

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

**SPERSALLERG®, Antazoline hydrochloride 0,5 mg/ml and Tetryzoline hydrochloride 0,4 mg/ml,
sterile eye drops**

Antazoline hydrochloride and Tetryzoline hydrochloride

Contains benzalkonium chloride 0,5 mg per 1 ml as preservative

Read all of this leaflet carefully because it contains important information for you

SPERSALLERG® is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use SPERSALLERG® carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SPERSALLERG® with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What SPERSALLERG® is and what it is used for
2. What you need to know before you use SPERSALLERG®
3. How to use SPERSALLERG®
4. Possible side effects
5. How to store SPERSALLERG®
6. Contents of the pack and other information

1. What SPERSALLERG® is and what it is used for

The active ingredients are 0,5 mg antazoline hydrochloride and 0,4 mg tetryzoline hydrochloride per mL of sterile eye drops. Antazoline, the anti-allergic active ingredient contained in SPERSALLERG®, reduces the

effects caused by the histamine which is released into the tissue, such as increased permeability and dilation of the capillaries, contraction of the smooth musculature, formation of oedema, itching and lacrimation. Tetryzoline, a sympathomimetic medicine closely related to naphazoline, causes a contraction of the conjunctival arterioles thereby reducing the inflammatory irritation and swelling of the conjunctiva. Tetryzoline may lead to a slight reduction in the intra-ocular pressure.

The combination of active ingredients in SPERSALLERG® is intended for a symptomatic treatment of allergic disorders of the conjunctiva, primarily conditions caused by histamine release. Lacrimation is slightly reduced, while pupil diameter, accommodation and intraocular pressure are practically not affected.

SPERSALLERG® eye drops are used for:

- allergic conjunctivitis as a consequence of drug sensitivity
- hay fever conjunctivitis
- conjunctivitis vernalis
- redness of the conjunctiva due to bleeding underneath the conjunctiva

2. What you need to know before you use SPERSALLERG®

Do not use SPERSALLERG®:

- if you are hypersensitive (allergic) to antazoline HCL, tetryzoline HCL or any of the other ingredients of SPERSALLERG® (listed in section 6).
- if you suffer from glaucoma caused by narrow angle glaucoma
- if you suffer from dry eye syndrome
- if you are taking antidepressants such as MOA inhibitors or within 14 days of its treatment
- for children under two years of age

Warnings and precautions

Take special care with SPERSALLERG®:

- soft contact lenses should be removed before the administration of the product. Thereafter wait at least 15 minutes before placing the lenses back into the eye.
- if you suffer from diabetes, severe heart disease including heart failure, rise in blood pressure, overactive thyroid gland and eye infections.
- if you have a small vascular noncancerous tumour that develops in an adrenal gland, causing irregular secretion of adrenalin and noradrenaline leading to attacks of raised blood pressure, palpitations, and headache.
- other therapeutic measures or medications should be chosen in case of chronic recurring allergies.

Children

Do not use in infants under 2 years of age.

Other medicines and SPERSALLERG®

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If your doctor recommends that you use SPERSALLERG® eye drops with another eye drop, there should be an application interval of at least 5 minutes between the two medications. SPERSALLERG® eye drops should always be the last medication instilled.

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).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult

your doctor, pharmacist or other healthcare provider for advice before using SPERSALLERG®.

Driving and using machines

It is not always possible to predict to what extent SPERSALLERG® may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which SPERSALLERG® affects you.

SPERSALLERG® may cause blurring of vision on installation.

SPERSALLERG® contains benzalkonium chloride

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use SPERSALLERG®

Do not share medicines prescribed for you with any other person.

Always use SPERSALLERG® exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure.

Adult

The usual dose is one drop 3 to 4 times daily into the lower eyelid.

Children 2 – 12 years

One drop 1 to 2 times daily.

Method of administration

1. Wash your hands.
2. Open the bottle. Tilt your head backward while seated, or while lying down on your back.
3. Pull your lower eyelid down to form a pocket between your eyelid and your eye.
4. Hold the inverted bottle vertically in your other hand. Place the tip close to your eyelid.
5. Lightly press on the sides of the container with your first finger and thumb until one drop of gel falls into your eye.
6. Close your eye for 3 minutes. Put the cap back on the bottle.

If you use more SPERSALLERG® than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

In case more than one drop is accidentally instilled to the eye this is usually not a problem as the excess solution will flow out of the eye. Accidental ingestion of SPERSALLERG® usually does not lead to severe effects in adults. On the other hand, nausea, somnolence, dysrhythmia/tachycardia and possibly shock may occur in children under 2 years.

If you forget to use SPERSALLERG®

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

SPERSALLERG® can have side effects.

Not all side effects reported for SPERSALLERG® are included in this leaflet. Should your general health

worsen or if you experience any untoward effects while using SPERSALLERG®, please consult your healthcare provider for advice.

If any of the following happens, stop using SPERSALLERG® and tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SPERSALLERG®. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects with unknown frequency:

- headaches, drowsiness, tremor and agitation
- a slight transient burning sensation may be felt immediately after instillation of the preparation
- blurred vision (after systemic absorption)
- dilatation of the pupil
- elevation of intraocular pressure
- systemic undesirable effects due to absorption
- ocular hyperaemia may develop
- abnormally rapid heart rate
- rise in blood pressure
- sweating

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of SPERSALLERG®.

5. How to store SPERSALLERG®

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

Discard 30 days after opening.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the label / carton / bottle

The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SPERSALLERG® contains

The active ingredients are antazoline hydrochloride 0,5 mg/ml tetrazoline hydrochloride 0,4 mg/L.

The other ingredients are benzalkonium chloride, cellulose hydroxy propyl methyl ether, dilute hydrochloric acid 1N, sodium chloride and water for injections.

What SPERSALLERG® looks like and contents of the pack

SPERSALLERG® is a clear, colourless, odourless solution, free of visible particulate matter.

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

Holder of Certificate of Registration

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