SUMMARY PRODUCT CHARACTERISTICS (SPC)

BETAMETHASONE AND NEOMYCIN EYE/EAR DROPS (Ivybetaneocin eye/ear drops)

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1. NAME OF MEDICINAL PRODUCT:

BETAMETHASONE AND NEOMYCIN EYE/EAR DROPS (Ivybetaneocin eye/ear drops)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition:
B**etamethasone Phosphate (as betamethasone sodium phosphate) BP**

Neomycin Sulphate BP

Quantitative composition:
Betamethasone (as betamethasone phosphate) 0.1%$^{w}/_{v}$ (1 mg/ml)
Neomycin sulphate 0.35%w/v (3.5 mg/ml)

For full list of Excipients, see section 6.1

3. PHARMACEUTICAL FORM OF THE DRUG PRODUCT

EYE/EAR DROP
10ml clear colourless to slightly yellow solution

4. CLINICAL PARTICULARS

4.1 INDICATIONS

For topical application.
For inflammatory conditions of the eye/ear where secondary infection is likely.

4.2 Posology and method of administration:

For Adults, Elderly and Children:
Eye: Initially one or two drops to be instilled every two hours. Frequency of administration should be reduced once the condition is under control.
Ear: Initially two or three drops instilled every three to four hours. Frequency of administration should be reduced once the condition is under control.

4.3 Contraindications:

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 the latter condition can lead to extension of the ulcer and marked visual deterioration. Otitis extema should not be treated when the eardrum is perforated due to the risk of ototoxicity.
Hypersensitivity to any component of the medicinal product.

4.4 Special warnings and pre cautions for use

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 used for more than 7 days in the absence of any clinical improvement, since prolonged use may lead to occult ex tension of infection due to the masking effect of the steroid. Prolonged use may also lead to

skin sensitization and the emergence of resistant organisms. 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. 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.

4.5 Interactions with other medicinal products and other forms of interactions

None known

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. Warn patients 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 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 selera, corticosteroid therapy may result in thinning of the globe leading to perforation.

This medicinal product contains thiomersal (an organomercuric compound) as a preservative and therefore, it is possible that sensitization reaction may occur.

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.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties

Neomycin sulphate is a broad-spectrum antibiotic effective against bacterial Infection. Corticosteroids are used to treat inflammatory conditions and are readily absorbed from sites of local application.

5.2 Pharmacokinetic properties

No data available.

Preclinical safety data

None available

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of ingredient	**Reference**	**Amount per 10 ml**	**Function/Reason For inclusion.**
Disodium edetate	BP	10mg	Chelating agent
Sodium metabisulphite	BP	50mg	Antioxidant
Benzalkonium chloride	BP	10mg	Preservative
Sodium phosphate dibasic	BP	320mg	Buffering agent
Sodium phosphate monobasic	BP	30mg	Buffering agent
Creatinine	BP	20mg	Solubilizer
Water for injection	BP	Quantity Sufficient to make up volume to 10ml	Solvent

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened shelf-life is 24 months.
Opened shelf-life 28 days.
But the patient is advised to discard any remaining drops after the prescribed course of treatment.

6.4 Special precautions for storage
Store in a cool place (Store below 25° C) away from light. Keep out of reach of children

6.5 Nature and contents of container
10ml low density polyethylene bottles with a polypropylene spiked cap.

6.6 Special precautions for disposal

No special requirement

7 MARKETING AUTHORISATION HOLDER

(Company) Name: **IVEE AQUA EPZ LTD.**

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8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST REGISTRATION/ RENEWAL OF REGISTRATION

10 DATE OF REVISION OF TEXT
November 2020-11-25

11 DOSIMETRY (IF APPLICABLE) Not Applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUICALS (IF APPLICABLE) Not applicable