Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Visine Relief

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml eye drops contain 0.5 mg (0.05% w/v) tetryzoline hydrochloride.

Excipients with known effect
Contains 7.5 µg phosphates per drop or 0.18 mg/ml.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

Clear, colorless to slightly yellowish solution.

4. CLINICAL PARTICULARS

4.1 Indications

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 (see sections 4.2 and 4.4).

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

4.2 Posology and method of administration

Dosage

Adults, adolescents and children aged 6 years and older:
The dosage is 1 to 2 drops in the affected eye 2 to 3 times daily.
This medicinal product should only be used for the shortest period of time required to control symptoms. There is a risk of rebound effect with prolonged use (see section 4.4).

Children
Use in children under 12 years of age requires supervision by an adult.
Children aged 2 years and older and under 6 years: This medicinal product may only be used in consultation with a physician (see section 4.4). The recommended dosage is 1 drop in the affected eye(s) 2 to 3 times daily.

This medicinal product is contraindicated in children under 2 years of age (see section 4.3).

Method of administration

For use in the eye.
After opening the cap, invert the bottle with the opening facing down. Squeeze the bottle gently to be able to dispense 1 to 2 drops into the eye without touching the eye.

To avoid contamination of the solution, do not allow the container tip to come into contact with anything other than the cap itself.

4.3 Contraindications

- Hypersensitivity to the active ingredient or any of the excipients listed in section 6.1.
- Angle-closure glaucoma.
- Children under 2 years of age.

4.4 Special warnings and precautions for use

Do not use Visine Relief in
- severe cardiovascular disease (e.g. coronary artery disease, hypertension, pheochromocytoma),
- prostatic hyperplasia,
- metabolic disorders (e.g. hyperthyroidism, diabetes, porphyria),
- rhinitis sicca,
- keratoconjunctivitis sicca,
- glaucoma (see below for details).

Overdose or long-term use of this medicinal product (longer than 3 to 5 days) may lead to tachyphylaxis and cause increased redness of the eyes (rebound hyperemia) or the nasal mucosa (rhinitis medicamentosa) and should be avoided.

Children
The use of this medicinal product in children aged 2 years and older and under 6 years may only take place in consultation with a physician.

Must not be used in children under 2 years of age.

Long-term use and overdose should be avoided, particularly in children. Therefore, use in children and at higher dosages may only take place under medical supervision.

Other precautions
Use in angle-closure glaucoma is contraindicated. For other forms of glaucoma, use should only take place with special caution and under medical supervision.

Even recommended topical dosages should be given with caution in hyperthyroidism, heart disease, high blood pressure and diabetes mellitus.

Patients using Visine Relief should be aware that eye irritation or eye redness is often a sign of a serious eye condition and therefore requires consultation with an ophthalmologist.

Visine Relief should only be used in milder eye irritations. If no improvement occurs within 48 hours, or if eye irritation or redness persists or increases, the use of this medicinal product should not be continued and a physician should be consulted.

Eye irritation or redness due to infections, foreign bodies or chemical damage to the cornea also require medical treatment. If eye pain, headache, loss of vision, visual disturbances (e.g. seeing floaters or double vision), severe acute or one-sided eye redness or pain in the eye with exposure to light occur, the product should be discontinued and a physician should be consulted immediately.

When using this medicinal product, the pupils may temporarily be dilated.

In general, contact lenses should not be worn with eye diseases. If contact lenses are worn, they must be removed before use of the medicinal product and reinserted after waiting at least 15 minutes.

4.5 Interactions with other medicinal products and other forms of interaction

Concomitant use of MAO inhibitors of the tranylcypromine type or tricyclic antidepressants together with drugs that have the potential to increase blood pressure (e.g. tetryzoline hydrochloride) may potentiate the vasoconstrictor effect and increase blood pressure. Their use in combination should therefore be avoided if possible.
A physician should be consulted before using this medicinal product together with other ophthalmic agents.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate and well-controlled studies available investigating the effect of tetryzoline in pregnancy.
This medicinal product should not be used during pregnancy unless a physician concludes that the possible benefit of treatment for the mother outweighs the possible risk for the fetus.

Breastfeeding
There are no adequate and well-controlled studies available that investigate the effect of tetryzoline while breastfeeding. It is not known whether the active substance and its metabolites are excreted in human milk.
This medicinal product should not be used while breastfeeding, unless a physician concludes that the possible benefit of treatment for the mother outweighs the possible risks for the breastfed child.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

Medicinal products for use in the eye can temporarily cause visual disturbances (blurred vision and mydriasis) that impair the ability to drive and use machines. Patients should therefore not participate in road traffic or use machines until this impairment has subsided.

4.8 Undesirable effects

Adverse reactions observed with tetryzoline 0.05% during clinical studies and after market introduction are categorized by system organ class (SOC) in the table below.

Information on the frequency of adverse reactions is classified based on the following categories:

Very common: ≥ 1/10
Common: ≥ 1/100, < 1/10
Uncommon: ≥ 1/1,000, < 1/100
Rare: ≥ 1/10,000, < 1/1,000
Very rare: < 1/10,000
Not known: Frequency cannot be estimated based on the available data

Adverse reactions are listed by frequency, based on
1) incidence in clinical or epidemiological studies, if available, or
2) if no frequencies are available, the frequency is listed as “not known.”

System organ class (SOC)	**Frequency**	**Undesirable effects**
Eye disorders	Common	Eye irritation (pain, stinging, burning), worsening of visual acuity
	Rare	Mydriasis
	Very rare	Epithelial keratinization (xerosis) of the conjunctiva with punctal occlusion and epiphora (watery eyes) after long-term use of tetryzoline hydrochloride
	Not known	Increased lacrimation
General disorders and administration site conditions	Common	Reactive hyperemia, mucosal burning, mucosal dryness
	Not known	Application site reactions (including ocular and periocular burning, erythema, irritation, edema, pain, itching)

Adverse reactions due to excipients
Very rarely, cases of calcium deposits in the cornea have been reported in some patients with severely damaged cornea associated with the use of phosphate-containing eye drops.

Reporting suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal 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

Based on the review of the available safety data, no adverse drug reactions related to overdose were identified. When used in the eye, symptoms of overdose are unlikely. However, tetryzoline may cause serious adverse reactions if accidentally swallowed.

Overdose or long-term use of this medicinal product (longer than 3 to 5 days) may lead to tachyphylaxis and cause increased redness of the eyes (rebound hyperemia) or the nasal mucosa (rhinitis medicamentosa) and should be avoided.

Symptoms of overdose
The clinical picture of intoxication with imidazole derivatives can be confusing, since phases of stimulation can alternate with phases of depression of the central nervous system and the cardiovascular system.

Symptoms of CNS stimulation include anxiety, agitation, hallucinations, and convulsions. Symptoms of CNS depression include lowering of body temperature, lethargy, drowsiness, and coma.

The following additional symptoms may occur: miosis, mydriasis, sweating, fever, pallor, cyanosis, nausea, vomiting, tachycardia, bradycardia, cardiac arrhythmia, palpitations, cardiac arrest, hypertension, shock-like hypotension, pulmonary edema, respiratory impairment, hypersalivation, and apnea.
Particularly in children, overdose by ingestion frequently leads to dominant CNS effects with spasms and coma, bradycardia, apnea, as well as hypertension that may be replaced by hypotension. As low as 0.01 mg tetryzoline hydrochloride per kilogram of body weight must be considered a toxic dose.

Treatment measures in the event of overdose
Administration of activated charcoal, gastric emptying, ventilation with oxygen, fever reduction and anticonvulsant therapy. Vasopressors are contraindicated in hypotension.
If anticholinergic symptoms occur, an antidote, e.g. physostigmine, must be used.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Decongestants for ophthalmic use, sympathomimetics

ATC code: S01GA02

Mechanism of action
Tetryzoline is a sympathomimetic agent belonging to the imidazoline group of decongestants. It directly stimulates α-adrenergic receptors of the sympathetic nervous system with no or low activity on β-adrenergic receptors.

Pharmacodynamic effects
As a sympathomimetic amine, it has vasoconstrictor and mucosal decongestant properties. When applied topically to the conjunctiva, it produces a temporary vasoconstricting effect on small blood vessels, thereby alleviating conjunctival vasodilation and edema.

Clinical efficacy and safety
In a double-blind, randomized, controlled study, symptom relief was observed within 30-60 seconds after treatment with tetryzoline 0.05%. Improvement lasted for 6 hours after use. However, 8 hours after use, the efficacy of tetryzoline in terms of relief of erythema was

similar to placebo. Overall, the decongestant effect of tetryzoline lasted between 6 and 8 hours.

A double-blind, randomized, single-day study in 120 patients showed that tetryzoline eye drops (0.05%) reduced eye redness from baseline and improved visual comfort for 12 hours 30 seconds after use according to the instructions. A patient questionnaire evaluating sensory secondary endpoints showed a significant improvement ($p < 0.001$) compared to the baseline value of eye moisture at 60 seconds, 10 hours and 12 hours after the first use of the eye drops.

5.2 Pharmacokinetic properties

Absorption
In a study of 10 healthy subjects, systemic absorption was different between subjects. The maximum serum concentration was between 0.068 and 0.380 ng/ml.

Absorption of tetryzoline hydrochloride is only minor with proper topical application. Systemic absorption after topical application, particularly in mucosal damage with epithelial injury, cannot be ruled out.

Distribution
No data is available.

Biotransformation
No data is available.

Elimination
In a study of 10 healthy subjects, tetryzoline concentrations were detectable in both serum and urine following therapeutic application to the eye. The mean plasma half-life was approx. 6 hours. After 24 hours, all subjects had measurable tetryzoline concentrations in the urine.

Linearity/non-linearity
No data is available.

Pharmacokinetic/pharmacodynamic associations
No data is available.

5.3 Preclinical safety data

Local toxicity
The application of a tetryzoline solution buffered to pH 5.5 (0.25% and 0.50%) administered twice a day on five consecutive days did not lead to eye irritation in rabbits.

Acute toxicity
Animal studies revealed no particular sensitivity to tetryzoline hydrochloride. The acute LD_{50} of tetryzoline hydrochloride when administered orally is 420 mg/kg for mice and 785 mg/kg for rats.

Chronic toxicity
No substance-related toxic effects occurred in rats after several weeks of oral administration of 10 or 30 mg tetryzoline hydrochloride per kilogram body weight. Rhesus monkeys showed sedation and hypnosis that lasted 120 days after intravenous administration of 5 or 10 mg/kg BW and 32 weeks after oral administration of 5 to 50 mg/kg BW. However, low systemic toxicity is expected when used as eye drops.

There are no preclinical data on the genotoxic and carcinogenic potential or the reproductive toxicity of tetryzoline.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
Shelf life after opening: 6 weeks.

6.4 Special precautions for storage

Store below 30ºC.
Discard 6 weeks after opening.

6.5 Nature and contents of container

15 ml solution in a bottle (LDPE) with a dropper (LDPE) and a child-resistant cap (PP/HDPE).

6.6 Special precautions for disposal and other handling

Discard the medicinal product if the solution changes color or becomes cloudy.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. REGISTRATION HOLDER

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

8. MANUFACTURER

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

9. REGISTRATION NUMBER

177-97-37088

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