SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

SPERSALLERG® sterile eye drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Antazoline HCl…….0,5 mg

Tetryzoline HCl……0,4 mg

Preservative: benzalkonium chloride 0,5 % *m/v*.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Sterile eye drops

Clear, colourless, odourless solution, free of visible particulate matter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Hay-fever conjunctivitis.
- Allergic conjunctivitis as consequence of drug sensitivity.
- Conjunctivitis vernalis.
- Conjunctivitis ecchymotosa.

4.2 Posology and method of administration

Adult

Instil 1 drop, 3 or 4 times daily, into the lower eyelid.

Children 2 – 12 years

Instil 1 drop daily or twice daily, into the lower eyelid.

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.

4.3 Contraindications

- Hypersensitivity to antazoline HCl, tetryzoline HCl or to any of the excipients of SPERSALLERG® (see section 6.1).
- Patients with dry eyes, especially keratoconjunctivitis sicca
- Patients at a risk of narrow angle glaucoma.
- Patients receiving monoamine oxidase inhibitors (MAOIs) or within 14 days of its treatment.
- Not recommended for children under two years of age, due to the greater incidence of systemic absorption and effects.

4.4 Special warnings and precautions for use

Soft contact lenses should not be worn during instillation of SPERSALLERG®. They can be reinserted after an interval of at least 5 minutes.

Tetryzoline should be given with care in cases of hypertension or hyperglycaemia (diabetes). Use with caution in patients with increased intraocular pressure, hypertension, cardiac irregularities including heart failure, in patients with poorly controlled hypertension and diabetes mellitus, hyperthyroidism or pheochromocytoma and eye infections.

Safety in pregnancy and lactation has not been established (see section 4.6).

Rebound congestion may follow continued use.

Other medications should be chosen in case of chronic recurring allergies.

Exceeding the dose or accidental ingestion of tetryzoline by mouth may cause central nervous system depression with excessive hypothermia and symptoms of drowsiness and coma, particularly in children.

Treatment (management) of this effect is symptomatic. If SPERSALLERG® has been taken recently by mouth, the stomach should be emptied by aspiration and lavage. Do not use when there is angle closure glaucoma. In patients using MAO inhibitors a severe hypertensive crisis may be provoked if a sympathomimetic medicine is administered. Use in infants or children may cause Central Nervous System (CNS) depression which could lead to coma and a marked drop in temperature.

SPERSALLERG® contains benzalkonium chloride

From the limited data available, there is no difference in the adverse event profile in children compared to adults.

Generally, however, eyes in children show a stronger reaction for a given stimulus than the adult eye. Irritation may have an effect on treatment adherence in children.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised.

Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended

period in patients with extensive ocular surface disease.

Regular ophthalmological examination is required.

4.5 Interaction with other medicines and other forms of interaction

No synergic effect can occur due to the low dose. In cases where another ophthalmic treatment is used, allow an interval of 5 minutes between each administration so as not to wash away the active ingredient.

Preparations containing tetryzoline may not be used in patients receiving MAO inhibitors until ten days after the last treatment with such active ingredients (increase in blood pressure resulting from the concomitant use of MAO inhibitors and tricyclic antidepressants).

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

No controlled studies are available either in animals, pregnant or nursing women.

It is not known whether either active substance of SPERSALLERG® passes into breast milk.

No data on fertility is available.

4.7 Effects on ability to drive and use machines

Patients with visual disturbances such as blurred vision after application of the SPERSALLERG® should not drive vehicles or use machines until their vision is restored.

4.8 Undesirable effects

Tabulated list of adverse reactions

MedDRA System Organ Class	**Frequency**	**Frequency unknown**
Immune system disorders	*Unknown frequency*	Hypersensitivity reactions may occur
Nervous system disorders	*Rare*	Headaches, drowsiness (particularly

		in children and the elderly), tremor, agitation
Eye disorders	*Rare*	Transient irritation may occur immediately after instillation, blurred vision (after systemic absorption), mydriasis, elevation of intraocular pressure, systemic undesirable effects due to absorption, reactive hyperaemia (after discontinuation of the treatment)
Cardiac disorders	*Rare*	Tachycardia (particularly in children and the elderly), pectanginous symptoms
Vascular disorders	*Rare*	Hypertension
Skin and subcutaneous tissue disorders	*Rare*	Perspiration

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Symptoms

After accidental ingestion, especially in children, overdosage is associated with antimuscarinic, 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

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 15.4 Ophthalmic preparations. Other

Pharmacotherapeutic group: Sensory organs, ophthalmologicals, decongestants and antiallergics, sympathomimetics used as decongestants, ATC code: S01GA53.

Antazoline, an antihistamine acts by blocking the action of histamine through competitive inhibition of H_1 receptors.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride

Methylhydroxypropyl cellulose

Dilute hydrochloric acid 1N

Sodium chloride

Water for injections

6.2 Incompatibilities

None

6.3 Shelf life

36 months

The shelf life after first opening is 30 days.

6.4 Special precautions for storage

Store in a cool place at or below 25 °C.

Do not use more than 30 days after opening.

6.5 Nature and contents of container

SPERSALLERG® is packed in 10 ml transparent plastic (LDPE) bottle, fitted with a plastic dropper (LDPE) of natural colour and a white (HDPE) cap.

6.6 Special precautions for disposal and other handling

Close the bottle immediately after use.

Do not use more than 30 days after opening.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand,

1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER(S)

H 1283 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: N/A (Old medicine)

10. DATE OF REVISION OF THE TEXT

21/02/2022

Namibia: NS2: 14/15/0414

Botswana: S3: B9323450

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