SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) of Vitricine® (Tetrahydrozoline Hydrochloride 0.05% w/v) Sterile Eye Drops

1. NAME OF THE MEDICINALPRODUCT

Vitricine®- (Tetrahydrozoline Hydrochloride 0.05% w/v) sterile eye drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of ophthalmic solution contains 0.5mg of Tetrahydrozoline Hydrochloride For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution/Drops

4. Clinical particulars

4.1 Therapeutic indications

Vitricine® sterile eye drops provides fast relief from burning, itching and redness due to minor irritation of the eye.

4.2 Posology and method of administration

Posology

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 precautions for use

Like other topically applied ophthalmic drugs, Vitricine may be absorbed systemically and occasionally cause systemic sympathomimetic effects such as hypertension, nervousness, nausea, dizziness, headache, insomnia, palpitation, tachycardia, and arrhythmia. Vitricine 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. Vitricine 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. Vitricine 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 Interaction with other medicinal products and other forms of interaction

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. Vitricine 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

Vitricine 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 Pharmacodynamics 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 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride

Disodium edetate

Sodium chloride

Sodium borate

Boric acid

Water for injection

6.2 Incompatibilities

NA

6.3 Shelf life

60 months

6.4 Special precautions for storage

Store below 30°C. Protect from light. Replace cap immediately after use. Discard after 28 days of opening the botle.

6.5 Nature and contents of container and special equipment for use, administration or implantation

Vitricine® is available in sterile plastic bottle containing 15ml of the eye drops.

6.6 Special precautions for disposal and other handling

No special requirements.

7 APPLICANT/MANUFACTURER

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