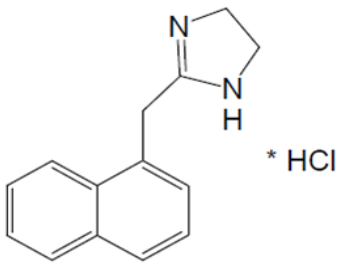
PRODUCT INFORMATION

SYSTANE RED EYES (naphazoline hydrochloride) Eye Drops

NAME OF THE MEDICINE

Naphazoline hydrochloride

Chemical structure:



Empirical formula:

$C_{14}H_{14}N_2$.HCl

Chemical name:

1H-Imidazole,4,5-dihydro-2-(1-naphthalenylmethyl) monohydrochloride

CAS Registry Number:

550-99-2

DESCRIPTION

SYSTANE RED EYES Eye Drops contain a decongestant prepared as a sterile solution for ophthalmic use.

SYSTANE RED EYES Eye Drops contain 1 mg/mL naphazoline hydrochloride and the excipients boric acid, sodium chloride, potassium chloride, disodium edetate, sodium carbonate monohydrate, hydrochloric acid and water-purified. The solution is preserved with benzalkonium chloride (0.1 mg/mL).

PHARMACOLOGY

SYSTANE RED EYES Eye Drops contain the active ingredient, naphazoline hydrochloride, which is an imidazoline derivative sympathomimetic amine. It has a vasoconstriction action through a local adrenergic mechanism on conjunctival blood vessels.

INDICATIONS

For use as a topical ocular vasoconstrictor.

For relief of red congested eyes.

CONTRAINDICATIONS

SYSTANE RED EYES Eye Drops are contraindicated in patients who have narrow-angle glaucoma or other serious eye conditions or who have hypersensitivity to any of the ingredients.

PRECAUTIONS

For topical ophthalmic use only.

Patients being treated with monoamine oxidase inhibitors (MAOIs) may experience a severe hypertensive crisis if administered a sympathomimetic drug.

Use with caution in children, the elderly, patients with severe cardiovascular disease including cardiac arrhythmia and patients with sympathetic denervation (e.g. patients with diabetes, orthostatic hypotension, hypertension, hyperthyroidism) due to the risk for possible systemic effects.

Prolonged and/or excessive use may lead to rebound ocular vasodilatation or congestion.

Systemic absorption may occur and cause interaction with other therapy, particularly antihypertensive drugs.

SYSTANE RED EYES Eye Drops contain benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to application of SYSTANE RED EYES Eye Drops and wait at least 15 minutes before reinsertion.

To prevent contaminating the dropper tip and solution, care should be taken to not to touch the eyelids or surrounding area with the dropper tip of the bottle.

Effects on fertility
Studies have not been performed to evaluate the effect of topical ocular administration of SYSTANE RED EYES on human fertility.

Use in pregnancy
There are no or a limited amount of data from the use of topical ophthalmic naphazoline in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.

Use in lactation
It is unknown whether topical naphazoline/metabolites are excreted in human milk. However, a risk to the breastfed child cannot be excluded.

Paediatric use
Safety and effectiveness in children under twelve years of age have not been established.

Genotoxicity
There are no or a limited amount of animal data describing the teratogenic effects of naphazoline.

Effects on the ability to drive and use machinery
SYSTANE RED EYES Eye Drops may cause transient mydriasis, temporary blurred vision or other visual disturbances that may affect the ability to drive or use machines. If there is mydriasis or if blurred vision occurs after instillation, the patient must wait until the vision clears before driving or using machinery.

INTERACTIONS WITH OTHER MEDICINES

Patients being treated with monoamine oxidase inhibitors (MAOIs) may experience a severe hypertensive reaction if administered with a sympathomimetic drug. Although this reaction has not specifically been reported with topical ophthalmic naphazoline, the possibility of such an interaction should be considered.

ADVERSE EFFECTS

Sensitivity reactions may occur. Transient stinging may occur after instillation. Rebound congestion may occur after prolonged or frequent use. The following adverse reactions have been identified from post-marketing surveillance following administration of SYSTANE RED EYES Eye Drops. Frequency cannot be estimated from the available data.

System Organ Classification	**MedDRA Preferred Term (v.14.1)**
Eye disorders	Mydriasis, ocular hyperaemia

Paediatric population
Accidental ingestion or excessive use of naphazoline in infants and young children may cause depression of the central nervous system and significant reduction in body temperature.

DOSAGE AND ADMINISTRATION

One or two drops in the conjunctival sac(s) results in prompt decongestion lasting several hours and subsiding slowly.
Instil 1 or 2 drops in the affected eye(s) every 3-4 hours as required, or as directed by your doctor or pharmacist.
Not for use in children.

Avoid prolonged use as rebound congestion, characterised by reactive hyperaemia, may occur.

OVERDOSAGE

In case of overdosage or accidental ingestion, naphazoline can cause the following, particularly in children: depression of the central nervous system with a clear fall in body temperature and symptoms of bradycardia, excessive sweating, drowsiness and coma; hypertension followed by hypotension. Treatment of an oral overdose is symptomatic and supportive.

For information on the management of overdose, contact the Poison Information Centre on 13 11 26.

PRESENTATION AND STORAGE CONDITIONS

SYSTANE RED EYES Eye Drops 15 mL DROP-TAINER®

Store below 25°C. Discard container 4 weeks after opening. Protect from excessive heat.

NAME AND ADDRESS OF SPONSOR

Novartis Pharmaceuticals Australia Pty Ltd
54 Waterloo Road
Macquarie Park NSW 2113
Phone Toll Free: 1 800 671 203

POISON SCHEDULE OF THE MEDICINE

Pharmacy Medicine (S2)

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (ARTG)

14 March 2017

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