Quantitative Declaration

Composition:

Betamethasone Sodium Phosphate	BP	0.1%w/v
Neomycin Sulphate BP	BP	0.5% w/v

3. Pharmaceutical Form

Eye/Ear Drops

4. Clinical Particulars

4.1 Therapeutic Indications

Eye

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.

Ear

Otitis externa or other steroid responsive conditions where prophylactic antibiotic treatment is also required.

4.2 Posology and Method of Administration

Posology

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.

Treatment should be the lowest effective dose for the shortest possible time. Normally, Beta-N Drops 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 After more prolonged treatment (over 6 to 8 weeks), the drops should be withdrawn slowly to avoid relapse.

Eyes

1 or 2 drops applied to each affected eye up to six times daily depending on clinical response.

Ears

2 or 3 drops instilled into the ear three or four times daily.

4.3 Contraindications

Viral, fungal, tuberculous or purulent conditions of the eye. Fungal infections of the ear. Use is contra-indicated if glaucoma is present or 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.

Otitis externa should not be treated when the eardrum is perforated because of the risk of ototoxicity.

Corticosteroids should not be used in patients with a perforated tympanic membrane.

Hypersensitivity to any component of the preparation.

4.4 Special Warning and Precautions for Use

A patient information leaflet should be supplied with this product.

Topical corticosteroids should never be given for an undiagnosed red eye as inappropriate use is potentially blinding.

Treatment with corticosteroid/antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement, since prolonged use may lead to occult extension of infection due to the masking effect of the steroid. Prolonged use may also lead to skin sensitisation and the emergence of resistant organisms.

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

Aminoglycoside antibiotics 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. Although this effect has not been

reported following topical ocular use, the possibility should be considered when high dose topical treatment is given to small children or infants.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serious chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Beta-N Drops contain phenyl mercuric nitrate as a preservative and therefore should not be used as eye drops 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.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

There is a risk of foetal ototoxicity if aminoglycoside antibiotic preparations are administered during pregnancy.

4.7 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.

4.8 Undesirable Effects

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.

Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

4.9 Overdose

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

Oral ingestion of the contents of one bottle (up to 10ml) is unlikely to lead to any serious adverse effects.

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

5.0 Pharmacological Properties

5.1 Pharmacodynamic properties

Betamethasone sodium phosphate has topical corticosteroid activity. The presence of neomycin sulphate should prevent the development of bacterial infection.

5.2 Pharmacokinetic properties

Betamethasone sodium phosphate and neomycin sulphate is found in measurable amounts in the aqueous humour following local application to the eye.

5.3 Preclinical Safety Data

None stated.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

- Anhydrous disodium hydrogen phosphate BP
- Phenyl mercuric nitrate BP
- Sodium chloride BP
- Sodium metabisulphite BP
- Sodium dihydrogen orthophosphate BP
- Polyethylene glycol BP
- Water for injections BP

6.2 Incompatibilities

None Known.

6.3 Shelf Life

Unopened:	36 Months
Opened	Within 1 month

6.4 Special Precautions for Storage

Store in a dark place at a temperature not exceeding 25ºc.

Content sterile until seal is broken.

Keep all medicines out of the reach of children.

6.5 Nature and Contents of Container

BETA-N (Betamethasone sodium phosphate and neomycin sulphate eye/ear drops) are available in 10ml dropper bottles.

6.6 Special Precautions for Disposal and Other Handling

None stated.

7. Registrant/Sole Agent

EMBASSY PHARMACEUTICAL & CHEMICAL LTD.

41, Ademola Street, South West Ikoyi,

Lagos, Nigeria. Tel.: 01-2900791

8. Manufacturer

LABORATE PHARMACEUTICALS INDIA LIMITED

51, Industrial area, Gondpur, Paonta Sahib, H.P. (INDIA)

HO: E-11, Industrial Area, Panipat – 132 103.

9. Date of Revision of Text

To be given after approval of product

10. Dosimetry (If applicable)

Not applicable

11. Instructions for Preparation of Radiopharmaceuticals (If applicable)

Not applicable