1 NAME OF THE MEDICINAL PRODUCT

Murine Red & Sore Eyes 0.12mg/ml Eye Drops, Solution

Cleareyes 0.12mg/ml Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active

Naphazoline hydrochloride 0.12 mg/ml

Excipient(s) with known effect:

This medicine contains 0.034 mg benzalkonium chloride in each drop which is equivalent to 0.1 mg/ml.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution

Clear, colourless liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of occasional, minor redness and irritation of the eye.

Murine is indicated in adults and children aged 12 years and over.

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/eye 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.

4.3 Contraindications

Hypersensitivity to the active substance 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 use Murine while taking monoamine oxidase inhibitors or within 14 days of stopping this medication (see section 4.5).

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.

Patients who are being treated for high blood pressure, depression, heart disease, arteriosclerosis, diabetes or increased thyroid activity, should consult their 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 (see section 4.9).

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

If there is any eye pain, vision changes, 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.

Patients who have had eye surgery should not take Murine until they have been advised by a doctor that their recovery is complete.

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., desflurane, sevoflurane).

Murine should not to be used in children younger than 12 years of age.

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

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.

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

4.5 Interaction with other medicinal products and other forms of interaction

- Murine may interact with other topically applied autonomic drugs used in the treatment of glaucoma.
- Murine may interact with monoamine oxidase inhibitors and should not be used by patients receiving such treatment or within 14 days of ceasing therapy.
- Murine may reverse the antihypertensive action of drugs used in the treatment of hypertension. There may be an increased risk of arrhythmias in patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited data about the use of naphazoline by pregnant women. In a published cohort study, use of eye-drops containing naphazoline and antazoline by 3061 women during the first trimester of pregnancy was not associated with major congenital malformations overall or with any specific major malformation. As a precaution, use of Murine should be avoided during pregnancy unless recommended by a healthcare professional.

Lactation

It is not known whether naphazoline is excreted in breast milk, and an effect on the breastfed child cannot be excluded.

Fertility

No known effects.

4.7 Effects on ability to drive and use machines

Do not drive or operate machinery if vision is blurred. Naphazoline has no or negligible other influence on the ability to drive and use machines.

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 (≥1/10); Common

(≥1/100 to <1/10); Uncommon (≥1/1000 to <1/100); Rare (≥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. Very occasionally transient eye irritation (including stinging and itching), transient blurred vision, and mydriasis (pupil dilation) have been reported.

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

Description of Selected Adverse Reactions

[1]Following 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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Overdosage or accidental administration by mouth may cause depression of CNS, headache, nausea, reduction of body temperature, bradycardia, sweating, drowsiness and coma, particularly in children. Hypertension may be followed by rebound 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.

Management

Treatment of side-effects is 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. It is a vasoconstrictor that reduces swelling and congestion when applied to mucous membrane.

Murine has an onset of effect within 1 minute after instillation and the effect is maintained for at least 3 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 SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride solution

Boric acid (E284)

Borax (E285)

Purified water

Disodium edetate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened 10 mL: 3 years

Unopened 5 mL: 2 years

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 solution in a LDPE plastic bottle, drop-forming LDPE plastic plug and polypropylene plastic cap.

10 ml of solution in a HDPE plastic bottle, drop-forming LDPE/DPE plastic plug and polypropylene plastic cap

6.6 Special precautions for disposal

Do not use if the solution changes colour or becomes cloudy.

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

7 MARKETING AUTHORISATION HOLDER

Prestige Brands (UK) Ltd

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St. Albans

AL1 1LA,

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/11/2018

10 DATE OF REVISION OF THE TEXT

07/08/2024