SUMMARY PRODUCT CHARACTERISTICS (SPC)

DEXAMETHASONE EYE DROPS (Ivydexone eye drops)

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1. NAME OF MEDICINAL PRODUCT:

DEXAMETHASONE EYE DROPS (Ivydexone eye drops)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition:

D**examethasone phosphate (as dexamethasone sodium phosphate) BP**

Quantitative composition:

Dexamethasone (as Dexamethasone phosphate) 0.1%$^{w}/_{v}$. (1 mg/ml)

For full list of Excipients, see section 6.1

3. PHARMACEUTICAL FORM OF THE DRUG PRODUCT

EYE DROP
5ml clear colourless solution

4. CLINICAL PARTICULARS

4.1 INDICATIONS

For the treatment of swelling, itching, redness and irritation of the eyes and eye lids. Ivydexone Eye Drops are therefore used in the non-infectious forms of conjunctivitis, keratitis and blepharitis especially of allergic origin.

4.2 Posology and method of administration:

The normal dosage is one drop to be put in the affected eye 3-5 times a day or more frequently as advised by your doctor.
Do not touch your eye with the dropper on the bottle as this may contaminate the drops.

4.3 Contraindications:

Use is contraindicated in cases of:
•Hypersensitivity to the active substance or to any component of the preparation.
•Epithelial herpes simplex keratitis.
•Vaccinia, varicella or other viral infection of cornea and conjunctiva.
•Fungal diseases of ocular structures
•Mycobacterial ocular infections
•In children, long-term, continuous corticosteroid therapy should be avoided due to possible adrenal suppression

4.4 Special warnings and pre cautions for use

For ocular use only, not for injection.

Should be used cautiously in patients with glaucoma and be considered carefully in patients with family history of this disease.

This product contains phosphates which may lead to corneal deposits or corneal opacity when topically administered. It should be used with caution in patients presenting with compromised corneal and in instances where the patient is receiving polypharmacy with other phosphate containing eye medications.

Contact lenses should not be worn during treatment with corticosteroid eye drops due to increased risk of infection.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the installation of the drops, this especially advisable in children.

4.5 Interactions with other medicinal products and other forms of interactions

The risk of increased intraocular pressure associated with prolonged corticosteroid therapy may be more likely to occur with concomitant use of anticholinergics, especially atropine and related compounds, in patients predisposed to acute angle closure.

The risk of corneal deposits or corneal opacity may be more likely to occur in patients presenting with compromised cornea and receiving polypharmacy with other phosphate containing eye medications.

Therapeutic efficacy of dexamethasone may be reduced by phenytoin, phenobarbitone, ephedrine and rifampicin.

Glucocorticoids may increase the need for salicylates as plasma salicylate clearance is increased.

4.6 Pregnancy and lactation

Topically applied steroids can be absorbed systemically and have been shown to cause abnormalities of foetal development in pregnant animals. Although the relevance of this finding to human beings has not been established, the use of this product during pregnancy should be avoided.

Topically applied dexamethasone is not recommended in breastfeeding mothers, as it is possible that traces of the dexamethasone may enter the breast milk.

4.7 Effects on ability to drive and use machines

Installation of this eye drop may cause transient blurring of vision. Warn patients not to drive or operate hazardous machinery until vision is clear.

4.8 Undesirable effects

Administration of Dexamethasone sodium phosphate 0.1% w/v Eye drops to the eye may rarely cause stinging, burning, redness or watering of the eyes.

Prolonged treatment with corticosteroids in high dosage is, rarely, associated with sub-capsular cataract. In diseases which cause thinning of the cornea or sclera, perforations of the globe have been known to occur. In addition, optic nerve damage and visual acuity and field defects may arise following long term use of this product.

The administration of phosphates contained in dexamethasone eye drops has caused isolated cases of corneal deposits or corneal opacity when administered in patients presenting with compromised cornea.

The systemic effects of corticosteroids are possible with excessive use of steroid eye drops.

4.9 Overdose
This product is a single dose unit therefore overdose is unlikely to occur.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Dexamethasone is a highly potent and long acting-glucocorticoid. It has an approximately seven times greater anti-inflammatory potency than prednisolone.

The actions of corticosteroids are mediated by the binding of the corticosteroid molecules to receptor molecules located within sensitive cells. Corticosteroids receptors are present in human trabecular meshwork cells and in rabbit iris ciliary body tissues.

Corticosteroids will inhibit phosphate A2 thereby preventing the generation of substances which mediate inflammation, for example, prostaglandins. Corticosteroids also produce a marked. Though transient, lymphocytopenia. This depletion is due to redistribution of the cells, the T lymphocytes being affected to a greater degree than the B lymphocytes. Lymphokine production is reduced, as is the sensitivity of macrophages to activation by lymphokines. Corticosteroids also retard epithelial regeneration, diminish post-inflammatory neo-vascularisation and reduce towards normal levels the excessive permeability of inflamed capillaries.

5.2 Pharmacokinetic properties

When given topically to the eye, dexamethasone is absorbed into the aqueous humour, cornea, iris, choroid, ciliary body and retina. Systemic absorption occurs but may be significant only at higher dosages or in extended paediatric therapy.

Up to 90% of dexamethasone is absorbed when given by mouth, peak plasma levels are reached between 1 and 2 hours after ingestion and show wide individual variations. Dexamethasone sodium phosphate is rapidly converted to

dexamethasone within the circulation. Upto 77% of dexamethasone is bound to plasma proteins, mainly albumin. This percentage, unlike cortisol, remains practically unchanged with increasing steroid concentrations. The mean plasma half-life of dexamethasone is 3.6 ± 0.9h.

Tissue distribution studies in animals show high a high uptake of dexamethasone by the liver, kidney and adrenal glands; a volume of distribution has been quoted as 0.58 l/kg. in man, over 60% of circulating steroids are excreted in the urine within 24 hours, largely as unconjugated steroid.

5.3 Preclinical safety data

The use of corticosteroids, including Dexamethasone sodium phosphate 0.1 % w/v Eye drops and its derivatives, in ophthalmology is well established. Little relevant toxicology has been reported, however, the breadth of clinical experience confirms its suitability as a topical ophthalmic agent.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of ingredient	Reference	Amount per ml	Function/Reason For inclusion.
Disodium edetate	BP	1mg	Chelating agent
Sodium metabisulphite	BP	3mg	Antioxidant
Benzalkonium chloride	BP	0.1mg	Preservative
Sodium phosphate dibasic	BP	32mg	Buffering agent
Sodium phosphate monobasic	BP	3mg	Buffering agent
Creatinine	BP	2mg	Solubilizer
Water for injection	BP	Quantity Sufficient to Volume	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 (below 25° C) away from light. Keep out of reach of children

6.5 Nature and contents of container
5ml 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

Registration number: **NAFDAC REG NO. 04 – 4167**

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