

PACKAGE INSERT

SCHEDULING STATUS

S4

PROPRIETARY NAME (AND DOSAGE FORM):

MINIMS* OXYBUPROCAINE HYDROCHLORIDE 0,4 % Eye Drops

COMPOSITION (per dispensing unit of 0,5 ml)

Oxybuprocaine Hydrochloride 2 mg

PHARMACOLOGICAL CLASSIFICATION

A 15.4 Ophthalmic preparations: other

PHARMACOLOGICAL ACTION

Oxybuprocaine hydrochloride is an effective surface anaesthetic which acts by blocking sensory nerve endings near the site of application. The solution produces little conjunctival irritation or hyperaemia and has no effect on the pupil; it has a bacteriostatic action and reduces the risk of exposure keratitis.

INDICATIONS

Used in applanation tonometry and for the fitting of contact lenses.

CONTRA-INDICATIONS

Caution should be observed when Oxybuprocaine hydrochloride is used in patients with allergies, cardiac disease, hyperthyroidism, or open lesions.

DOSAGE AND DIRECTIONS FOR USE

Adults and children: To be used as directed by the ophthalmologist. 1-3 drops of 0,4% solution, depending on the degree of anaesthesia required. Onset of action is 6-20 seconds and duration of effect is 15 minutes.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Eye disorders

Frequency unknown: Eye allergy, allergic blepharitis

Systemic toxicity is rarely seen following ocular administration, but is identical to that for amethocaine hydrochloride; namely cardiovascular collapse due to idiosyncrasy and occasionally, convulsions and hyperexcitability.

In rare cases, local anaesthetic preparations have been associated with allergic reactions (in the most severe instances, anaphylactic shock).

Immune system disorders

Frequency unknown: Hypersensitivity, anaphylactic reaction/shock.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT

Not applicable.

IDENTIFICATION

Clear, colourless solution.

PRESENTATION

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

STORAGE INSTRUCTIONS

Store in the refrigerator, protected from strong light. DO NOT FREEZE.

Keep out of reach of children.

REGISTRATION NUMBER

C/15/4/44

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

Soflens (Pty) Ltd

254 Hall Street

Centurion

0157

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August 26, 1970