AUSTRALIAN PRODUCT INFORMATION – ALBALON® (NAPHAZOLINE HYDROCHLORIDE) EYE DROPS

1 NAME OF THE MEDICINE

Naphazoline hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of ALBALON® eye drops contains 1 mg naphazoline hydrochloride.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Eye drops, solution.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For use as a topical ocular vasoconstrictor.

4.2 DOSE AND METHOD OF ADMINISTRATION

1 or 2 drops every three to four hours.

In order to minimise systemic absorption of ALBALON® eye drops, apply pressure to the tear duct immediately following administration of the drug.

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

Do not use in children under 12 years of age.

4.3 CONTRAINDICATIONS

Hypersensitivity to any component of these medications; narrow angle glaucoma or anatomically narrow angle.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions

This preparation should not be used in patients who have glaucoma or other serious eye conditions.

Potential systemic effects

A severe hypertensive crisis may ensue in patients under MAOI medication from use of a sympathomimetic drug.

Use only with caution in patients with hypertension, cardiac diseases, hyperglycaemia (diabetes), hyperthyroidism, and in individual under treatment with antidepressants or when other medications are being used.

ALBALON® eye drops should be given with care to patients with prostatic enlargement as it may increase difficulty in micturition.

If the condition requiring treatment does not respond promptly (i.e. within 48 hours) or if symptoms recur following treatment, medical opinion should be sought.

This preparation should not be used for prolonged periods (i.e. more than 14 days) except on medical advice.

Eye inflammation

ALBALON® eye drops should be used with caution on the inflamed eye, as significant hyperemia greatly increases the rate of systemic absorption through the conjunctiva and prolonged or frequent use, especially in inflamed eye, may result in increased absorption and possible systemic effects.

Use with contact lenses

ALBALON® eye drops contain the preservative benzalkonium chloride, which may be absorbed by and cause discolouration of soft contact lenses. Patients wearing soft (hydrophilic) contact lenses should be instructed to remove contact lenses prior to administration and wait at least 15 minutes following administration before reinserting soft contact lenses.

Potential of eye injury or contamination

To prevent eye injury or contamination, care should be taken to avoid touching the dispensing container to the eye or to any other surface. The use of the bottle by more than one person may spread infection.

Examination of patient

If symptoms persist or worsen after a short period of treatment (approximately 2-3 days), consult a doctor.

Use in the elderly

No data available.

Paediatric use

Safety and effectiveness in children have not been established [see Section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)]. Use in children, especially infants, may result in CNS depression leading to coma and marked reduction in body temperature.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Concurrent use of methyldopa, maprotiline or tricyclic antidepressants and naphazoline may potentiate the pressor effect of naphazoline. Patients under therapy with MAOI medication may experience a severe hypertensive crisis if given a sympathomimetic drug [see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE].

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

Animal reproduction studies have not been conducted with naphazoline. It is also not known whether naphazoline can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Naphazoline should be given to a pregnant woman only if clearly needed.

Use in lactation

It is not known whether naphazoline is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when naphazoline is administered to a nursing woman.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

As with other ocular medication, if transient blurred vision occurs at instillation, the patient should wait until their vision clears before driving or using machinery.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Pupillary dilation with increased intraocular pressure, systemic effects due to absorption (hypertension, cardiac irregularities, hyperglycaemia). Drowsiness may be experienced in some patients.

Postmarketing experience

The following adverse reactions have been identified during postmarketing use of ALBALON® eye drops. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made.

Eye disorders: Eye oedema, eye irritation, eye pain, mydriasis, ocular hyperemia, vision blurred.

Immune system disorders: Hypersensitivity (including allergic dermatitis).

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

ALBALON® eye drops can cause peripheral vasoconstriction and severe central nervous depression including hypertension followed by reflex braddycardia and hypotension, marked reduction in body temperature, sweating, drowsiness and coma particularly in susceptible adults and children.

In case of overdosage, flush the affected eye(s) with water or normal saline.

Accidental ingestion (especially in children) may cause marked sedation requiring emergency treatment.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Naphazoline constricts the vascular system of the conjunctiva. It is presumed this effect is due to direct action of the drug upon the α-(excitory) receptors of the vascular smooth muscle. It is characterised by a relatively long duration of action and belongs to the imidazoline class of sympathomimetics.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Genotoxicity was either not assessed or not identified as part of the registration of this medicine.

Carcinogenicity

Carcinogenicity was either not assessed or not identified as part of the registration of this medicine.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Polyvinyl alcohol 14 mg/mL, with benzalkonium chloride, disodium edetate, citric acid, sodium citrate, sodium chloride, sodium hydroxide and purified water.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

3 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25ºC. Protect from light.

Do not use if solution changes colour or becomes cloudy.

To avoid contamination of the solution, keep container tightly closed.

Do not touch dropper tip to any surface.

Contents are sterile if seal is intact.

6.5 NATURE AND CONTENTS OF CONTAINER

ALBALON® eye drops solution is supplied in dropper bottles. Each bottle has a fill volume of 15 mL.

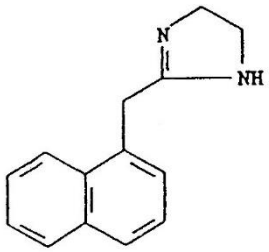
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Discard unused contents 4 weeks after opening the bottle.

6.7 PHYSICOCHEMICAL PROPERTIES

Naphazoline hydrochloride is a white, odourless crystalline powder. Freely soluble in water and in alcohol; very slightly soluble in chloroform; practically insoluble in ether. A 1% solution in water has a pH of 5.0 to 6.6.

Chemical structure



Chemical Name: 4,5,-dihydro-2-(1-naphthalenylmethyl)-1H-imidazole hydrochloride.
MW: 246.7
Empirical Formula: $C_{14}H_{14}N_2$,HCl

CAS number: 550-99-2

7 MEDICINE SCHEDULE (POISONS STANDARD)

S2 - Pharmacy Medicine

AUST R 23197

8 SPONSOR

AbbVie Pty Ltd
241 O'Riordan Street
Mascot NSW 2020
Australia

9 DATE OF FIRST APPROVAL

14 November, 1995

10 DATE OF REVISION

24 August 2023

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
Dosage and Administration	Changed “Not for use in children, unless under medical advice” to “Do not use in children under 12 years of age”.
Sponsor	Sponsor Details updated.