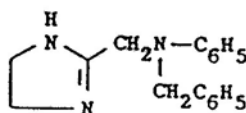
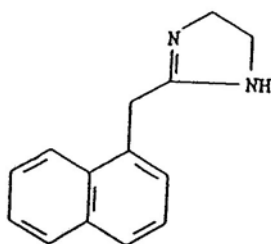


## ALBALON®-A Eye Drops

### 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<sub>14</sub>H<sub>14</sub>N<sub>2</sub>,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<sub>17</sub>H<sub>19</sub>N<sub>3</sub>,H<sub>3</sub>PO<sub>4</sub>

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  $\alpha$ -(excitatory) 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<sub>1</sub>-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**

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

Use only with caution in the presence of hypertension, cardiac irregularities, hyperglycaemia (diabetes), hyperthyroidism, and 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.

**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.

**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 sympathomimetic 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.

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

## **DOSAGE AND ADMINISTRATION**

1 or 2 drops every three to four hours.

In order to minimise systemic absorption of ALBALON<sup>®</sup>-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**

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

## **PRESENTATION**

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°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

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**Poison Schedule:** S2

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