

**Patient package insert according to
Pharmacists' Regulations (Preparations)- 1986**
This medicine can be sold without a physician's prescription

V-ZOLINE, Eye Drops

Composition:

Tetrahydrozoline Hydrochloride 0.05% W/V.

Each 1 ml contains: 0.5 mg Tetrahydrozoline Hydrochloride.

Inactive ingredients and allergens in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

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

Use this medicine according to the instructions in section 3 "How to use this medicine?" in this leaflet. Consult the pharmacist if you need additional information. Refer to a doctor if the symptoms of your illness get worse or if they do not improve after 3 days.

1. What is the medicine intended for?

The medicine is intended for relief from soreness, burning, itching, irritation and redness due to congestion of the eyes.

Therapeutic group: Sympathomimetic decongestants.

2. Before using this medicine

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredient (Tetrahydrozoline Hydrochloride) or to any of the other ingredients this medicine contains (see section 6 "Additional Information").
- You suffer from narrow-angle glaucoma.
- Do not use this medicine in patients under the age of two years.

Special warnings regarding the use of this medicine

- **Before using the medicine, tell the doctor** if you are suffering from an infection, the presence of a foreign body and mechanical or chemical injury of the eye.
- Use the medicine only for mild irritation of the eyes.
- Use of the medicine is not recommended in complex conditions of the eye, such as glaucoma.
- Avoid contact of the medicine with the skin in cases of inflammation or injury, due to the presence of Boric Acid among the medicine's ingredients.
- Discontinue use and refer to a doctor if the signs of the illness (symptoms) do not improve within 3 days, or if the discomfort and redness intensify or persist, or in the event of eye pain, or if visual disturbances occur.
- Use of the medicine may cause temporary dilation of the pupil.
- Prolonged use and abuse of the medicine could cause the eye redness to increase or reoccur.
- Remove contact lenses before using the medicine.
- To avoid contamination, do not allow contact between the tip of the bottle and any surface.

Children and adolescents:

The medicine is intended for adults and children above the age of 6 years. For use in children below this age, refer to a doctor.

Drug interactions:

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

Pregnancy, breastfeeding and fertility:

No adequate controlled studies have been performed on the use of Tetrahydrozoline in pregnant or breastfeeding women.

It is not known whether Tetrahydrozoline or its metabolites are secreted into breastmilk.

Do not use the medicine during pregnancy or breastfeeding except in cases in which the potential benefit to the mother outweighs the potential risk to the unborn baby or to the breastfeeding baby.

Consult the doctor before commencing treatment if you are pregnant, planning to become pregnant or are breastfeeding.

Driving and using machines:

The use of the medicine could cause temporary blurring of vision.

Important information about some of the ingredients of this medicine

The medicine contains the preservative Benzalkonium Chloride, which could be absorbed by soft contact lenses and change their color. Remove contact lenses before using the medicine and reinsert them after 15 minutes from the time of use.

Benzalkonium Chloride could also cause eye irritation, especially if you suffer from dry eyes or disorders of the cornea. If you have an abnormal feeling in the eyes, stinging or eye pain after using the medicine, refer to your doctor.

This medicine contains 0.1 mg of Benzalkonium Chloride in each 1 ml, which is equivalent to 0.1 mg/ ml.

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

For adults and children above the age of 6, the usual dosage is generally: 1-2 drops into each eye, up to 4 times a day.

For children 2 to 6 years of age: Use under the supervision of healthcare professionals.

Do not use in children under the age of two years.

Should be used in children under the age of 12 with an adult supervision.

Do not exceed the recommended dose.

Method of administration:

Do not swallow! This medicine is intended for external use only.

Instructions for use:

1. Wash your hands thoroughly before using the eye drops.
2. Tilt back your head or lie down on a bed and with the aid of a finger, pull the lower eyelid away slightly from the eye and create a gap.
3. Instill the medicine into the gap, then keep your eyes closed for 1-2 minutes and do not blink.
4. To prevent contamination of the solution, take care not to allow the tip of the bottle to come in contact with any surface, including the finger and the eye and close the bottle tightly.

If you have accidentally taken a higher dosage

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

If you forgot to take the medicine

If you forgot to take this medicine at the designated 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 on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of **V-Zoline** 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.

The following are side effects that have been observed following the use of drops that contain Tetrahydrozoline for ocular use.

Very rare side effects (effects that appear in less than one out of 10,000 users):

- Vision disturbances- dilated pupils and increased tearing.
- Reactions at the medicine administration site (including a burning sensation in or around the eye, redness, irritation, edema, pain and itching).

Additional side effects

The frequency, type and severity of side effects in children are expected to be similar to those in adults.

Swallowing **V-Zoline** could cause instability in the cardiovascular system (blood vessels and heart system), suppression of the central nervous system (including sleepiness and coma) as well as respiratory depression, including cessation of breathing.

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

Report of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications and drugs" on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by following the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/ or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store below 25°C.
- Keep the bottle tightly closed.
- The medicine can be used for up to 30 days after the bottle is first opened and not later than the expiry date, that appears on the package.
- Throw the medicine out if the solution changes color or becomes cloudy.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

Boric Acid, Sodium Borate (Borax), Benzalkonium Chloride 50% Solution, Disodium Edetate, Sodium Hydroxide/ Hydrochloric Acid, Purified Water.

What the medicine looks like and what the package contains:

A bottle containing an aqueous, clear, colorless solution.

Approved package size: 10 ml.

Manufacturer and registration holder:

Vitamed Pharmaceutical Industries Ltd., 6 Hatahana St., P.O.B. 114, Binyamina 3055002, Israel.

Revised in June 2023 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

069-78-28589-00