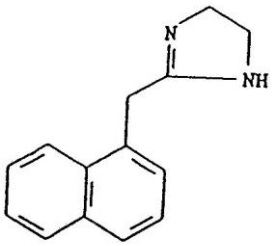
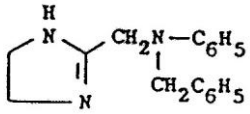
ALBALON®-A Eye Drops

NAME OF THE DRUG

The active constituents of ALBALON®-A eye drops are naphazoline hydrochloride and antazoline phosphate.

(structure of naphazoline)





(structure of antazoline)

DESCRIPTION

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

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.

Chemical Name: 4,5-dihydro-N-phenyl-N-(-phenylmethyl)-1H-imidazole-2-methanamine phosphate.
MW: 363.4

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

ALBALON-A eye drops contain naphazoline hydrochloride 0.5 mg/mL, antazoline phosphate 5 mg/mL, polyvinyl alcohol (LIQUIFILM®) 14 mg/mL, benzalkonium chloride, disodium edetate, povidone, sodium chloride, sodium acetate, sodium hydroxide and purified water.

PHARMACOLOGY
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.

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

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

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 of 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 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.

Paediatric Use: Safety and effectiveness in children have not been established (see Adverse Reactions). Use in children, especially infants, may result in CNS depression leading to coma and marked reduction in body temperature.
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.

Drug 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 symapthomimetic drug (see Precautions).

ADVERSE REACTIONS
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).

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

DOSAGE AND 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.

OVERDOSAGE

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.

PRESENTATION and STORAGE CONDITIONS

Eye drops:	naphazoline hydrochloride 0.5 mg/mL (0.05%) antazoline phosphate 5 mg/mL (0.5%) 15 mL (dropper bottle).
Storage:	Store below 25^{o}C. Protect from light.
Shelf life:	3 years.

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.
Discard unused contents 4 weeks after opening the bottle.
Contents are sterile if seal is intact.

AUST R 23091

NAME and ADDRESS OF THE SPONSOR

Allergan Australia Pty Ltd
810 Pacific Highway
Gordon NSW 2072

ABN: 85 000 612 831

TGA Approval Date: 14 October 1991
Date of most recent amendment: 16 March 2015

Poison Schedule: S2