PROBETA DROPS

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

PROBETA Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Probeta Drops contains Betamethasone Sodium Phosphate 0.1% w/v

Excipients with known effect
Benzalkonium chloride – 0.02%w/v

Excipient: For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye/ Ear/ Nose drops (solution)
Clear colorless aqueous solution that is sterile until the bottle is opened.

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

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. After more prolonged treatment (over 6 to 8 weeks), the drops should be withdrawn slowly to avoid relapse.

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

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

Hypersensitivity to the preparation.
Probeta Eye Drops contain Benzalkonium Chloride as a preservative and therefore, should not be used to treat patients who wear soft contact lenses.

4.4 Special warnings and precautions for use

Precaution: Probeta contents should not be used more than four weeks after first opening the bottle.

Excipients with specified warnings
This medicine contains benzalkonium chloride in each dose. Benzalkonium chloride may be absorbed by soft contact lenses and may change the color 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.

Steroids should not be administered to 'red eyes' until a definitive diagnosis is made.
Treatment with steroid preparations should not be repeated or prolonged without regular review to exclude raised intra-ocular pressure or unsuspected infections.

Topical administrations of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established; however, topical steroids should not be used extensively in pregnancy i.e. in large amounts or for prolong periods.

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 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 Side effects
Eye drops containing corticosteroids cause a serious rise in intra-ocular pressure in a small percentage of the population, including most of those with a family history of glaucoma. A milder rise may be experienced by a larger proportion of subjects if treatment is continued for longer than a few weeks.
Thinning of the cornea leading to perforation has occurred with use of topical corticosteroids.
Acute sensitization to neomycin is a rare event.
Cataract is reported to have occurred after unduly prolonged treatment of eye conditions with topical corticosteroids.
Excessive and prolonged intranasal usage above the recommended dose may induce systemic side effects.

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. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
ATC Code: S03CA
Betamethasone has topical corticosteroid activity.

5.2 Pharmacokinetic properties
Not applicable as the drops are applied topically.

5.3 Preclinical safety data
Pre-clinical safety data does not add anything of further significance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Benzalkonium Chloride Solution
Phenylethyl Alcohol

Disodium Hydrogen Phosphate Dihydrate
Sodium Format
Thiomersal
Ortho Ophosphoric Acid
Water for Injection

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
02 years.
Discard 4 weeks after first opening.
The solution turns yellow on storage. This does not affect efficacy of the product.

6.4 Special precautions for storage
Do not store above 30°C, protect from light and do no freeze.
Keep out of the reach of children.
Bottle must be stored upright.

6.5 Nature and contents of container
7.5 ml bottle with DROP-TAINER dispensing system consisting of a transparent low density polyethylene bottle and dispensing plug and white polypropylene closure. Tamper evidence is provided by a security seal around the closure of the bottle.
Pack size: box containing 1 bottle

6.6 Special precautions for disposal and other handling
Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
ATCO Laboratories Limited
B-18, S.I.T.E., Karachi-75700, Pakistan

8. MARKETING AUTHORISATION NUMBER(S)
011978

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
December 09, 1990 / December 08, 2015

LEGAL CATEGORY
Prescription Only Medicine