

DATA SHEET

NAME OF MEDICINE

ALBALON RELIEF™ phenylephrine hydrochloride 1.2 mg per mL.

PRESENTATION

Contains: phenylephrine hydrochloride 0.12%, polyvinyl alcohol (Liquifilm) 1.4%, disodium edetate, disodium phosphate monobasic, sodium phosphate dibasic heptahydrate, sodium acetate, sodium thiosulphate, sodium hydroxide or hydrochloric acid and purified water.

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

USES: Actions

A soothing, lubricating, decongestant eye drop. It also improves the appearance of the eye through the blanching effect of the mild vasoconstrictor, phenylephrine.

PHARMACOKINETICS

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

INDICATIONS

ALBALON RELIEF™ is a preservative free decongestant, vasoconstrictor lubricating eye drops, for the relief of minor eye irritations caused by colds, hayfever, dust, smog, contact lenses, sun, wind, swimming and allergy.

DOSAGE AND ADMINISTRATION

Use one or two drops in the affected eye(s). May be repeated in three to four hours as needed.

CONTRAINDICATIONS

Hypersensitivity to phenylephrine hydrochloride or any of the other components. Should not be used in the presence of narrow angle glaucoma or other serious eye conditions, or with soft contact lenses (see precautions).

WARNINGS AND PRECAUTIONS

To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Pupils may dilate in some individuals. If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor. Overuse of this product may produce increased redness of the eye. If solution changes colour or becomes cloudy, do not use.

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.

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 if there is concern over possible accidental ingestion.

PHARMACEUTICAL PRECAUTIONS

Store below 25°C. Open single-use container immediately before applying eye drops. Use once only and then discard.

MEDICINE CLASSIFICATION

General Medicine.

PACKAGE QUANTITIES

Eye Drops, 0.4 mL sterile unit dose containers in packs of 5s.

NAME AND ADDRESS

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