**SUMMARY PRODUCT CHARACTERISTICS (SPC)**

**TETRAHYDROZOLINE EYE DROPS** (Ivysine eye drops)

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## 1. NAME OF MEDICINAL PRODUCT:

**TETRAHYDROZOLINE EYE DROPS** (Ivysine eye drops)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition:
**Tetrahydrozoline USP**
Quantitative composition:
**Tetrahydrozoline 0.05% $^{w}/_{v}$.**
For full list of Excipients, see section 6.1

## 3. PHARMACEUTICAL FORM OF THE DRUG PRODUCT

EYE DROP
10ml clear colourless solution

## 4. CLINICAL PARTICULARS

### 4.1 INDICATIONS

For the temporary relief of redness and itching of the eye due to seasonal and perennial allergies such as hay fever or house dust allergy.

### 4.2. Posology and method of administration:

Adults, children and infants:
The normal dosage is 1-2 drops in each eye two to three times daily.
• Do not touch your eye with the dropper on the bottle as this may contaminate the drops.

### 4.3 Contraindications:

Contraindicated in:
• Hypersensitivity to any of the ingredients of the formulation.
• Presence of narrow angle glaucoma
• Use with contact lenses
• Use in patients receiving monoamine oxidase inhibitors or within 14 days of stopping such treatment.

### 4.4 Special warnings and pre cautions for use:

Like other topically applied ophthalmic drugs, Ivysine may be absorbed systemically and occasionally cause systemic sympathomimetic effects such as hypertension, nervousness, nausea, dizziness, headache, insomnia, palpitation, tachycardia, and arrhythmia.
Ivysine should be used with caution in elderly patients with severe cardiovascular disease, including arrhythmia, poorly controlled hypertension, or diabetes.
Use with caution in the presence of hypertension, cardiac irregularities, hyperthyroidism diabetes mellitus or phaeochromocytomas.

Ivysine should also be used with caution in patients with conditions causing urinary retention such as prostatic hypertrophy and should also be used in caution in patients who are currently receiving other sympathomimetic drugs.
Not suitable for patients suffering from dry eyes without first seeking medical advice. Rebound hyperaemia may follow prolonged frequent use.
Ivysine should not be used without supervision over a long period of time. If the symptoms do not improve after 2 days, medical advice should be sought to rule out the possibility of a bacterial infection. Inflammation arising from infection should receive appropriate anti-bacterial therapy.
Eye drops are not for injection. They should never be injected subconjunctivally, nor should they be directly introduced into the anterior chamber of the eye.

**4.5 Interactions with other medicinal products and other forms of interactions**
This product should not be used in patients receiving monoamine oxidase inhibitors or within 14 days of stopping such treatment.
Sedating anti-histamines can enhance the sedating effects of CNS depressants including alcohol, hypnotics, opioid analgesics, anxiolytic sedatives, and antipsychotics.
They also have an additive anti-muscarinic action with other antimuscarinic drugs, such as atropine, and some antidepressants. Ivysine should be used with caution in patients receiving other medications such as digitalis, beta-adrenergic blockers, guanethidine, reserpine, methyldopa or anti-hypertensive agents.
Concurrent use with halogenated anaesthetic agents such as chloroform, cyclopropane, halothane, enflurane of isoflurane may provoke or worsen ventricular arrhythmias

**4.6 Pregnancy and lactation**

In line with common practice, the use of medication during pregnancy is not recommended unless considered essential.

It is not known whether the active ingredients are distributed in human milk.

It should therefore not be administered to nursing mothers or breast feeding should be interrupted for 48 hours after administration.

**4.7 Effects on ability to drive and use machines**
Any patients who experiences blurred vision should not drive or operate machines.

**4.8 Undesirable effects**
Ivysine is generally well tolerated. In a few cases, slight transient local stinging on instillation has been reported. Other side effects which have been reported very

occasionally are blurred vision, mydriasis, headache, drowsiness and reactive hyperaemia.
Local allergic reactions (e.g., rash, oedema, pruritus) and eye irritation have also been reported post-marketing.
Systemic side effects which may occur in sensitive patients are tachycardia (especially in small children), palpitations, arrhythmia, hypertension, occipital headache, nausea, paleness and sweating.

**4.9 Overdose**

Excessive dosage and or prolonged or too frequent use of Xylometazoline hydrochloride, especially in children, may cause adverse systemic effects. Excessive dosage in children may cause profound CNS depression possibly necessitating intensive supportive care. CNS depression, shock-like hypotension, and coma have occurred following overdose of naphazoline and tetrahydrozoline; the possibility that this may occur with Xylometazoline should be kept in mind.

## 5. PHARMACOLOGICAL PROPERTIES

**5.1 Pharmacodynamic properties**

Is an imidazole derivative with sympathomimetic activity. Applied locally to the eye or nose, tetrahydrozoline binds to and activates alpha-adrenergic receptors, resulting in vasoconstriction and decreased nasal and ophthalmic congestion.

5.2 Pharmacokinetic properties

No formal studies have been conducted.

**5.3 Pre-clinical safety data**

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

## 6. PHARMACEUTICAL PARTICULARS

**6.1 List of excipients**

| **Name of ingredient** | **Reference** | **Amount per ml** | **Function/Reason For inclusion.** |
|---|---|---|---|
| Benzalkonium chloride | BP | 0.1mg | Preservative |
| Disodium edetate | BP | 1mg | Chelating agent |
| Sodium chloride | BP | 7mg | Tonicity adjusting agent |
| Sodium phosphate dibasic | BP | 1mg | Buffering agent |
| Sodium phosphate monobasic | BP | 5mg | Buffering agent |
| 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 (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

**Registration number:** 04-5313

## 9 DATE OF FIRST REGISTRATION/ RENEWAL OF REGISTRATION

1999

## 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