

NEW ZEALAND DATA SHEET

Topicaine, Topical solution

1 PRODUCT NAME

Topicaine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Adrenaline acid tartrate 0.18% w/v, Lidocaine hydrochloride 4% w/v, Tetracaine hydrochloride 0.5% w/v

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Topicaine is a clear, colourless to pale yellow, sterile topical solution provided in a topical syringe.

4 CLINICAL PARTICULARS

Tetracaine, a para-aminobenzoic acid ester, is an extremely potent local anaesthetic, which acts by preventing the generation and transmission of impulses along nerve fibres and at nerve endings as well as by inhibition of depolarisation and ion exchange.

Lidocaine is an amide-type local anaesthetic with a much lower potency than tetracaine.

Adrenaline is a potent sympathomimetic. The main action of adrenaline in Topicaine is vasoconstriction.

The combined local anaesthetics in Topicaine take approximately 30 minutes to work and the effect generally lasts for 4 – 6 hours.

4.1 Therapeutic indications

Topicaine is intended for use in adults and children older than 1 year, as a topical anaesthetic for pain management when repairing wounds, particularly facial or scalp wounds. Its key feature is avoidance of the anaesthetic needle, which can be particularly traumatic for children and some adults with laceration injuries.

4.2 Dose and method of administration

The product is supplied ready for administration in a 5 mL topical syringe. Do not remove from carton or over wrap until ready to use. Usual dose is approximately 0.1 mL/kg.

Since the solution takes approximately 30 minutes to take full effect, it may be appropriate to attend to patients promptly upon presentation with lacerations. Some clinics find it useful for the nurse to apply Topicaine to wounds prior to consultation with the physician. Even wounds that do not require suturing will benefit, since anaesthesia allows more thorough, high pressure irrigation (e.g. 18 G plastic catheter on a 30 mL syringe), using 200 mL or more of sterile normal saline, which has been shown to reduce infection rates without risk of irrigation induced tissue inflammation¹ and painless inspection.

To apply the anaesthetic, dribble the solution from the syringe onto a sterile gauze square, divided as appropriate to the wound size, until well soaked. Pack the soaked gauze into the wound using gloved fingers and/or forceps. Add further Topicaine to the gauze in the packed wound and cover with an occlusive dressing such as Tegaderm. Wait at least 30 minutes for the anaesthetic to take effect.

The adrenaline in the preparation causes blanching of the skin in the application area and this should be taken as a measure of the adequacy of application. The goal is complete blanching of tissue edges. It may be helpful to reassure patients that blanching is a sign of

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good anaesthesia and is not a concern. Initial stinging and some bleeding may occur during application but this is not a cause for concern unless excessive. Some bleeding will produce good tissue edges to anaesthetise.

If anaesthesia is inadequate, supplemental lidocaine infiltration may be used, although experienced workers have reported that with good technique, this is almost never required.

The solution is intended for single use only. Any solution remaining after use is to be discarded.

Reference 1: Longmire AW, Broom LA and Burch J, Wound infection following high-pressure syringe and needle irrigation. American Journal of Emergency Medicine 1987, 5:179-181.

4.3 Contraindications

Topicaine may not be effective on larger wounds. As with any drug, local anaesthetics are contraindicated in patients with known hypersensitivity. They should be used with caution in patients with complete heart block and should not be administered in patients with low plasma cholinesterase levels (pregnancy, infants below 3 months of age and patients with liver disease or familial plasma cholinesterase deficiency). The solution should be avoided in patients with impaired cardiac conduction or respiratory function, shock or hepatic impairment.

4.4 Special warnings and precautions for use

Topicaine is dangerous on extremities and may be absorbed from mucous membranes. It must not be used on fingers, toes, ears, penis, scrotum or mucous membranes.

Attending staff must wear gloves when handling the solution because the adrenaline in the solution may cause profound ischaemia in the fingers.

Topicaine is intended for use directly from the topical syringe in which it is supplied. It is not possible to fit a needle to this syringe and it is critical that the solution is not injected. Do not use the solution unless it is clear, not pink and not darker than pale yellow.

Gloves are to be worn when using the product both to ensure aseptic technique and to avoid contact with fingers. The adrenaline in the solution may cause profound ischaemia in the fingers. Avoid contact with extremities or mucous membranes.

4.5 Interaction with other medicines and other forms of interaction

Adrenaline interacts with many medications, but in the case of local anaesthetics containing adrenaline, there is no clinical evidence of dangerous interactions with either tricyclic antidepressants or monoamine oxidase inhibitors. It is very important that Topicaine is not injected intravenously, but note in this regard that it is not possible to fit a needle to the topical syringe in which the medication is provided.

4.6 Fertility, pregnancy and lactation

Both adrenaline and lidocaine carry a Category A pregnancy classification (lowest risk) but tetracaine safety has not been classified, therefore Topicaine should be used in pregnancy only when considered essential by the physician. Low cholinesterase levels, which are common in pregnancy, are a contraindication to use of Topicaine.

4.7 Effects on ability to drive and use machines

The action of adrenaline is too short-lived to be significant and neither tetracaine nor lidocaine is reported to cause drowsiness. The product is therefore presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery. Despite this, the effect

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of laceration repair on ability to drive and use machinery should be considered and tasks requiring concentration should be avoided for several hours.

4.8 Undesirable effects

Effects

Adverse effects have been reported to be extremely rare, but may occur. Signs of local anaesthetic toxicity include periorbital tingling, decreased level of consciousness and fitting. Cardiac arrhythmias may also occur.

Treatment

Transfer the patient to a resuscitation area, attach oxygen and full monitoring and attend to ABC and seizures as necessary.

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

The adverse effects of Topicaine reported above (periorbital tingling, decreased level of consciousness, fitting and cardiac arrhythmias) are more likely in the case of overdosage. If any of these symptoms occur, immediate help should be sought. Transfer the patient to a resuscitation area, attach oxygen and full monitoring and attend to ABC and seizures as necessary.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetics for topical use

ATC Code: D04AB01

5.2 Pharmacokinetic properties

Both tetracaine and lidocaine are readily absorbed through mucous membranes and through damaged skin. They are both weak bases and at tissue pH can diffuse through connective tissue and cellular membranes to reach the nerve fibre where ionisation can occur. Ester-type anaesthetics, such as tetracaine, are hydrolysed by esterases in the plasma and, to a lesser extent, in the liver. Amide type anaesthetics, such as lidocaine, are metabolised in the liver and, in some cases, the kidneys. There is little protein binding with tetracaine, but lidocaine is considerably bound.

Adrenaline is absorbed following topical application, but the local vasoconstriction it causes slows the absorption. The adrenaline that is absorbed is rapidly inactivated (half-life about 1 minute) by processes that include uptake into adrenergic neurones, diffusion and enzymatic degradation in the liver and body tissues.

5.3 Preclinical safety data

No information held by the sponsor.

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6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium metabisulfite 0.5% w/v as antioxidant
Water for Injection

There are no antimicrobial preservatives.

6.2 Incompatibilities

No information available.

6.3 Shelf life

18 months from date of manufacture.

6.4 Special precautions for storage

The solution is light-sensitive and should be stored in the refrigerator (2 °C to 8 °C) inside the over wrap and carton in which it is supplied. The solution is intended for single use only. Any solution remaining after use is to be discarded.

6.5 Nature and contents of container

Packed in 5 mL topical syringes over wrapped with polyethylene and packed into individual, light-tight, tamper-evident cartons. Sold singly.

6.6 Special precautions for disposal

No special requirement.

7 MEDICINE SCHEDULE

Restricted medicine

8 SPONSOR

Biomed Limited
52 Carrington Road
Point Chevalier
Auckland
Phone: 0800 833 133

9 DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:
21 December 2006

10 DATE OF REVISION OF THE TEXT

25 June 2018

SUMMARY TABLE OF CHANGES

DATE	CHANGE
25/06/18	Update to SPC format; removed active ingredients properties from the further information section