1. Name of the medicinal product

XBETA, Betamethasone sodium phosphate eye/ear and nose drops 0.1% w/v

2. Qualitative and quantitative composition

Each 1ml of solution contains

Betamethasone sodium phosphate B.P equivalent to Betamethasone phosphate B.P 0.1% w/v

Excipient with known effect: Benzalkonium chloride - 0.02% w/v

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Ophthalmic, Otic and nasal drops, solution

Clear, colorless to faintly yellow solution.

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 After more prolonged treatment (over 6 to 8 weeks), the drops should be withdrawn slowly to avoid relapse.

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 preparation's 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 special 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.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

Nasal administration of corticosteroids is not advised if an untreated nasal infection is present, or if the patient has pulmonary tuberculosis or following nasal surgery (until healing has occurred).

Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioral effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

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 serous 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

Since it contains Benzalkonium chloride, it should not be used as eye drops to patients with 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 abnormal fetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such defects in the human fetus.

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.

Use of topical corticosteroids 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 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.

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.

Following nasal administration, the most common effects are nasal irritation and dryness, although sneezing, headache, light headedness, urticaria, nausea, epistaxis, rebound congestion, bronchial asthma, perforation of the nasal septum, ulceration of the nasal septum, anosmia, parosmia and disturbance to sense of taste have also been reported.

Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. Growth retardation has been reported in children receiving nasal corticosteroids at licensed doses.

It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid, if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should also be given to referring the patient to a pediatric specialist.

Vision, blurred (see also section 4.4)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

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

Pharmacotherapeutic group: Corticosteroids, ATC code: S03BA03

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

5.2 Pharmacokinetic properties

Not available.

5.3 Preclinical safety data

Not available.

6. Pharmaceutical particulars

6.1 List of excipients

- Benzalkonium chloride B.P
- Sodium chloride B.P
- Disodium edetate
- Water for injection

6.2 Incompatibilities

None known

6.3 Shelf life

36 months from date of manufacture.

28 days from first opening.

6.4 Special precautions for storage

Store below 30°C, but do not freeze.

6.5 Nature and contents of container

The product is a clear, colorless to faintly yellow solution in a plastic container.

The solutions are supplied in 10/5ml sealed transparent plastic ampoules, packed in baby cartons.

6.6 Special precautions for disposal and other handling

Use as directed by physician. Keep out of reach of children.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorization holder and manufacturer

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8. Marketing authorization number(s)

N/A

9. Date of first authorization/renewal of the authorization

N/A

10. Date of revision of the text

N/A