Spersallerg®/ Spersallerg® SDU

Composition

Multiple-dose units

Active substances: Antazoline hydrochloride, tetryzoline hydrochloride
Excipients: 0.05 mg benzalkonium chloride as preservative; excipients to 1 ml

Single-dose units (SDUs)

Active substances: Antazoline hydrochloride, tetryzoline hydrochloride
Excipients: Excipients to 1 ml

Pharmaceutical form and quantity of active substance per unit

Eye drops
0.5 mg antazoline hydrochloride per ml and 0.4 mg tetryzoline hydrochloride per ml

Indications / Potential uses

Non-infectious irritant conjunctivitis, allergic-inflammatory conditions of the conjunctiva, hay fever conjunctivitis and vernal conjunctivitis.

Dosage and Administration

Adolescents and adults
1 drop every three hours during the acute phase; 1 drop 2–3 times per day is sufficient for maintenance therapy.
Children between 2 and 12 years of age
1–2 drops per day.

Contraindications

– Hypersensitivity to substances contained in Spersallerg.
– Glaucoma caused by a narrow iridocorneal angle (narrow angle glaucoma)
– Concomitant treatment with MAO inhibitors (see Interactions)
– Children under 2 years of age

Warnings and Precautions

In patients with chronic recurring allergies, other therapeutic measures or medications should be chosen.
This product is not intended for long-term use. If treatment is to last longer than 2–3 days, it must be prescribed and monitored by a physician.
Caution is required in patients with rhinitis sicca. Eye infections may be masked.
Spersallerg should be used with caution in children, in elderly patients and in patients with severe cardiovascular disease, including arrhythmia, poorly controlled hypertension, hyperthyroidism, phaeochromocytoma or diabetes.
Spersallerg is not suitable for patients suffering from dry eyes who have not first sought medical advice. Patients with rhinitis sicca should perform nasolacrimal occlusion to prevent the medicinal product from reaching the nasal region.

Note for contact lens wearers
Contact lenses should be removed prior to application of Spersallerg and should not be reinserted until at least 15 minutes after the application. Spersallerg may reduce tear production, resulting in reduced tolerance for contact lenses.

Interactions

Concomitant use of sympathomimetic agents and MAO inhibitors may cause a hypertensive crisis. Concomitant use with MAO inhibitors is therefore contraindicated (see **Contraindications**).
Sedating antihistamines may enhance the sedating effects of CNS depressants such as alcohol, hypnotics, opioid analgesics, anxiolytics and antipsychotics. They also have an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and some antidepressants (tricyclics and MAO inhibitors). Systemic absorption of antazoline is possible, and caution should therefore be exercised when using Spersallerg concomitantly with these medicinal products.

Pregnancy and Lactation

There have been no controlled studies in animals, in pregnant women or in infants. The product should therefore not be used in women who are pregnant or breastfeeding unless clearly necessary.
It is not known whether antazoline or tetryzoline are excreted in breast milk.

Effects on ability to drive and use machines

No relevant studies have been carried out. Immediately after application of Spersallerg, the ability to use machines or drive may briefly be impaired by drowsiness, light-headednness, somnolence or blurred vision. These activities should not be undertaken until the patient's vision has returned to normal.

Adverse effects

Eye disorders
Slight, transient burning may occasionally be observed immediately after instillation of Spersallerg eye drops. The following may also occur: iris pigment dispersion, mydriasis, blurred vision; acute, chronic or follicular conjunctivitis.
Reactive hyperaemia might occur following withdrawal of the product.

Immune system disorders
Rare: Hypersensitivity reactions.

Nervous system disorders
Headache, drowsiness, dizziness, tremor and excitation are possible.

Cardiac disorders
Angina pectoris, hypertension and tachycardia.

General disorders and administration-site reactions
Burning sensations in the eye have been reported, and sweating may also occur.

Overdose

Correct ophthalmic use of the product makes overdosage unlikely. Accidental oral ingestion of Spersallerg usually does not cause any serious consequences in adults. Howeever, nausea, drowsiness, arrhythmia/tachycardia and, possibly, shock may occur in children, especially in infants under 2 years of age.

Properties and Actions

ATC code: S01GA52

Mechanism of action – pharmacodynamics – clinical efficacy
α-Adrenergic stimulation by tetryzoline, a sympathomimetic agent closely related to naphazoline, causes constriction of the conjunctival arterioles, thereby reducing the inflammmatory irritation and swelling of the conjunctiva. Tetryzoline may bring about a slight reduction in intraocular pressure.
Antazoline, the antiallergic active substance of Spersallerg, competitively blocks the HI-receptors in the effector cells, thereby diminishing the effects exerted by histamine released in tissue, e.g. increased permeability and dilation of the capillaries, contraction of smooth musculature, oedema, itching and lacrimation.
The combination of active substances in Spersallerg allows treatment of allergic symptoms, affecting the conjunctiva, that are caused primarily by histamine release. Lacrimattion is slightly reduced, while pupil diameter, accommodation and intraocular pressure are practically unaffected.
Spersallerg SDU eye drops are suitable in patients hypersensitive to benzalkonium chloride.

Pharmacokinetics

The pharmacokinetics of Spersallerg have not been investigated either in humans or in animals. Tetryzoline has a rapid onset of effect, and the effect can persist for 4–8 hours. Like all alpha-sympathomimetic agents, tetryzoline is absorbed systemically through the blood vessels.
HI-antihistaminic agents (antazoline), too, are usually absorbed rapidly and effectively.
No data are available on the extent of systemic absorption.

Preclinical data

No product-specific data of relevance for use are available.

Other information

Shelf-life

Spersallerg Multiple-dose units
Unopened packs of Spersallerg eye drops may be used until the expiry date (= EXP) printed on the pack.

Spersallerg SDU
The strip of SDUs from an opened pouch should not be kept for more than one month. Unopened pouches may be used until the expiry date (= EXP) printed on the pack.
Spersallerg SDU contains no preservatives. Individual dose units, and any leftover product contained in them, should be discarded immediately after use.

Special precautions for storage
See folding box

Instructions for use and handling
Close the dropper bottle immediately after use and always keep it tightly closed. The dropper tip must not touch either the hands or the eyes.

Pack sizes
Country specific pack sizes

Manufacturer
See folding box

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January 2007

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® = registered trademark

Novartis Pharma AG, Basle, Switzerland

This is a medicament
– A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
– Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
– The doctor and the pharmacist are experts in medicine, its benefits and risks.
– Do not by yourself interrupt the period of treatment prescribed for you.
– Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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