

## 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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**DATE OF PUBLICATION OF THIS PACKAGE INSERT**

August 20, 1981

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