

ALBALON RELIEF™ Eye Drops

PRODUCT DESCRIPTION

Active: Phenylephrine hydrochloride 0.12% w/v, Molecular formula: C₉H₁₃NO₂, HCl
CAS: 61-76-7. MW:203.7

Inactives: Polyvinyl alcohol (LIQUIFILM®) 1.4% w/v, disodium edetate, sodium acetate, sodium phosphate monobasic, sodium phosphate dibasic heptahydrate, sodium thiosulfate, sodium hydroxide or hydrochloric acid, purified water. Contains no antimicrobial agent.

Phenylephrine hydrochloride is a white or almost white crystal or crystalline powder that is freely soluble in water and alcohol.

PHARMACOLOGY

ALBALON RELIEF™ contains phenylephrine hydrochloride which has a topical decongestant vasoconstrictive action.

ALBALON RELIEF™ is a lubricating, decongestant eye drop that relieves minor irritations, and contains LIQUIFILM® as a lubricant to relieve dry, irritated eyes.

PHARMACOKINETICS

Since phenylephrine is absorbed through the mucosa, systemic effects may follow application to the eyes.

INDICATIONS

Decongestant, vasoconstrictor, lubricating eye drop for the relief of minor eye irritations caused by colds, hayfever, dust, smog, contact lenses, sun, wind, swimming and allergy.

CONTRAINDICATIONS

Hypersensitivity to phenylephrine hydrochloride or any of the other components. Not to be used in the presence of glaucoma or other serious eye conditions, or while wearing soft contact lenses (see 'Precautions').

PRECAUTIONS

Pupillary dilation may occur in some individuals. Patients should be advised that prolonged use of this product may result in rebound congestion. Patients should also be advised to discontinue use and seek medical advice if symptoms persist for more than 72 hours or worsen.

Patients using other eye products should be advised to seek medical advice before using ALBALON RELIEF™ eye drops. For external use only.

Not for use while wearing soft contact lenses. Patients wearing soft contact lenses should be instructed to remove their lenses prior to instilling ALBALON RELIEF™ eye drops and wait at least 15 minutes before reinserting the lenses.

Use in pregnancy: Category B2.

The Australian Categorisation definition of Category B is as follows:

Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed.

Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage.

Use in Lactation

Since many drugs are excreted in human milk, caution should be exercised if ALBALON RELIEF™ eye drops are administered to a breastfeeding woman.

ADVERSE REACTIONS

Pupillary dilation may occur in some individuals. Prolonged use may result in increased redness of the eye. Some patients may also experience epithelial xerosis from prolonged topical instillation of local decongestants, which may exacerbate the symptoms.

DOSAGE AND ADMINISTRATION

1 or 2 drops should be instilled in the affected eye(s). Patients should be advised that instillation may be repeated in three to four hours as needed.

Patients should be advised that to avoid contamination, the ampoule tip should not be touched to any surface and to discard unused contents after opening.

OVERDOSAGE

No information on overdosage is available in humans. Should accidental overdosage in the eye(s) occur, flush eye(s) with water or normal saline. Contact the Poison's Information Centre (13 11 26) if there is concern over possible accidental ingestion.

PRESENTATION

Eye drops:	Eye drops (sterile, single use ampoules) 1.2 mg/mL (0.12%), 0.4 mL: 5's
Storage:	Store below 25°C.

AUST R 52293
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Poisons schedule : Unscheduled

ABN: 85 000 612 831

Date of TGA Approval 17 May 2004

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