AUSTRALIAN PRODUCT INFORMATION – ALBALON®-A (NAPHAZOLINE HYDROCHLORIDE/ ANTAZOLINE PHOSPHATE) EYE DROPS

1 NAME OF THE MEDICINE

Naphazoline hydrochloride and antazoline phosphate.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of ALBALON®-A eye drops contains 0.5 mg (0.05%) naphazoline hydrochloride and 5 mg (0.5%) antazoline phosphate.

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 relief of ocular irritation and/or congestion, and for the treatment of allergic, inflammatory ocular conditions.

4.2 DOSE AND METHOD OF ADMINISTRATION

1 or 2 drops every three to four hours.

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

Not for use in children, unless under medical advice.

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.

Keep bottle tightly closed when not in use.

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 which contains naphazoline should not be used in patients who have glaucoma or other serious eye conditions

Potential systemic effects

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

ALBALON® A eye drops should be given with care to patients with prostatic enlargement as it may increase difficulty in micturition. This precaution is relevant to the naphazoline component only.

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

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

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

Eye inflammation

ALBALON®-A eye drops which contain naphazoline 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. This precaution is relevant to the naphazoline component only.

Use with contact lenses

ALBALON® A 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 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 and/or antazoline. It is also not known whether naphazoline and/or antazoline can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Naphazoline and/or antazoline should be given to a pregnant woman only if clearly needed.

Use in lactation.

It is not known whether these drugs are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when naphazoline and/or antazoline 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 most frequently reported events were eye irritation and eye pain. These events were most often reported as 'burning sensation in the eye' and 'stinging sensation in the eyes' which occurred upon instillation of the product.

The following adverse reactions have been identified during post marketing use of ALBALON® eye drops which contains naphazoline. Because they were reported voluntarily from a population of unknown size, estimates of frequency could not 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®A eye drops which contain naphazoline 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 reduction 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.

Antazoline is an H_1-receptor blocking agent which inhibits most muscle responses to histamine.

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

Inactive: polyvinyl alcohol (LIQUIFILM®) 14 mg/mL, disodium edetate, povidone, sodium chloride, sodium acetate, sodium hydroxide and purified water.

Preservative: benzalkonium chloride

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

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

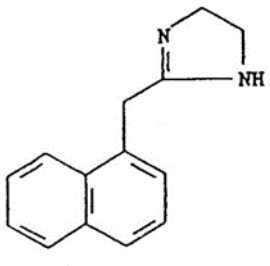
Discard unused contents 4 weeks after opening the bottle.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure and CAS numbers

Naphazoline hydrochloride

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.



(structure of naphazoline)

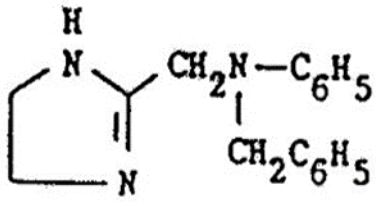
Chemical Name: 4,5,-dihydro-2-(1-naphthalenylmethyl)-1H-imidazole hydrochloride.

MW: 246.7
Empirical Formula: $C_{14}H_{14}N_2$,HCl

CAS number: 550-99-2

Antazoline phosphate

Antazoline phosphate is a white to off-white crystalline powder. Soluble in water, sparingly soluble in methyl alcohol; practically insoluble in ether. A 2% solution in water has a pH of 4.0 to 5.0.



(structure of antazoline)

Chemical Name: 4,5-dihydro-N-phenyl-N-(-phenylmethyl)-1H-imidazole-2-methanamine phosphate.

MW: 363.4
Empirical Formula: $C_{17}H_{19}N_3,H_3PO_4$

CAS number: 154-68-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

S2 – Pharmacy Medicine

AUST R 23091

8 SPONSOR

Allergan Australia Pty Ltd
810 Pacific Highway
Gordon NSW 2072
ABN: 85 000 612 831

9 DATE OF FIRST APPROVAL

14 October 1991

10 DATE OF REVISION

11 February 2021

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	The PI has be reformatted in line with the TGA's approved form for PIs.