

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

The medicine is dispensed without a doctor's prescription

Visine® Original
Eye Drops

Active ingredients -

Tetrahydrozoline HCl 0.05%

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.

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

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 signs of the illness worsen or do not improve after 3 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

Visine Original Eye Drops:

For relief of burning, stinging, irritation and redness of the eyes.

Therapeutic group: Sympathomimetic decongestants.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine (see details in section 6 – "Further Information").
- You suffer from narrow-angle glaucoma.
- Do not use this medicine in patients under the age of two years.

! Special warnings regarding use of the medicine

Before treatment with 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.
- Throw the medicine out if the solution changes color or becomes cloudy.

! 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 operating machinery

The use of eye drops could cause temporary blurring of vision.

! Important information about some of the ingredients of the 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 0.100 mg of benzalkonium chloride in each milligram.

This medicine contains 0.0864 mg of boron in each drop of solution. The maximum amount of solution a patient may receive daily is 16 drops.

Do not administer to a child under 2 years of age, as this medicine contains boron and may impair fertility in the future.

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 preparation.

For adults and children over 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.

Instructions for use:

If the medicine package comes with child-resistant closure:

To open the cap: Press on the cap and turn it to the left.

To close the cap, turn the cap to the right until you hear a click: Close the cap tightly to ensure that the child-resistant closure is closed.

Do not exceed the recommended dose

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

If you accidentally take a higher dosage

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a hospital emergency room, and bring the package of the medicine with you (see also section 4 - "Side Effects").

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 Visine Original Eye Drops 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 occur in less than one user in 10,000:

- Vision disturbances - dilated pupils, 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 Visine Original Eye Drops 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 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 at a temperature below 25°C.
- Keep the bottle tightly closed. Do not use the medicine for more than 28 days from first opening the bottle.
- Do not use the medicine if the solution changes color or becomes cloudy.
- Do not use if the safety seal printed on the bottle cap is damaged or missing.
- Do not throw away medicines in water or in the trash. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help you to protect the environment.
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6. FURTHER INFORMATION

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

Visine Original Eye Drops:

Sodium Chloride, Boric Acid, Edetate Disodium, Benzalkonium Chloride 50% Solution, Sodium Borate, Purified Water

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

- **Visine Original Eye Drops:** 15 ml bottle.

Registration holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer: Janssen Pharmaceutica NV, Beerse, Belgium

Revised in September 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Visine Original Eye Drops: 126-09-24800