

Package leaflet: Information for the user

Viset 0.5 mg/ml eye drops, solution

tetryzoline hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

What is in this leaflet

1. What Viset is and what it is used for
2. What you need to know before you use Viset
3. How to use Viset
4. Possible side effects
5. How to store Viset
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1. What Viset is and what it is used for

Viset eye drops, solution is a sterile solution that does not contain a preservative.

It contains the active substance tetryzoline hydrochloride which belongs to the group of medicines which narrow the blood vessels in the eye.

This medicine is used if you have non-infectious irritation/redness of the eye induced by smoke, wind, chlorinated water and light, as well as if you have allergic inflammation of the eye (e.g. seasonal allergy, allergy to pollen).

Local application of this medicine to the conjunctiva of the eye in a few minutes leads to constriction of blood capillaries (vasoconstriction) that lasts for 4 to 8 hours.

This medicine should only be used for mild eye irritations.

Irritation or redness of the eye may often be signs of serious eye disease (see section 2. What you need to know before you use Viset). In case of doubt, contact your doctor before you use this medicine.

You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

2. What you need to know before you use Viset

Do not use Viset:

- if you are allergic to tetryzoline hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- in patients with narrow angle glaucoma
- if you have severe disease of heart and blood vessels (e.g. coronary heart disease, high blood pressure)
- if you have tumor of the core of the adrenal gland (pheochromocytoma)
- if you have metabolic disorders: overactive thyroid gland (hyperthyroidism), porphyria or diabetes

- if you are taking monoamine oxidase inhibitors (MAO), tricyclic antidepressants or other medicines that may cause increase in blood pressure (see section Other medicines and Viset)
- if you have benign prostate enlargement (benign prostatic hyperplasia)
- in children younger than 2 years

Warnings and precautions

Talk to your doctor or pharmacist before using Viset:

- if you have dry inflammation of the nose (rhinitis sicca), inflammation of the cornea and conjunctiva (keratoconjunctivitis)
- if you have increased eye pressure (glaucoma).

If you have a history of contact hypersensitivity to silver, you should not use this product.

In case of severe eye pain, headache, loss of vision, occurrence of "floating" specks in the visual field, highly expressed acute or unilateral redness of the eye, occurrence of pain when exposed to light, double vision, contact your doctor immediately.

In case the irritation or redness of the eye is due to the severe eye disease e.g. eye infection, foreign body in the eye, or chemical injury of the cornea, contact your doctor immediately.

Prolonged and erroneous administration of this medicine, especially in doses higher than recommended, may decrease its effect and lead to redness of the conjunctiva and persistent nasal congestion.

Long-term use should be avoided, especially in children.

Children

Viset must not be used in infants and children younger than 2 years.

Always consult a doctor about the use of the medicine in children.

Other medicines and Viset

Concomitant treatment with the following medicines may intensify the effect of vasoconstriction and raise blood pressure (see also Do not use Viset):

- MAO inhibitors, used in the treatment of Parkinson's disease or depression, e.g. selegiline, rasagiline, moclobemide, tranylcypromine
- tricyclic antidepressants, e.g. amitriptyline and maprotiline
- other medicines that may increase blood pressure

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines not prescribed by a doctor.

Pregnancy and breast-feeding

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

No data are available on the passage of tetrahydrozoline hydrochloride through the placenta and its excretion in breast milk.

Do not use Viset if you are pregnant or breast-feeding.

Driving and using machines

Dilatation of pupils, light-induced blindness and blurred vision may occur after instillation of this medicine, which may affect your ability to drive and use machines. Before driving and using machines check how you react to the medicine.

3. How to use Viset

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

Posology

Adults and adolescents older than 12 years

If not otherwise prescribed, instill one drop in each affected eye 2 to 3 times daily.

Children aged 2-12 years

Use of this medicine is not recommended in children aged 2-12 years without previously consulting a doctor.

Children younger than 2 years

Viset must not be used in infants and children younger than 2 years.

Always consult a doctor about the use of the medicine in children.

Duration of use

If there is no improvement during the first 2 days, or if irritation and redness of the eye persist or intensify, you should immediately discontinue the use of the medicine and consult a doctor. It is possible that you have an eye disease that requires a different treatment.

Use of the medicine longer than 3 days is allowed only under medical supervision.

Method of administration

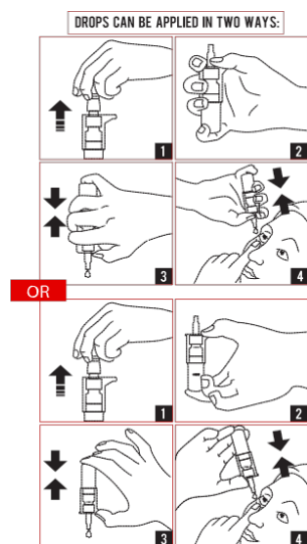
To be administered in the eyes only.

Do not swallow.

Information for contact lens users

In case of eye disease, contact lenses should not be worn. If, in special situations, it is allowed to wear contact lenses, they must be removed before application of the medicine. Lenses can be reinserted 15 minutes after application of the medicine.

Instructions for use:



1. Wash your hands.
2. Remove the protection cap from the bottle (picture 1).
3. Grasp the bottle with your hand (picture 2).

4. Turn the bottle upside down and activate the pump until the first drop appears (picture 3).

Before the first application after the first drop appears it is necessary to discard at least another 5 drops. Before each subsequent application it is necessary to discard 2 drops. If the medicine has not been used for more than 15 days, it is necessary to discard 5 drops before the application.

5. Tilt your head backwards and gently pull down your lower eyelid to form a pocket between lower eyelid and eye and holding the bottle upside down and by pressing the pump instill one drop in the eye (picture 4).

Do not touch anything with a dropper tip in order to avoid contamination of the solution.

6. Immediately after instillation press a finger into the corner of your eye, by the nose, or close your eyelids for 1-2 minutes. This helps to stop the medicine from getting into the rest of the body.

7. If you are using the medicine in the other eye as well, repeat the steps 5 and 6.

8. Close the bottle with the protection cap immediately after use.

If you use more Viset than you should

In case of overdose or ingestion of the medicine, immediately contact your doctor, pharmacist or nearest hospital and take this medicine or this package leaflet with you.

Signs of excessive local or systematic administration of the medicine are mydriasis (dilated pupils), cyanosis (bluish discoloration of the skin and mucous membranes), fever, convulsions, tachycardia (rapid heartbeat), cardiac arrhythmia (heart rhythm disorder), cardiac arrest, hypertension (high blood pressure), pulmonary edema (accumulation of fluid in the lungs), respiratory and mental disorders.

The risk of occurrence of overdose symptoms is particularly pronounced in infants and small children due to absorption as the result of ingestion of the medicine. Central nervous system disorders, respiratory and circulatory failure can occur.

If you forget to use Viset

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people)

- increased swelling of the mucous membrane of the eye (reactive hyperaemia), burning or dryness of the mucous membrane of the eye, palpitations (awareness of heartbeats), headache, tremor, weakness, sweating, increase in blood pressure, rapid pulse.

Rare (may affect up to 1 in 1,000 people)

- mydriasis (dilated pupils).

Very rare (may affect up to 1 in 10,000 people)

- keratinization (cornification) of the surface of conjunctiva with the closure of the tear ducts and epiphora ("watery eyes") after prolonged use of the medicine.

Not known (frequency cannot be estimated from the available data)

- stinging in the eye or around the eye, redness, swelling, pain, itching, blurred vision, irritation of the conjunctiva.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#).

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Viset

Keep this medicine out of the sight and reach of children.

Store below 30°C.

After first opening, the expiry date is 28 days. Store below 30°C after first opening.

Do not use this medicine after the expiry date which is stated on the package after "EXP".

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Viset contains

The active substance is tetryzoline hydrochloride.

One ml of eye drops, solution contains 0.5 mg of tetryzoline hydrochloride.

The excipients are: sodium chloride, boric acid, borax, water, purified.

What Viset looks like and contents of the pack

Clear and colourless solution. Does not contain preservative.

10 ml of solution in white plastic bottle with dropper pump, protection cap and red applicator, 1 bottle in cardboard box.

Marketing Authorisation Holder and Manufacturer

JADRAN-GALENSKI LABORATORIJ d.d

Svilno 20, 51000 Rijeka, Croatia

This medicinal product is authorised in the Member States of the EEA under the following names:

Poland: Starazolin Free

Slovenia: Neored 0,5 mg/ml kapljice za oko, raztopina

This leaflet was last revised in January 2020.