

DATA SHEET

NAME OF MEDICINE

OPHTHETIC[®] (proxymetacaine hydrochloride) 5 mg/mL eye drops

PRESENTATION

Clear, colourless to slightly yellow solution.

USES

Actions

Topical anaesthetics stabilise the neuronal membrane and prevent initiation and transmission of nerve impulses thereby effecting local anaesthesia. OPTHETIC[®] eye drops are a rapidly acting topical anaesthetic with induced anaesthesia lasting 15 minutes or longer.

Pharmacokinetics

Nil

Indications

Procedures in which a topical ophthalmic anaesthetic lasting 15 minutes or longer is indicated: corneal anaesthesia of short duration, e.g. tonometry, gonioscopy, removal of corneal foreign bodies and for short corneal and conjunctival procedures.

DOSAGE AND ADMINISTRATION

Removal of Foreign Bodies and Sutures, Tonometry:

1 to 2 drops (in single instillations) in affected eye(s), before operating.

Deep Ophthalmic Anaesthesia:

One drop in affected eye every 5 to 10 minutes for 5-7 doses.

In order to minimise systemic absorption of OPTHETIC[®] eye drops, apply pressure to the tear duct immediately following administration of the drug.

Note: Because the "blink" reflex is temporarily eliminated, it is suggested that the eye be covered with a patch following this procedure.

CONTRAINDICATIONS

Contraindicated in patients with known hypersensitivity to any ingredients of this preparation (see FURTHER INFORMATION).

WARNINGS AND PRECAUTIONS

Prolonged use of a topical ocular anaesthetic is not recommended due to diminished duration of anaesthesia and retardation of wound healing. It may produce permanent corneal opacification with accompanying visual loss or corneal perforation may occur.

OPHTHETIC[®] eye drops are for topical use only. OPTHETIC[®] eye drops should only be administered by suitably qualified personnel. Proxymetacaine hydrochloride should be used sparingly in patients with known allergies, cardiac disease or hyperthyroidism. Although very rare (<0.01%), it should be borne in mind that systemic toxicity (manifested by central nervous system stimulation followed by depression) may occur.

Protection of the eye from irritating chemicals, foreign bodies and rubbing during the period of anaesthesia is very important. Tonometers soaked in sterilising or detergent solutions should be thoroughly rinsed with sterile distilled water prior to use.

Patients should be advised not to touch or rub the eye(s) until the effect of the anaesthetic has worn off.

Use in Pregnancy and lactation

Animal reproduction studies have not been conducted with OPTHETIC[®] eye drops. It is also not known whether proxymetacaine hydrochloride can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Proxymetacaine hydrochloride should be administered to a pregnant woman only if clearly needed.

It is not known whether the drug is excreted in human milk. Caution should be exercised when proxymetacaine hydrochloride is administered to a woman who is breast feeding.

Paediatric Use

Controlled clinical studies have not been performed with OPTHETIC[®] eye drops to establish safety and effectiveness in children.

ADVERSE EFFECTS

Instillation of proxymetacaine in the eye at the recommended concentration and dosage usually produces little or no signs of sensitivity. Occasional temporary stinging, burning and conjunctival redness have been reported after use of proxymetacaine, as well as a rare, severe, immediate-type, apparently hyperallergic corneal reaction, with acute, intense and diffuse epithelial keratitis, a grey, ground glass appearance, sloughing of large areas of necrotic epithelium, corneal filaments and sometimes iritis with descemetitis.

Allergic contact dermatitis from proxymetacaine with drying and fissuring of the fingertips has been reported.

Pupillary dilation or cycloplegic effects have been very rarely (<0.01%) observed with proxymetacaine hydrochloride.

Softening and erosion of the corneal epithelium and conjunctival congestion and haemorrhage have been reported.

INTERACTIONS

Nil

OVERDOSAGE

In the eye: Flush eye with water or normal saline. Protect eye from pressure.
Taken orally: Induce emesis, and gastric lavage. Check blood pressure, and heart beat. If respiration is obstructed, start immediate oxygen therapy, and maintain a patent airway.

PHARMACEUTICAL PRECAUTIONS

To avoid contamination of the solution, keep container tightly closed. Do not touch dropper tip to any surface. Contents are sterile if seal is intact.

Do not use if solution is discoloured (amber).

Shelf life: 1 year

Storage: Store between 2-8° C. Refrigerate, do not freeze.

Bottle must be stored in unit carton to protect contents from light.

Discard contents 4 weeks after opening the bottle.

MEDICINE CLASSIFICATION

Prescription Medicine

PACKAGE QUANTITIES

Dropper bottle, 15 mL

FURTHER INFORMATION

List of excipients

PRESERVATIVE: benzalkonium chloride

INACTIVES: glycerol, sodium chloride sodium hydroxide and purified water.

NAME AND ADDRESS

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DATE OF PREPARATION

16th June 2000