

PACKAGE INSERT

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

MINIMS* TROPICAMIDE 1 % Eye Drops.

COMPOSITION

Each dispensing unit of 0,5 ml contains:

Tropicamide 5,0 mg

Excipient includes purified water.

PHARMACOLOGICAL CLASIFICATION

A 15.4 Ophthalmic preparations: Other

PHARMACOLOGICAL ACTION

Tropicamide is an anticholinergic drug, having mydriatic and some cycloplegic activity.

It has a rapid onset of action (15 – 30 minutes) and a short duration of effect which varies from less than an hour up to four hours. Tropicamide is inadequate for cycloplegia in children.

INDICATIONS

Tropicamide is indicated when mydriasis and cycloplegia of rapid onset and brief duration are required.

CONTRAINDICATIONS

Tropicamide should not be used in patients with a narrow angle between the iris and cornea.

DOSAGE AND DIRTECTIONS FOR USE

Sterile if unopened. Use once and discard.

Adults: 2 drops at 5 minute intervals, with a further 1 or 2 drops after 30 minutes if required.

Children: At the discretion of the ophthalmologist.

SIDE EFFECTS

Photophobia; may cause conjunctival irritation in sensitive persons. Although absorption into the bloodstream from the conjunctival sac is minimal systemic toxicity can occur, particularly in small children. Such side-effects include dryness of the mouth with difficulty in swallowing, bradycardia followed by tachycardia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Toxic effects include tachycardia, and depressant and stimulant action of the central nervous system. Physostigmine salicylate 1-2 mg should be injected subcutaneously, intra-muscularly or intravenously to control toxic effects. Locally, mydriatic effects may be counteracted by the instillation of pilocarpine eye drops, 1 % to 4 %.

IDENTIFICATION

Clear, colourless sterile solution reasonably free from visible particulate matter, contained in a sealed polypropylene tube fitted with a pull off cap and overwrapped in a polypropylene pouch sealed onto paper.

PRESENTATION

Sterile, single dose disposable eye drops in cartons of 10 units, each containing approximately 0,5 ml.

STORAGE INSTRUCTIONS

Store between 2 – 8 °C, protected from light. DO NOT FREEZE. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

N/15.4/123

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE
OF REGISTRATION**

Soflens (Pty) Ltd

254 Hall Street

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0157

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