SUMMARY PRODUCT CHARACTERISTICS (SPC)

PREDNISOLONE OPHTHALMIC SUSPENSION (Ivysolone ophthalmic suspension)

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1. NAME OF MEDICINAL PRODUCT:

PREDNISOLONE OPHTHALMIC SUSPENSION (Ivysolone ophthalmic suspension)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition:

Prednisolone acetate BP

Quantitative composition:

Prednisolone acetate 1%$^{w}/_{v}$. (10 mg/ml)

For full list of Excipients, see section 6.1

3. PHARMACEUTICAL FORM OF THE DRUG PRODUCT

OPHTHALMIC SUSPENSION EYE DROP

A smooth white suspension

4. CLINICAL PARTICULARS

4.1 INDICATIONS

Prednisolone eye drops is indicated for non-infected inflammatory conditions of the eye

Ivysolone ophthalmic suspension is used for the short term treatment of eye inflammation. It reduces the irritation, burning, redness and swelling of eye inflammation caused by chemicals, heat, radiation or foreign objects in the eye.

It is sometimes used after eye surgery.

4.2 Posology and method of administration:

- Adults, children and infants:

The normal dosage is one drop to be put in the affected eye 2-4 times a day. It should not normally be used for longer than one week. However, follow your doctor's advice.

- Do not touch your eye with the dropper on the bottle as this may contaminate the drops.

4.3 Contraindications:

Use is contraindicated in viral, fungal, tuberculous and other bacterial infections.

Prolonged application to the eye of preparations containing corticosteroids has caused increased intraocular pressure and therefore the drops should not be used in patients with glaucoma.

In children, long-term, continuous topical corticosteroid therapy should be avoided due to possible adrenal suppression.

4.4 Special warnings and pre cautions for use

Care should be taken to ensure that the eye is not infected before Ivysolone ophthalmic suspension is used.
Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.).

4.5 Interactions with other medicinal products and other forms of interactions

Corticosteroids are known to increase the effects of barbiturates, sedative hypnotics and tricyclic antidepressants.
They will, however, decrease the effects of anticholinesterases, antiviral eye preparations and salicylates.

4.6 Pregnancy and lactation

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development and although the relevance of this finding to human beings has not been established, the use of Ivysolone ophthalmic suspension during pregnancy should be avoided

4.7 Effects on ability to drive and use machines

The use of these eye drops may cause a transient blurring of vision and stinging on instillation. Do not drive or operate machinery until vision is clear. Some patients may experience sensitivity to bright lights.
Care should be taken in driving and in the use of hazardous machinery if vision is affected.

4.8 Undesirable effects

None known.

4.9 Overdose

Overdose is unlikely to occur.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The actions of corticosteroids are mediated by the binding of the corticosteroid molecules to receptor molecules located within sensitive cells. Corticosteroid receptors are present in human trabecular meshwork cells and in rabbit iris ciliary body tissue.
Prednisolone, in common with other corticosteroids, will inhibit phospholipase A2 and thus decrease prostaglandin formation.
The activation and migration of leucocytes will be affected by prednisolone. A 1% solution of prednisolone has been demonstrated to cause a 5.1% reduction in polymorphonuclear leucocyte mobilisation to an inflamed cornea. Corticosteroids

will also lyse and destroy lymphocytes. These actions of prednisolone all contribute to its anti-inflammatory effect.

5.2 Pharmacokinetic properties

The oral availability, distribution and excretion of prednisolone are well documented. A figure of 82 ± 13% has been quoted as the oral availability and 1.4 ± 0.3ml/min/kg as the clearance rate. A half-life of 2.1 - 4.0 hours has been calculated.

With regard to ocular pharmacokinetics, prednisolone sodium phosphate is a highly water soluble compound and is almost lipid insoluble. Therefore, theoretically it should not penetrate the intact corneal epithelium. Nevertheless, 30 minutes after instillation of a drop of 1% drug, corneal concentrations of 10µg/g and aqueous levels of 0.5µg/g have been attained. When a 0.5% solution was instilled in rabbit eyes every 15 minutes for an hour, an aqueous concentration of 2.5µg/ml was measured. Considerable variance exists in the intraocular penetration of prednisolone depending on whether the cornea is normal or abraded.

It can be seen that only low levels of prednisolone will be absorbed systemically, particularly where the cornea is intact.

Any prednisolone which is absorbed will be highly protein-bound in common with other corticosteroids.

5.3 Preclinical safety data

The use of prednisolone in ophthalmology is well-established. Little specific toxicology work 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 chloride	BP	7mg	Tonicity adjusting agent
Sodium acetate	BP	0.5mg	Buffering agent
Benzalkonium chloride	BP	0.1mg	Preservative
Hydroxypropyl methyl cellulose	BP	10mg	Viscosity adjusting agent
Boric acid	BP	6mg	Buffering agent
Polysorbate 80	BP	200mg	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
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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