

Package Insert

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME (AND DOSAGE FORM):

MINIMS* PROXYMETACAINE HYDROCHLORIDE 0,5 % Eye Drops

COMPOSITION (per dispensing unit of 0,5 ml)

Proxymetacaine Hydrochloride 0,0025 g.

PHARMACOLOGICAL CLASSIFICATION

A 15.4 Ophthalmic preparations - Other

PHARMACOLOGICAL ACTION

Proxymetacaine reversibly blocks the initiation and conduction of nerve impulses by decreasing the permeability of the neuronal membrane to sodium ions.

INDICATIONS

To be used as a topical ocular anaesthetic.

CONTRA-INDICATIONS

Do not use in patients with a known hypersensitivity to any component of the preparation.

Do not use in premature babies, due to the immaturity of the enzyme system which metabolises the ester type local anaesthetics.

Do not use in the presence of ocular inflammation and / or infection.

WARNINGS:

Use with caution in patients with known allergies, cardiac disease or hyperthyroidism because of the increased risk of sensitivity reactions.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children:

To be used as a single dose treatment.

Deep anaesthesia: Instil 1 drop every 5 – 10 minutes for 5 – 7 applications.

Removal of sutures: Instil 1 or 2 drops 2 to 3 minutes before removal of stitches.

Removal of foreign bodies: Instil 1 or 2 drops prior to operating.

Tonometry: Instil 1 or 2 drops immediately before measurement.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Pupillary dilatation or cycloplegic effects, as well as irritation of the conjunctiva have occurred less frequently. A severe, immediate-type apparently hyperallergic corneal reaction may less frequently occur.

This includes acute, intense and diffuse epithelial keratitis; a grey ground-glass appearance; sloughing of large areas of necrotic epithelium; corneal filaments and sometimes, iritis.

Allergic contact dermatitis has also been reported.

Patients should be warned not to rub or touch the eye while anaesthesia persists and the anaesthetised eye should be protected from dust and bacterial contamination.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF

ITS TREATMENT:

See "side-effects and special precautions". Treatment is symptomatic and supportive.

IDENTIFICATION:

Clear, colourless to pale yellow solution.

PRESENTATION:

Sterile, single-dose, disposable eye drops in cartons of 20 units, each unit containing approximately 0,5 ml.

STORAGE INSTRUCTIONS:

Store at 2 – 8 °C in the refrigerator. DO NOT FREEZE.

Keep out of reach of children

REGISTRATION NUMBER:

35/15.4/0088

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Soflens (Pty) Ltd

254 Hall Street

Centurion

0157

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