1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed

1. Name of the medicinal product:

1.1 Name of the medicinal product :

OCULLERG EYE DROPS (Antazoline Hydrochloride 0.05 % w/v and Tetryzoline Hydrochloride 0.04% w/v Eye drops)

1.2 Strength :

Antazoline Hydrochloride BP : 0.5 mg

Tetryzoline Hydrochloride BP : 0.4 mg

1.3 Pharmaceutical form:

Eye Drops

2. Qualitative and quantitative composition

Each ml contains:

Antazoline Hydrochloride BP (0.5 mg)

Tetryzoline Hydrochloride BP (0.4 mg)

Hydroxypropyl Methyl Cellulose BP (3.0 mg)

Benzalkonium Chloride BP (0.15 mg)

Water for Injections BP (QS)

Qualitative declaration:

Antazoline Hydrochloride BP

Tetryzoline Hydrochloride BP

Hydroxypropyl Methyl Cellulose BP

Benzalkonium Chloride BP

Water for Injections BP

Quantitative declaration:

Antazoline Hydrochloride BP (0.5 mg)

Tetryzoline Hydrochloride BP (0.4 mg)

Hydroxypropyl Methyl Cellulose BP (3.0 mg)

Benzalkonium Chloride BP (0.15 mg)

For Excipients see section 6.1

3. Pharmaceutical form

Eye Drops

4. Clinical particulars:

4.1 Therapeutic 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

Posology

Adults: 1 or 2 drops instilled 2 - 3 times a day.

Paediatric population: Children aged 12 years and over: 1 drop instilled 2 to 3 times a day.

No specific studies are available in this patient group. Due to possible systemic effects, OCULLERG EYE DROPS is not recommended for use in children younger than 12 years of age

Elderly

1 drop instilled 2 to 3 times a day.

OCULLERG EYE DROPS should not be used for more than seven consecutive days.

Method of administration

For local administration to the eye.

The dispenser remains sterile until the original closure is broken. Patients must be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures as this may contaminate the solution.

If more than one medication needs to be instilled in the eye, an interval of at least 5 minutes between application of the different medicinal products must be allowed.

- Recommended route of administration : Ophthalmic

4.3 Contraindications

- 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, OCULLERG EYE DROPS may be absorbed systemically and occasionally cause systemic sympathomimetic effects such as hypertension, nervousness, nausea, dizziness, headache, insomnia, palpitation, tachycardia, and arrhythmia.

OCULLERG EYE DROPS 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.

OCULLERG EYE DROPS 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. OCULLERG EYE DROPS 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 (see section 4.3).

Sedating anti-histamines can enhance the sedating effects of CNS depressants including alcohol, hypnotics, opioid analgesics, anxiolytic sedatives and anti-psychotics. They also have an additive anti-muscarinic action with other anti-muscarinic drugs, such as atropine and some antidepressants. OCULLERG EYE DROPS 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 or 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 patient who experiences blurred vision should not drive or operate machines.

4.8 Undesirable effects:

OCULLERG EYE DROPS 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:

This medicine may be harmful if swallowed. Symptoms of overdose may include drowsiness, severe sweating, decreased body temperature, slow/shallow breathing Seek emergency medical attention. Excessive dosage in children may cause profound CNS depression possibly necessitating intensive supportive care.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Pharmacodynamic effects

Antazoline is an H1 receptor antagonist. It has antihistaminic, anticholinergic and local anaesthetic properties. The primary mediator of inflammation in allergic conjunctivitis appears to be histamine. Antazoline reduces histamine induced responses including itching. In clinical studies, OCULLERG EYE DROPS was shown to cause a small mydriatic response but no change in intraocular pressure. The mydriatic response is too small to be of clinical significance or to impose any risk of pupil block or irido-corneal angle glaucoma, even in susceptible subjects.

Tetrahydrozoline (tetryzoline) hydrochloride is a sympathomimetic amine. It's topical use has decongestive and vasoconstriction effects.

Tetrahydrozoline hydrochloride leads to rapid relief and exerts a rapid decongestive effect on the inflamed mucosa, reducing hyperemia and edema.

5.2 Pharmacokinetic Properties

The effect of tetryzoline appears rapidly and may last for 4 to 8 hours. Like any other alpha-sympathomimetic agent tetryzoline is rapidly absorbed through the blood vessels. H1-antihistaminic agents (antazoline) are usually well and rapidly resorbed. However, no specific data on the degree of resorption are available.

5.3 Preclinical safety data

In dogs, signs of intoxication may include vomiting, bradycardia, cardiac arrhythmias, poor capillary refill time, hypotension or hypertension, panting, increased upper respiratory sounds, depression, weakness, nervousness, hyperactivity, or shaking. These signs appear within 30 min

to 4 hr postexposure. In general, imidazoline decongestant exposure may affect the GI, cardiopulmonary, and nervous systems

6. Pharmaceutical particulars

6.1 List of excipients

Sr. No.	Ingredient	Specification
1.	Benzalkonium Chloride BP (50%)	BP
2.	Sodium Chloride	BP
3.	Hydroxypropyl Methylcellulose	BP
4.	Propylene Glycol	BP
5.	Disodium Hydrogen Phosphate Dihydrate	BP
6.	Anhydrous Sodium Dihydrogen Phosphate	BP
7.	Polysorbate 80	BP
8.	Disodium EDTA	BP
9.	Hydrochloric Acid	BP
10.	Water for injection	BP

6.2 Incompatibilities

None

6.3 Shelf life

24 months (2 Years) from date of manufacturing

6.4 Special precautions for storage

Store in a cool place, below 25°C.

Keep medicines out of reach of children.

6.5 Nature and contents of container

10 ml low density polyethylene white bottle with label. Such 1 bottle packed in a carton along with pack insert.

6.6 Special precautions for disposal :

None

7. Registrant :

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8. MANUFACTURER

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