

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

Visine® Relief

Eye drops, solution.

Active ingredient -

Tetryzoline hydrochloride 0.5 mg/ml (0.05% w/v)

For inactive and allergenic ingredients: see section 6 "*Further Information*".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Use this medicine in accordance with the instructions in the dosage section in this leaflet. Consult the pharmacist if you need further information. Refer to the doctor if the signs of the disease (symptoms) worsen or do not improve within 48 hours.

1. WHAT IS THE MEDICINE INTENDED FOR?

Temporary relief of hyperemia of the eye secondary to non-infectious eye irritations e.g., due to smoke, dust, wind, chlorinated water, light or allergic conjunctivitis.

Visine Relief is indicated in adults, adolescents and children aged 2 years and older.

Visine Relief is indicated in children over 2 and below 6 years only following advice from a healthcare professional.

Therapeutic group: Sympathomimetic decongestants for ophthalmic use.

2. BEFORE USING THIS MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see details in section 6 – "*Further Information*").
- you have glaucoma (closed angle glaucoma).
- in children under 2 years of age.

Special warnings regarding use of the medicine

Before treatment with the medicine, tell the doctor if you suffer from one of the following conditions:

- severe cardiovascular disease (e.g. coronary artery disease, hypertension, pheochromocytoma).
- benign prostate enlargement.
- metabolic disorders (e.g. hyperthyroidism, diabetes, disorder of hemoglobin formation).
- rhinitis sicca (dry nasal mucosa due to chronic inflammation).
- keratoconjunctivitis sicca (dryness of the conjunctiva and cornea).
- glaucoma (eye disease in which the optic nerve connecting the eye to the brain is damaged). See also "*Do not use the medicine if*".

If there is no improvement after 48 hours, or if eye irritation or redness persists or worsens, or if eye pain or vision problems occur, stop using the medicine and contact your doctor.

Eye irritation or eye redness due to infection, a foreign body in the eye or chemical injury to the cornea should be treated by an eye doctor.

If headache, vision loss or visual disturbances (e.g. double vision or seeing floaters in front of the eyes), severe acute or one-sided eye redness or pain in the eye on exposure to light occur, the medicine should be discontinued and a doctor should be consulted, as these are often signs of a serious eye condition that cannot be treated with this medicine.

Do not use more of this medicine than you should, and do not use it for too long (i.e., no longer than 3 to 5 days in a row), as this may cause a reduction in the effect of the medicine, worsen your eye redness or cause nasal symptoms. See also section 3 "*How should the medicine be used*".

If you use this medicine, the pupils of the eyes may temporarily be dilated.

Notes for contact lens wearers

In general, contact lenses should not be worn if you have eye diseases.

Remove the contact lenses before using the medicine and wait 15 minutes before you put them back in.

Children and adolescents:

The medicine is indicated in adults, adolescents and children aged 6 years and older; for use in children over 2 and under 6 years of age, please refer to a physician.

Children under 12 years of age should be supervised by an adult when using this medicine.

Children aged 2-6 years

Use in children must only take place under medical supervision.

Children under 2 years of age

Do not use this medicine in infants and children under 2 years of age.

Interactions with other medicines:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, especially if you are taking:

- medicines for use in the eye.
- medicines such as antidepressants, MAO inhibitors or tricyclic antidepressants, you should avoid using Visine Relief, as this may cause an increase in blood pressure.

Pregnancy, breastfeeding and fertility:

There are no adequate and well-controlled studies available that investigate the effect of tetrahydrozoline in pregnancy and breastfeeding.

Pregnancy: This medicinal product should not be used during pregnancy unless a physician concludes that the benefit of treatment for the mother outweighs the possible risk to the fetus.

Breastfeeding: It is not known whether the medicine is excreted in human milk. This medicinal product should not be used while breastfeeding, unless a physician concludes that the benefit of treatment for the mother outweighs the possible risk to the breastfed child.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Use of Visine Relief may cause blurred vision and dilation of the pupils. In this case, do not drive or use machines until your vision is completely restored.

Important information about some of the ingredients of the medicine

This medicine contains 7.5 µg phosphates per drop. If you suffer from severe damage to the cornea (transparent layer in the front of the eye), phosphates can cause clouding (cloudy spots) of the cornea in very rare cases due to calcium accumulation during treatment.

3. HOW SHOULD THE MEDICINE BE USED?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the product.

The usual dosage is generally:

Children aged 6 years and older, adolescents and adults

Unless otherwise prescribed by the doctor, instill 1 to 2 drops in the affected eye(s) 2 to 3 times daily. Remove contact lenses beforehand (see “Notes for contact lens wearers”).

Children aged 2-6 years

For children aged 2-6 years, only use this medicine under medical supervision. Unless otherwise prescribed, the recommended dose is 1 drop in the affected eye 2 to 3 times daily.

Children under 2 years of age

Do not use this medicine in children under 2 years of age.

Method of administration:

Visine Relief is intended for use in the eyes.

1. Prior to the first use, remove the plastic seal on the neck of the bottle by tearing it open along the perforation.
2. Remove the child-resistant cap by pressing it and turning it counterclockwise.
3. After opening the cap, invert the bottle with the opening facing down. Tilt your head back slightly. Squeeze the bottle gently and instill 1 to 2 drops in the conjunctival sac. In order to avoid contamination of the solution in the bottle, the dropper of the bottle must not come into contact with anything other than the cap itself. Never touch the eye with the dropper!
4. After instilling drops, close and slightly open the eye for a few seconds to distribute the drops evenly in the eye.
5. Close the cap by turning it clockwise to the end. Never touch the dropper of the bottle. Close the bottle tightly immediately after use.

Do not exceed the recommended dose.

Duration of use

Visine Relief should be used for the shortest period of time required (no longer than 5 consecutive days) for the treatment of symptoms.

Repeated use should be conducted with caution, as long-term use (even with brief interruptions/pauses of a few days) or excessive use may lead to chronic swelling and/or shrinkage of the conjunctiva. Long-term use may increase eye redness.

If no improvement occurs within 48 hours, or if eye irritation or redness persists or increases, stop using Visine Relief and consult a doctor.

If you accidentally take a higher dosage

When used in the eyes, symptoms of overdose are unlikely. However, accidental ingestion can lead to serious side effects or poisoning, especially in children.

These serious side effects may include: cardiovascular instability (cardiovascular problems), drowsiness, coma, hypothermia (decrease in body temperature), bradycardia (slow heartbeat), hypotension (low blood pressure) or hypertension (high blood pressure), shock-like conditions, respiratory arrest, circulatory problems, vomiting, drooling and other systemic effects such as miosis (excessive constriction of the pupil), listlessness (lack of energy), dryness of the mucous membranes and atypical chest pain, increased redness of the mucous membranes of the eyes and nose.

Do not use more of this medicine than you should, and do not use it for too long (i.e., no longer than 3 to 5 days in a row), as this may cause a reduction in the effect of the medicine, worsen your eye redness or cause nasal symptoms.

If you accidentally took an overdose or if a child has swallowed the medicine, refer immediately to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of this medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Common side effects:

(effects that occur in 1-10 users in 100):

- Increased blood flow (reactive hyperemia)
- Burning of the mucous membranes
- Dryness of the mucous membranes
- Eye irritation (pain, stinging, burning)
- Worsening of vision

Rare side effects:

(effects that occur in 1-10 users in 10,000):

- Dilation of pupils

Very rare side effects:

(effects that occur in less than 1 user in 10,000):

- Drying of the conjunctiva with blocked tear duct after long-term use of tetrahydrozoline
- Watery eyes after long-term use of tetrahydrozoline

The following unknown frequency side effects may also occur:

(effects whose frequency has not been determined yet):

- Burning in and around the eyes, redness, irritation, swelling, pain, itching
- Excess tear flow

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and on the bottle. The expiry date refers to the last day of that month.
- Store below 30°C.
- After opening, use within 6 weeks and store below 30°C.
- Do not use this medicine if the solution changes color or becomes cloudy.
- Dispose of used Visine Relief sensibly and away from children and animals. Medicines should not be disposed of via household waste or wastewater. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Purified water, macrogol 400, boric acid, glycerol, hypromellose, potassium chloride, sodium lactate solution (50%), disodium phosphate, magnesium chloride hexahydrate, polixetonium chloride (also called polyquaternium-42), dextrose monohydrate, sodium citrate, glycine, ascorbic acid.

What the medicine looks like and the contents of the package:

Visine Relief is a clear, colorless to slightly yellowish, particle-free solution.

Visine Relief is available as 15 ml eye drops in a plastic bottle (LDPE) with a dropper (LDPE) and a child-resistant cap (HDPE/PP).

Registration holder: Kenvue Hellas Commercial Single Member S.A., Yakum, 6097200, Israel

Manufacturer: JNTL Consumer Health I (Switzerland) GmbH, Zug, Switzerland

Revised in 09.2025.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 177-97-37088

SH112395 PL v1