

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

Naphazoline Hydrochloride 0.012 % w/v.

Excipient: 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

As a decongestant for relief of minor eye irritation.

4.2 Posology and method of administration

Adults and Children 12 years and over:

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

4.3 Contraindications

Glaucoma, corneal damage, acute iritis and other serious eye disease. Known sensitivity to the ingredients.

This product should not be used prior to peripheral iridectomy in eyes capable of angle closure because mydriatic action may precipitate angle block.

4.4 Special warnings and precautions for use

Not to be used at the same time as contact lenses.

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

As with other sympathomimetics, use with caution in the presence of hypertension, diabetes, hyperthyroidism, cardiovascular abnormalities and arteriosclerosis.

Benzalkonium chloride, used as a preservative, has been reported to cause punctuate keratopathy and/or toxic ulcerative keratopathy. It may cause eye irritation and is known to discolour soft contact lenses. Take out contact lenses before putting the drops into the eyes; re-insert contact lenses about 15 minutes after putting the drops into the eyes.

4.5 Interaction with other medicinal products and other forms of interaction

Currently there is no information regarding the use of Murine and the absorption of concomitant ocular products. However, 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.

4.6 Fertility, pregnancy and lactation

No special precautions.

4.7 Effects on ability to drive and use machines

Do not drive or operate machinery if vision is blurred.

4.8 Undesirable effects

May cause slight dilation of pupil.

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 HPRA 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

Overdosage or accidental administration by mouth may cause depression of CNS, reduction of body temperature, drowsiness and coma, particularly in children. In addition, overdosage may cause increased redness of the eye. Treatment of side-effects is symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Naphazoline is a sympathomimetic agent with marked alpha-adrenergic activity. It is a vasoconstrictor with a rapid and prolonged action in reducing swelling and congestion when applied to mucous membrane.

5.2 Pharmacokinetic properties

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

Prestige Brands (UK) Ltd.
46 High Street
Yatton
Somerset
BS49 4HJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA1118/001/001

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

August 2017