SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vistamethasone Drops or Betamethasone Drops.

2. Qualitative and Quantitative Composition

Betamethasone Sodium Phosphate 0.1% w/v

3. Pharmaceutical Form

Eye, ear or nose drops.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the topical treatment of inflammatory non-infected conditions of the eye, ear or nose.

4.2. Posology and Method of Administration

Dosage schedule:

Administration for topical ocular use.

Adults, Elderly and Children:

Initially one or two drops to be instilled into the affected eye(s) every two hours. Frequency of administration should be reduced once the condition is under control.

Administration for topical otic use.

Adults, Elderly and Children:
Initially two or three drops to be instilled into the affected ear(s) every three to four hours. Frequency of administration should be reduced once the condition is under control.

**Administration for topical nasal use.**

*Adults, Elderly and Children:*

Two or three drops to be instilled into each nostril twice daily as required.

### 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.

### 4.4. Special Warnings and Precautions for Use

Topical 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.

### 4.5. Interactions with other Medicaments and other forms of Interaction

Vistamethasone / Betamethasone drops contain benzalkonium chloride as a preservative and therefore, should not be used to treat patients who wear soft contact lenses.

### 4.6. 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 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.
4.7. **Effects on Ability to Drive and Use Machines**

May cause transient blurring of vision on instillation into the eye. Warn patient not 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.

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.

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.

5 **PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic properties**

Betamethasone Sodium Phosphate is a corticosteroid used topically in the treatment of inflammatory conditions.

5.2. **Pharmacokinetic Properties**

No data available.
5.3. Preclinical Safety Data
None available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Benzalkonium Chloride Solution
Disodium Edetate
Sodium Phosphate
Purified Water

6.2 Incompatibilities
None Known.

6.3 Shelf Life
24 months from manufacture.
28 days from first opening.

6.4 Special Precautions for Storage
Store upright below 25°C.
Protect from light.

6.5 Nature and Contents of Container
5 or 10ml of the sterile solution is contained in a low density polythene bottle and dropper nozzle sealed by a tamper evident high density polythene cap.

6.6 Instruction for Use/Handling
No special instructions.
7. Marketing Authorisation Holder

Martindale Pharmaceuticals Limited
Bampton Road,
Harold Hill,
Romford,
RM3 8UG

8. Marketing Authorisation Number

PL 00156/0083

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/11/2008

10. DATE OF REVISION OF THE TEXT

26/11/2008