

SCHEDULING STATUS:

S2

PROPRIETARY NAME: SPERSALLERG**(AND DOSAGE FORM): Sterile Eye Drops****COMPOSITION:**

Each 1 ml contains:

Antazoline HCl.....0,5 mg

Tetryzoline HCl.....0,4 mg

Benzalkonium chloride.....0,005 % *m/v*
(as preservative)**PHARMACOLOGICAL CLASSIFICATION:**

A 15.4 Ophthalmic preparations. Other

PHARMACOLOGICAL ACTION:

Antazoline, an antihistamine acts by blocking the action of histamine through competitive inhibition of H₁ receptors.

Tetryzoline a sympathomimetic agent with alpha-adrenergic activity, acts as a local vasoconstrictor.

INDICATIONS:

Hay-fever conjunctivitis. Allergic conjunctivitis as consequence of drug sensitivity.

Conjunctivitis vernalis. Conjunctivitis ecchymotosa.

CONTRAINDICATIONS:

1. Hypersensitivity to any of the ingredients
2. Patients with dry eyes, especially keratoconjunctivitis sicca.
3. Patients at a risk of narrow angle glaucoma.

4. Patients receiving monoamine oxidase inhibitors or within 14 days of its treatment.
5. Not recommended for children under two years of age, due to the greater incidence of systemic absorption and effects.

WARNINGS:

1. As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations cannot be excluded, regular ophthalmological examination is required.
2. Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.
3. Soft contact lenses should not be worn during instillation of Spersallerg Eye Drops. They can be reinserted after an interval of at least 5 minutes.
4. Use with caution in patients with increased intra-ocular pressure, hypertension, cardiac irregularities, hyperthyroidism and diabetes mellitus.
5. Safety in pregnancy and lactation has not been established.
6. Rebound congestion may follow continued use.

DOSAGE AND DIRECTIONS FOR USE:

Adult: Instill 1 drop, 3 or 4 times daily, into the lower eyelid.

Children 2 – 12 years: Instill 1 drop daily or twice daily.

Not recommended for children under the age of 2 years.

If redness or irritation continues, gets worse or lasts for more than 3 days consult your doctor.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Transient irritation may occur immediately after instillation.

Systemic reactions may occur after the use of these eye drops, such as headache, drowsiness, and tachycardia. Children and the elderly are more susceptible to these systemic reactions.

Antimuscurinic effects, including blurred vision, have been described after systemic absorption of Spersallerg Eye Drops.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

After accidental ingestion, especially in children, overdose is associated with antimuscurinic, extrapyramidal and CNS stimulation and depression. CNS stimulation causes ataxia, excitement, tremors, psychoses, hallucinations, convulsions, hyperexia may also occur. Deepening coma and cardiorespiratory collapse may follow. CNS depression causes drowsiness, coma, convulsions, progressing to respiratory failure or possible cardiovascular collapse.

Treatment is symptomatic and supportive, including artificial respiration if necessary. If patient is conscious and has not lost the gag reflex and not having seizures, emesis should be induced. If emesis cannot be induced, gastric lavage is indicated.

IDENTIFICATION:

Clear, colourless, odourless solution.

PRESENTATION:

Plastic dropper bottle of 10 ml

STORAGE INSTRUCTIONS:

Store in a cool place below 25°C. Discard 30 days after opening. Keep out of reach of children.

APPLICATION NUMBER:

H 1283 (Act 101/1965).

NAME AND BUSINESS ADDRESS OF APPLICANT:

Adcock Ingram Limited (Pty) Ltd.

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