NEW ZEALAND DATA SHEET

1. PRODUCT NAME

ALCAINE™ proxymetacaine hydrochloride Eye Drops 0.5%.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Alcaine™ Eye Drops contain the active ingredient proxymetacaine hydrochloride 0.5% (5 mg/mL).

Excipient with known effect

Benzalkonium chloride 0.1 mg in 1 mL as a preservative.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Sterile preserved eye drops, solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Alcaine™ Eye Drops are indicated for procedures in which a rapid and short-acting topical ophthalmic anaesthetic is indicated such as in cataract surgery and suture removal from the cornea, and in tonometry, gonioscopy, removal of corneal foreign bodies, conjunctival scraping for diagnostic purposes, and other short corneal and conjunctival procedures.

4.2. Dose and method of administration

For ocular use only. Single patient use only.

After the cap is removed, if tamper evident snap collar is loose, remove before using product.

If more than one topical ophthalmic product is being used, the products must be administered at least 5 minutes apart. Eye ointments should be administered last.

To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip. Keep the bottle tightly closed when not in use.

For tonometry and other procedures of short duration, instil one or two drops just prior to evaluation. For minor surgical procedures such as foreign body or suture removal, instil one to two drops every five to ten minutes for one to three doses. For prolonged anaesthesia as in cataract extraction, instil one to two drops in the eye(s) every five to ten minutes for three to five doses.

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

Patients should be advised to avoid touching or rubbing the eye until the anaesthesia has worn off.

4.3. Contraindications

Alcaine™ is contraindicated in patients with known hypersensitivity to proxymetacaine hydrochloride or any of the excipients listed under section 6.1.

4.4. Special warnings and precautions for use

NOT FOR INJECTION INTO THE EYE

Prolonged use of a topical ocular anaesthetic may produce a diminished duration of the effect, thus more and more of the medication is required to produce the desired anaesthetic effect. Prolonged use or abuse may result in corneal epithelial toxicity and may manifest as epithelial defects, subsequent corneal damage, corneal infection, corneal perforation and/or corneal opacification with accompanying permanent loss of vision. The long term toxicity of proxymetacaine hydrochloride is unknown; prolonged use may possibly delay wound healing. Although exceedingly rare with ophthalmic application of local anaesthetics, it should be borne in mind that systemic toxicity (manifested by central nervous system stimulation followed by depression) may occur.

Local anaesthetics should be used cautiously and sparingly in patients with known allergies, epilepsy, cardiac disease, hyperthyroidism or in patients with respiratory problems. Patients who suffer from myasthenia gravis are particularly sensitive to the effects of anaesthetics. Patients with a low amount of acetylcholinesterase in the plasma, and patients being treated with cholinesterase inhibitors exhibit an increased risk for systemic side effects during topical application of ester-type anaesthetics.

Protection of the eyes 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.

Advise patients that, due to the effect of the anaesthetic, their eyes will be insensitive and that care should be taken to avoid accidental eye injuries.

Alcaine™ Eye drops may cause allergic contact dermatitis. Avoid contact with the skin.

Alcaine Eye Drops are intended for administration by a healthcare professional for ophthalmic procedures. Topical ophthalmic anaesthetics are not intended for use by patients for self-administration.

Paediatric use

Controlled clinical studies have not been performed with Alcaine™ Eye Drops to establish safety and effectiveness in children, however, the literature cites the use of proxymetacaine hydrochloride as a topical ophthalmic anaesthetic agent in children.

Use in the elderly

There is no information available for use in patients above 65 years of age.

Use in patients with hepatic or renal impairment

The safety and efficacy of proxymetacaine ophthalmic solution in patients with hepatic or renal impairment have not been established.

Contact lenses

Alcaine™ contains the preservative benzalkonium chloride, which may cause eye irritation, discolour and be deposited in soft (hydrophilic) contact lenses. Contact lens wear is not recommended until the anaesthetic effect has worn-off.

4.5 Interactions with other medicinal products and other forms of interactions

The metabolism of local anaesthetics derived from esters may be inhibited by anticholinesterases thus increasing the risk of systemic toxicity.

4.6 Fertility, pregnancy and lactation

Pregnancy

Category B2.

Animal reproduction studies have not been conducted with Alcaine™ Eye Drops. It is not known whether proxymetacaine hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Proxymetacaine hydrochloride is not recommended during pregnancy.

Breast-feeding

It is not known whether this drug is excreted in human milk however, a risk to the suckling child cannot be excluded. Because many drugs are excreted in human milk, caution should be exercised when proxymetacaine hydrochloride is administered to a breastfeeding woman.

Use only when considered essential by the physician.

Effects on fertility

No study has been conducted to determine the possible adverse effects of proxymetacaine hydrochloride on fertility.

4.7 Effects on ability to drive or use machines

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after administration, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable effects

Pupillary dilatation or cycloplegic effect have rarely been observed with proxymetacaine hydrochloride. The drug appears to be safe for use in patients sensitive to other local anaesthetics, but local or systemic sensitivity occasionally occurs. Instillation of proxymetacaine in the eye at recommended concentration and dosage usually produces little or no initial irritation, stinging, burning, conjunctival redness, lacrimation or increased winking. However, some local irritation and stinging may occur several hours after instillation.

Rarely, a severe, immediate-type, apparently hyperallergic corneal reaction may occur which include acute, intense and diffuse epithelial keratitis; a grey, ground-glass appearance; sloughing of large areas of necrotic epithelium; corneal filaments and, sometimes, iritis and descemetitis.

Allergic contact dermatitis with drying and fissuring of the fingertips has been reported. Softening and erosion of the corneal epithelium and conjunctival congestion and haemorrhage have been reported.

Postmarketing experience

The following adverse reactions have been reported following use of proxymetacaine topical ocular preparations. Frequencies cannot be estimated from the available data. Within each System Organ Class, adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	MedDRA Preferred Term (v.25.1)
Immune system Disorders	Hypersensitivity.
Nervous system Disorders	Syncope, dizziness.
Eye Disorders	Corneal erosion, corneal opacity, corneal oedema, keratitis, vision blurred, photophobia, mydriasis, eye pain, eye irritation, eye swelling, ocular discomfort, ocular hyperaemia, lacrimation increased.

Additionally, overuse, uncontrolled use or abuse of the product may lead to ocular lesions due to the toxic effects of the anaesthetic to the epithelium.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting.

4.9 Overdose

In the event of overdose or accidental ingestion, systemic effects may manifest as central nervous system (CNS) stimulation and may include nervousness, tremors, or convulsions; followed by depression in CNS, which may result in loss of consciousness and respiratory depression. A topical overdose of Alcaine™ Eye Drops can be flushed from the eyes with warm water. Appropriate symptomatic treatment is indicated if any systemic effects are observed.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sensory organ; ophthalmologicals; local anaesthetic ATC Code SO1HA04.

Mechanism of action

Proxymetacaine hydrochloride is a potent topical anaesthetic of the ester type.

The main site of anaesthetic action is the nerve cell membrane where proxymetacaine interferes with the large transient increase in the membrane permeability to sodium ions that is normally produced by a slight depolarisation of the membrane. As the anaesthetic action progressively develops in a nerve, the threshold for electrical stimulation gradually increases and the safety factor for conduction decreases; when this action is sufficiently well developed, a block of conduction is produced.

The exact mechanism whereby proxymetacaine and other local anaesthetics influence the permeability of the cell membrane is unknown; however, several studies indicate that local anaesthetics may limit sodium ion permeability through the lipid layer of the nerve cell membrane. This limitation prevents the fundamental change necessary for the generation of the action potential.

Pharmacodynamic effects

Proxymetacaine hydrochloride is a rapid acting local anaesthetic suitable for ophthalmic use. With a single drop, the onset of anaesthesia usually begins within 30 seconds and persists for 15 minutes or longer.

Proxymetacaine hydrochloride is a potent topical anaesthetic of the ester type.

5.2 Pharmacokinetic properties

After topical administration, proxymetacaine hydrochloride is absorbed into the system and generally decomposes quickly in the plasma; however, high doses can cause undesirable systemic effects.

5.3 Preclinical safety data

Carcinogenicity

The carcinogenic potential of proxymetacaine hydrochloride has not been investigated in long-term animal studies.

Mutagenicity

No study has been conducted to determine the potential mutagenicity of proxymetacaine hydrochloride.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzalkonium chloride 0.1 mg in 1 mL as a preservative
Glycerol
Hydrochloric acid and/or sodium hydroxide to adjust pH
Purified water.

6.2 Incompatibilities

Unknown.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at 2° C to 8° C. Refrigerate do not freeze.
Protect from light.
Discard container 4 weeks after opening.

6.5 Nature and contents of container

Alcaine™ Eye Drops come in a 15 mL, dropper bottle consisting of a low-density polyethylene.

6.6 Special precautions for disposal

No special requirements for disposal.

7. MEDICINE SCHEDULE

Prescription Only Medicine.

8. SPONSOR

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9. DATE OF FIRST APPROVAL

2 October 2014 (provisional consent).

10. DATE OF REVISION OF THE TEXT

22 June 2023.

Summary Table of Changes

4.8 Undesirable effects	Update MEDRA Preferred term to v25.1. Add “dizziness” and “Corneal oedema” to list of adverse events identified from posmarketing surveillance.