



Shampur-Kadamtali I/A, Dhaka-120

**Product Name: Aristobet-N Eye Ointment**

(Betamethasone Sodium Phosphate & Neomycin Sulphate Eye Ointment, 0.1%/0.5% w/w)

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. Name of The Medicinal Product

**Aristobet-N Eye Ointment**

### 2. Qualitative and Quantitative Composition

Each g contains Betamethasone sodium phosphate 0.1% and Neomycin sulphate 0.5%.  
Preservative: Methylparaben, Propylparaben  
For a full list of excipients, mention in section 6.1.

### 3. Pharmaceutical Form

Eye Ointment

A very light yellow semi- solid greasy mass (Ointment) free from any visible extraneous matter.

### 4. Clinical Particulars

#### 4.1 Therapeutic indications

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.

#### 4.2 Posology and method of administration

Aristobet-N Eye Ointment should be applied thinly and evenly to the conjunctival sac at night (If eye drops used during day) or 3-4 times daily (if ointment used alone).

#### Method of Administration

For ophthalmic use only.

#### 4.3 Contraindications

Hypersensitivity to any of the preparations components. Viral, fungal, tuberculous or purulent conditions of the eye. Use is contraindicated if Glaucoma is present or Herpetic keratitis (e.g. dendritic ulcer), is considered a possibility. Use of topical steroids in this condition can lead to extension of the ulcer and marked visual deterioration. Otitis externa should not be treated when the eardrum is perforated due to the risk of ototoxicity.

Primary cutaneous viral infections. Hypersensitivity to the preparations.

**Product Name: Aristobet-N Eye Ointment**

(Betamethasone Sodium Phosphate & Neomycin Sulphate Eye Ointment, 0.1%/0.5% w/w)

**4.4 Special warnings and precautions for use****Betamethasone Sodium Phosphate**

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

Prolonged use may lead to the risk of adrenal suppression in infants. Ophthalmological treatment with corticosteroid preparations should not be repeated or prolonged without regular review to exclude raised intraocular pressure, cataract formation or unsuspected infections.

**Neomycin:**

Aminoglycosides such as neomycin can cause irreversible ototoxicity; and neomycin has nephrotoxic potential. In renal impairment, the plasma clearance of neomycin is reduced.

**4.5 Interaction with other medicinal products and other forms of interaction****Betamethasone Sodium Phosphate**

No interaction studies have been performed.

**Neomycin:**

Neomycin sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents following systemic absorption. However, if used in accordance with the recommendations systemic exposure to neomycin sulphate is expected to be minimal and drug interactions are unlikely to be significant.

**4.6 Fertility, pregnancy and lactation****Betamethasone Sodium Phosphate**

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 abnormal foetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such defects in the human foetus.

**Neomycin:**

There is little information to demonstrate the possible effect of topically applied neomycin in pregnancy and lactation. However, neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus the use of neomycin Ointment is not recommended in pregnancy and lactation.



Shampur-Kadamtali I/A, Dhaka-120

**Product Name: Aristobet-N Eye Ointment**

(Betamethasone Sodium Phosphate & Neomycin Sulphate Eye Ointment, 0.1%/0.5% w/w)

**4.7 Effects on ability to drive and use machines**

**Betamethasone Sodium Phosphate**

May cause transient blurring of vision on instillation into the eye.

Warn patient not drive or operate hazardous machinery unless vision is clear.

**Neomycin:**

Ointment is not expected to have any effect.

**4.8 Undesirable effects**

**Betamethasone Sodium Phosphate**

Gastrointestinal disorders

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

Use of topical steroids may result in 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 the 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.

**Neomycin :**

Exacerbation of symptoms may occur.

**4.9 Overdose**

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

**Product Name: Aristobet-N Eye Ointment**

(Betamethasone Sodium Phosphate &amp; Neomycin Sulphate Eye Ointment, 0.1%/0.5% w/w)

**5. Pharmacological Properties****5.1 Pharmacodynamic Properties**

Betamethasone Sodium Phosphate has a corticosteroid activity. The presence of neomycin should prevent the development of bacterial infection.

**5.2 Pharmacokinetic Properties**

No data available.

**5.3 Preclinical safety data**

None stated

**6. Pharmaceutical Particulars****6.1 List of excipients**

- Anhydrous Lanolin
- Liquid Parafin
- Methylparaben
- Propylparaben
- White Petroleum Jelly

**6.2 Incompatibilities**

None known.

**6.3 Shelf life**

3 years

**6.4 Special precautions for storage**

- Store below 30°C
- Protect from light
- Keep out of reach of children



Shampur-Kadamtali I/A, Dhaka-120

**Product Name: Aristobet-N Eye Ointment**

(Betamethasone Sodium Phosphate & Neomycin Sulphate Eye Ointment, 0.1%/0.5% w/w)

**6.5 Nature and contents of container**

Aluminium collapsible tube and Cap. Carton containing 1 tube with a package insert.

**6.6 Special precautions for disposal and other handling**

No special instructions.

**7. Marketing Authorisation Holder**

Name : Aristopharma Limited.  
Physical Address : Plot # 14 -22, Road # 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204,  
Bangladesh  
Telephone number : +880-2-9351691-93  
Fax number : +880-2-8317005  
e-mail : parvez@aristopharmabd.com

**8. Marketing Authorisation Number**

**Aristobet-N Eye Ointment:** 143-173-052

**9. Date of First Authorisation**

Date of first authorisation: 11<sup>th</sup> June, 2002

**10. Date of Revision of the Text**

To be given after approval of the product