

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Murine irritation & redness relief, 0.012% w/v, eye drops solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Actives

Naphazoline Hydrochloride 0.012 % w/v.

Excipients with known effect:

Contains Benzalkonium Chloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Drops solution (eye drops).

A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For temporary symptomatic relief of redness of the eye due to minor eye irritations.

4.2 Posology and method of administration

Posology

Adults and Children 12 years and over:

The recommended dosage is one or two drops into each eye two or three times daily.

This product is for intermittent or occasional use only (see section 4.4).

Paediatric Population

The safety and efficacy of Murine in children aged 0 to 12 years have not been established. No data are available.

Method of Administration: For ocular use

If other eye drops/ointments are additionally being used, an interval of approximately 15 minutes should be observed between the doses and any eye ointment should always be applied last (see section 4.5).

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

Murine is contraindicated in subjects with: angle-closure glaucoma, a narrow chamber angle (at risk for acute glaucoma), previous attacks of acute glaucoma due to a narrow chamber angle, iritis or corneal damage. This product must not be used prior to peripheral iridectomy in eyes susceptible to angle closure because mydriatic action may precipitate angle block.

Do not take if you are suffering from serious eye disease or have had previous eye surgery.

Do not use while taking monoamine oxidase inhibitors or within 14 days of stopping this medication (see section 4.5).

Use in patients with contact lenses.

Not to be used in children younger than 12 years of age.

4.4 Special warnings and precautions for use

This product is for intermittent or occasional use only. Rebound effects have been reported after prolonged and/or excessive use of naphazoline containing eye drops.

If you are being treated for high blood pressure, depression, heart disease, arteriosclerosis, diabetes or increased thyroid activity consult your doctor before using the drops as naphazoline may exacerbate vasoconstriction. For the same reason this product should not be used as a long term ocular irrigant.

Murine should not be used if there is an eye condition characterised by continued redness, pain or blurring of vision.

If you experience severe eye pain, changes of vision or discharge from the eye, photophobia, continued redness or irritation of the eye, or if after 24 hours the condition worsens or shows no sign of improvement, discontinue use and consult a doctor.

Use of naphazoline in the eye may liberate pigment granules from the iris, especially when given in high doses to elderly patients.

Discontinue use prior to use of anaesthetics which sensitise the myocardium to sympathomimetics (e.g. cyclopropane, halothane).

Contains benzalkonium chloride which may cause eye irritation. Avoid contact with soft contact lenses; remove contact lenses prior to application and wait at least 15 minutes before re-insertion; known to discolour soft contact lenses.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

If the solution changes colour or becomes cloudy do not use.

4.5 Interaction with other medicinal products and other forms of interaction

Patients should be advised to leave a short interval between the administration of Murine and other ocular products. It is generally recommended this interval should be of 15 minutes duration.

May interact with other topically applied autonomic drugs used in the treatment of glaucoma.

May interact with monoamine oxidase inhibitors and should not be used by patients receiving such treatment or within 14 days of ceasing therapy.

May reverse the antihypertensive action of drugs used in the treatment of hypertension. There may be increased risk of arrhythmias in patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited data from the use of naphazoline in pregnant women. As a precautionary measure, it is preferable to avoid the use of the product during pregnancy unless recommended by the healthcare professional.

Breast-feeding

Although the safety of Murine during lactation has not been established, it is unlikely that sufficient amounts of the active ingredients will reach the breastfed infant to be harmful.

Fertility

No known effects

4.7 Effects on ability to drive and use machines

This product may have minor influence on the ability to drive and use machines. Dizziness may occur following administration of the product (see Section 4.8) and vision may be blurred due to adding liquid to the eye.

4.8 Undesirable effects

Adverse events which have been associated with naphazoline hydrochloride are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common ($\geq 1/10$); Common ($\geq 1/100$ to $< 1/10$); Uncommon ($\geq 1/1000$ to $< 1/100$); Rare ($\geq 1/10,000$ to $< 1/1000$); Very rare ($< 1/10,000$); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity
Nervous System Disorders	Not known	Headache, dizziness
Eye Disorders	Not known	Eye irritation, eye pain, ocular hyperaemia ¹
Gastrointestinal Disorders	Not known	Nausea

Description of Selected Adverse Reactions

¹Following long term use a rebound secondary hyperaemia may occur.

Reporting of 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. Healthcare professionals are asked to report any suspected adverse reactions via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

Symptoms

If applied in excessive quantities to the eye, it may give rise to irritation and stinging. Overdosage or accidental administration by mouth may cause headache, nausea, depression of CNS, reduction of body temperature, bradycardia, sweating, drowsiness and coma, particularly in children.

Hypertension may be followed by hypotension.

Excessive or long-term use of this product may result in allergic conjunctivitis, allergic blepharitis or rebound conjunctival hyperaemia. Prolonged use may also lead to epithelial xerosis which can exacerbate symptoms of irritation, pain and dryness experienced in allergic conjunctivitis.

Indiscriminate use of decongestants, such as naphazoline, in an irritated eye can induce papillary dilation and precipitate angle-closure glaucoma in eyes that have narrow anterior chamber angles.

Overuse may produce increased redness of the eye. Should this occur, discontinue use. If the redness continues consult a doctor.

Post marketing data has shown that excessive systemic exposure, for example due to intentional or accidental overdose of naphazoline (including inadvertent oral ingestion), may lead to severe cardiovascular and/or cerebrovascular adverse reactions.

Management

Treatment of adverse effects should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sympathomimetics used as decongestants ATC code: S01GA01

Mechanism of action: Naphazoline is a sympathomimetic agent with marked alpha-adrenergic activity and as a consequence has vasoconstrictor activity. Applied as an eye drop, it causes conjunctival vasoconstriction within 10 minutes. Effects can last for up to 6 hours.

5.2 Pharmacokinetic properties

Absorption: Absorbed following instillation into conjunctival sacs.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Boric acid (E284)
Borax (E285)
Purified water
Disodium edetate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years.
Once opened: 1 month.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

5 ml of liquid in a LDPE bottle fitted with a LDPE drop-forming plug and a polypropylene cap.

10 ml of liquid in a HDPE bottle fitted with a LDPE/DPE drop-forming plug and a polypropylene cap.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Do not use if the solution changes colour or becomes cloudy. Discard one month after opening.

7 MARKETING AUTHORISATION HOLDER

Elara Pharmaservices Europe Limited
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8 MARKETING AUTHORISATION NUMBER

PA22637/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983

Date of last renewal: 1st April 2008

10 DATE OF REVISION OF THE TEXT

July 2025