SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Visine original eye drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION in active ingredients

Tetryzoline Hydrochloride 0.05% w/v

3. PHARMACEUTICAL FORM

Ophthalmic solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Relief from soreness, burning, itching, irritation redness due to congestion of the eyes.

4.2 Posology and method of administration

Adults and children aged 6 years and older:
Instil 1-2 drops of Visine original eye drops on each eye, 4 times per day at most.
Children aged 6-12 years old :
Use under the supervision of an adult.
Children aged 2-6 years old:
Use under the supervision of a healthcare professional.

4.3 Contraindications

- Known hypersensitivity to the active ingredient or to any of the excipients.
- Narrow angle glaucoma.
- Children under 2 years old.

4.4 Special warnings and precautions for use

Visine original eye drops must be used only for light ophthalmic irritations. In cases of infections, presence of foreign objects in the eyes and mechanical or chemical eye trauma, it is necessary to consult your doctor. The use of Visine original eye drops is not indicated for serious ophthalmic conditions, such as glaucoma.
In addition, contact between Visine original eye drops and the skin must be avoided in presence of an inflammation or trauma, due to the boric acid contained.
Visine original eye drops 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.

The use of the product must be stopped and the condition evaluated by a healthcare professional if no relief occurs within 72 hours or if the disturbance and hyperaemia persist or increase, or if pain develops in the eye, along with changes in vision.
The long-term use and abuse of the product could lead to increase or reactive hyperaemia.
When using the product, the pupils of the eyes may temporarily enlarge.
The use of the product may cause temporary mydriasis.
The container nozzle must not come into contact with any surface to prevent contamination. The solution should be discarded if it has changed color or cloudy.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

No sufficient and properly controlled studies have been performed in order to specify the effect of tetryzoline hydrochloride on pregnant or breast-feeding women. It is not known if the product is excreted in human milk.
The product should not be used during pregnancy or lactation unless the potential benefit to the mother overcomes the potential risk to the developing fetus or nursing infant.
Although the product is not intended for systematic use, it is recommended for a healthcare professional to evaluate the risk/benefit, prior use by pregnant or breast-feeding women.

4.7 Effects on the ability to drive and use machines

Use of eye drops may cause temporary blurred vision.

4.8 Side effects

The side effects identified based on experience after the marketing of the Visine original eye drops ophthalmic solution are included in the following table. The incidence is noted in accordance with the following conventions:

Very common	≥1/10
Common	≥1/100 to <1/10,
Uncommon	≥1/1000 to <1/100,
Rare	**≥1/10,000 to <1/1,000,**
Very rare	**<1/10,000,**
Not known	**(cannot be estimated from the available data)**

Side effects resulting based on experience after the marketing of the tetryzoline ophthalmic solution, per frequency category.

Frequency category	**Side effect**
Visual deficit	
Very rare Very rare	Mydriasis Increased tearing
General disorders and administration site conditions	
Very rare	Reactions at the application site (the following are included: ophthalmic and periophthalmic

	burn, erythema, irritation, oedema, pain, and pruritus.

The frequency, type and gravity of the side effects in children is expected to be similar to those for adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medical product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il/

4.9 Overdose

Post-marketing safety data showed no adverse events associated with overdose.

From 1985 to 2012, FDA identified 96 cases of accidental ingestion of products containing tetryzoline, oxymetazoline or naphazoline by young children ages 1 month to 5 years. Fifty-three cases reported hospitalization due to symptoms including nausea, vomiting, lethargy, tachycardia, decreased respiration, bradycardia, hypotension, sedation, somnolence, mydriasis, stupor, hypothermia, drooling and coma.

Symptoms of overdosing in ophthalmic use are unlikely to occur, however, swallowing of the Visine original eye drops eye solution may be associated with serious side effects such as cardiovascular instability, CNS depression (including somnolence and coma) as well as respiratory depression, including apnea.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: S01GA02

Tetryzoline is a sympathomimetic agent belonging to the group of imidazoline decongestants. It stimulates directly the alpha-adrenergic receptors of the sympathetic neural system, with a small or no effect on beta-adrenergic receptors. When applied locally on the mucosa of the conjunctiva, it causes a temporary vasoconstrictive effect on blood microvessels, thus relieving from the vasodilatation of the conjunctiva and from the oedema.

5.2 Pharmacokinetic properties

In a study of 10 healthy volunteers, tetryzoline concentrations were detected both in serum and in urine, following therapeutic ophthalmic administration. The average half-life for tetryzoline in the serum was approx. 6 hours. The systematic absorption was different between the subjects, while the maximum serum concentrations ranged between 0.068 and 0.380 ng/ml. Within 24 hours, all patients had detectable tetryzoline concentrations in urines.

5.3 Preclinical safety data

Preclinical studies to evaluate the mutagenic, carcinogenic or teratogenic potential of the product, or of its ability to affect fertility or development have not been found.

The LD50 values reported for tetrazoline are 335 (oral), 252 (subcutaneous), 116 (intraperitoneal) and 48.1 (intravenous) mg / kg in mice. When is used as recommended, minimal systemic toxicity is expected due to poor application site absorption.

6. PHARMACEUTICAL DATA

6.1 List of excipients:

Sodium chloride, boric acid, sodium borate, benzalkonium chloride solution 50%, disodium edetate, purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store at temperatures between 15ºC to 25ºC.
To be used up to 28 days after opening.

6.5 Nature and contents of container

Visine original eye drops aseptic and colourless solution is marketed inside a plastic dropper vial of 15 ml.

6.6 Instructions for use/handling

Keep away from children and outside their field of view.

It is recommended to have an adult supervise use in children younger than 12 years of age.
The nozzle of the container must not come in contact with any surface, in order to avoid infections.
Place the lid of the container, after use, back on the container. The solution must be discarded if it has changed colour or become hazy.
Direct contact with contact lenses must be avoided.

7. Registration holder

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

8. Manufacrurer

Janssen Pharmaceutica N.V., Beerse, Belgium

9. Registration number

126-09-24800

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