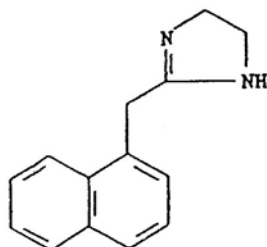


ALBALON® Eye Drops

NAME OF THE DRUG

The active constituent of ALBALON® eye drops is naphazoline hydrochloride.



(structure of naphazoline)

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: C₁₄H₁₄N₂,HCl

ALBALON® eye drops contain naphazoline hydrochloride 1 mg/mL, polyvinyl alcohol 14 mg/mL, with benzalkonium chloride, disodium edetate, citric acid, sodium citrate, sodium chloride, 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 -(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.

INDICATIONS

For use as a topical ocular vasoconstrictor.

CONTRAINDICATIONS

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

PRECAUTIONS

A severe hypertensive 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 (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.

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.

Paediatric Use: Safety and effectiveness in children have not been established (see Adverse Reactions).

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® 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.
Not for use in children, unless under medical advice.

OVERDOSAGE

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

PRESENTATION

Eye drops:	naphazoline hydrochloride 1 mg/mL 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.

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Poison Schedule: S2

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