

PACKAGE INSERT

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

MINIMS* TETRACAINE HYDROCHLORIDE 1,0 % Eye drops

COMPOSITION

Each dispensing unit of 0,5 ml contains:

Tetracaine hydrochloride 5,0 mg (1,0 % m/v)

Excipients include purified water.

PHARMACOLOGICAL CLASSIFICATION

A 15.4 Ophthalmic preparations: Other

PHARMACOLOGICAL ACTION

Tetracaine hydrochloride is a local surface anaesthetic which acts by blocking sensory nerve endings near the site of application.

INDICATIONS

In ophthalmology tetracaine hydrochloride is used to anaesthetise the cornea during ophthalmological procedures. Tetracaine hydrochloride is used for minor conjunctival and corneal surgery and is especially useful for the removal of foreign bodies. It is also used for gonioscopy in cases of suspected glaucoma since it does not cause dilation of the pupil.

CONTRAINDICATIONS

Patients with a known sensitivity to tetracaine. Tetracaine hydrochloride is hydrolysed in the body to p-aminobenzoic acid which inhibits the action of sulphonamides; amethocaine should therefore not be used in patient being treated with sulphonamides.

WARNINGS AND SPECIAL PRECAUTIONS

The use of tetracaine hydrochloride may give rise to dermatitis in sensitive patients. Cardiovascular collapse may occur due to idiosyncrasy and occasionally, convulsions and hyperexcitability.

DOSAGE AND DIRECTIONS FOR USE

To be used as directed by the ophthalmologist. Onset of action is 9 – 26 seconds, and the duration of effect is 10-20 minutes.

SIDE EFFECTS

Instillation of tetracaine hydrochloride causes conjunctival irritation, and punctate corneal damage may occur due to the accumulation of lactic acid.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS

TREATMENT

See **SIDE EFFECTS** and **WARNINGS AND SPECIAL PRECAUTIONS**.

Treatment is supportive and symptomatic.

IDENTIFICATION

Clear, colourless 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 20 units, each containing approximately 0,5 ml.

STORAGE INSTRUCTIONS

Store in the refrigerator between 2-8 °C protected from light. DO NOT FREEZE. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

C/15.4/47

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

Soflens (Pty) Ltd

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