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Appendix 4 Adverse reactions data-Redacted version. SMARs data and additional CARM data on reactions to dental use of local anaesthetics

[redacted]

Appendix 6 Broadbent, JM, Thomson, WM. The readiness of New Zealand general dental practitioners for medical emergencies. New Zealand Dental Journal. 2001; 97: 81-86

Appendix 7 Other references

(i) Nash DA, Friedman JW, Kardos TB, Kardos RL, Schwarz E, Satur J et al. Dental therapists: a global perspective. International Dental Journal. 2008;58(2):61-70. doi:10.1111/j.1875-595X.2008.tb00177.x.

(ii) Giovannitti JA, Rosenberg MB, Phero JC. Pharmacology of local anesthetics used in oral surgery. Oral and Maxillofacial Surgery Clinics of North America. 2013; 25: 453-65. 10.1016/j.coms.2013.03.003.

Appendix 8 Datasheets for dental local anaesthetic agents

(i) 3% Citanest® Dental with Octapressin® Data Sheet. (prilocaine with felypressin). Dentsply 2014

(ii) 2% Xylocaine Dental with Adrenaline 1:80,000 Data Sheet. Dentsply (NZ) Ltd, Auckland, 2014

(iii) Ubistesin data sheet. (Ubistesin: 4% Articaine with Adrenaline 1/200 000; Ubistesin forte: 4% Articaine with Adrenaline 1/100 000). Auckland: 3M 2010.

(iv) Septanest (articaine hydrochloride 4% with adrenaline 1:100,000): IVOCLAR VIVADENT Ltd, Auckland, 2011.

Additional references provided in the appendices:

i. Broadbent JM and Thomson WM. The readiness of New Zealand general dental practitioners for medical emergencies. New Zealand Dental Journal. 2001 (429), 82-6.

ii. Giovannitti JA Jr, Rosenberg MB, and Phero JC. Pharmacology of local anesthetics used in oral surgery. Oral and Maxillofacial Surgery Clinics of North America, 2013. 25 (3), 453-465

iii. Nash, DA., Friedman, JW., Kardos, TB., Kardos, RL., Schwarz, E., Satur, J., Berg, DG., Nasruddin, J., Mumghamba, EG., Davenport ES. and Nagel R. Dental therapists: a global perspective.International Dental Journal. 2008 (58), 61-70

Oral health practitioners who can administer local anaesthetics (LA) in dentistry across New Zealand, Australia, UK, Singapore and USA

	Dentists/ Dental specialists	Dental therapists	Dental hygienists	Oral health therapists (OHT)
New Zealand	√	√ Patients up to age 18 No direct clinical supervision for any scope activities, including administration of LA – practise within working relationship with dentist/dental specialist and signed agreement	√ Any age patient Administration of LA under direct clinical supervision – dentist/dental specialist on-site	√ Majority of scope activities (incl. LA) on any age patient within a consultative professional relationship with a dentist/dental specialist – not required to be on-site Restorative activities on patients up to 18 years of age
Australia	√	√ No direct clinical supervision for any scope activities, including LA No age limit described by the regulator – capabilities determined by education or competence <u>Age limits for scope varies across states:</u> NSW: 18 years	√ No direct clinical supervision Patient can be any age Work within a structured professional relationship with a dentist/dental specialist	√ No direct clinical supervision Patient can be any age for majority of scope activities (including LA) For restorative activities within the OHT scope – same age limits as for dental therapy alone. Some recent oral health graduates' education

	Dentists/ Dental specialists	Dental therapists	Dental hygienists	Oral health therapists (OHT)
		ACT: 19 years Northern territory: 18 Queensland: 4-17 South Australia: 18 Victoria: 25 Tasmania: no specified age limit – commensurate with education or competence WA: activities listed as per legislation, no specified age limit Work within a structured professional relationship with a dentist/dental specialist		includes an "adult care" component that allows treatment on a patient of any age Work within a structured professional relationship with a dentist/dental specialist
UK	√	√ Supervision not required for any scope activities, including LA Patient can be any age	√ Supervision not required for any scope activities, including LA Patient can be any age	No OHT scope of practice - practitioners educated in both hygiene and therapy register in both scopes – same practising conditions apply

	Dentists/ Dental specialists	Dental therapists	Dental hygienists	Oral health therapists (OHT)
		Can carry out treatment direct to patients or under prescription from a dentist	Can carry out treatment direct to patients or under prescription from a dentist	
Singapore	√	√ Patients up to age 18 Work under clinical supervision of a dentist for first 5 years After that – in 'collaboration'; not direct clinical supervision	√ Patient can be any age Work under clinical supervision of a dentist for first 5 years After that – in 'collaboration'; not direct clinical supervision	√ Patient can be any age for majority of scope activities (including LA) For dental therapy activities within the OHT scope – same age limit as for dental therapy alone (up to 18 years of age) Work under clinical supervision of a dentist for first 5 years After that – in 'collaboration'; not direct clinical supervision
U.S.A	√	X Dental therapy not well established in U.S.A. – only licensed in Minnesota, Alaska, Maine[1]	√ Supervision requirements for LA vary by State[2]: • 6 states - not a permitted function	X Don't have OHT scope of practice An 'Advanced dental therapist' exists only in Minnesota – a registered

[1] http://mn.gov/boards/assets/Delegated%20Duties_tcm21-46116.pdf
[2] https://www.adha.org/resources-docs/7511_Permitted_Services_Supervision_Levels_by_State.pdf

	Dentists/ Dental specialists	Dental therapists	Dental hygienists	Oral health therapists (OHT)
		In Minnesota, LA can be administered by a dental therapist under 'general supervision' i.e. the dentist may or may not be on-site	• 37 states – Direct supervision levels (D); dentist needs to be present • 4 states – General supervision levels (G); dentist needs to authorize prior to services, but need not be present • 1 state – Indirect supervision levels (I); dentist must authorize procedure and be in the dental office while the procedure is performed • 1 G/A - General supervision levels; dentist needs to authorize prior to services, but need not be present/ Direct access supervision levels; hygienists can provide services as s/he determines as appropriate without specific authorization • 2 D/G • 1 I/D	hygienist who has additional education so they can perform activities similar in nature to our dental therapy Work within a collaborative arrangement with a dentist/dental specialist In Minnesota, LA can be administered by an advanced dental therapist under 'general supervision' i.e. the dentist may or may not be on-site

Medical Emergencies in Dental Practice – Practice Standard

December 2016

Dental Council
Te Kaunihera Tiaki Niho

Contents

This practice standard was last reviewed in September 2014. This version incorporates updates made in December 2016 to reflect the NZRC CORE course changes, and the new sedation practice standard resuscitation training requirements approved in October 2016.

1. Purpose

1.1. Oral health practitioners have a responsibility to put their patients' interests first, and to protect those interests by practising safely and providing good care. The practitioner's ability to deal with medical emergencies that arise in practice is a significant aspect of meeting their responsibility to, and the expectations of, their patients.

1.2. Medical emergencies can and do occur in dental practice[1]. The early and effective management of a medical emergency significantly improves the outcomes and reduces the adverse effects of such an occurrence. Oral health practitioners need to have appropriate skills, training and equipment available to deal with potentially life threatening conditions[2, 3].

1.3. The purpose of the Dental Council Medical Emergencies in Dental Practice - Practice Standard ('practice standard') is to set the minimum standards for registered oral health practitioners for the level of resuscitation training; the recertification intervals; and the equipment and drugs that need to be available in the case of a medical emergency. The standards include recommendations for implementation in the practice of dentistry, including subset scopes of practice defined for oral health practitioners.

1.4. The minimum standard requirements in relation to equipment and drugs specified in the practice standard apply in environments where scope of practice activities of a clinical nature are undertaken by a registered oral health practitioner. These include preventive care and care delivered at "off-site" facilities such as mobile units, domiciliary care or rest homes.

2. Interpretation of requirements

Must – A requirement expressed as "must" is a minimum standard that all oral health practitioners must adhere to and comply with.

Should – A requirement expressed as "should" is a strong recommendation, but compliance will not be monitored.

[1] Broadbent, J.M., Thomson, W.M. The readiness of New Zealand General Dental Practitioners for Medical Emergencies. NZDJ 97: 82-86; 2001.

[2] Zacharias, M., Hunter, K.MacD. Cardiopulmonary Resuscitation in Dental Practice – an update. NZDJ 90: 60-65; 1994.

[3] New Zealand Resuscitation Council. Basic Resuscitation 2002 Resuscitation 2000

3. Practitioners' legal and ethical responsibility

3.1. It is an oral health practitioner's ethical and legal obligation to attend to a medical emergency. Further, it is the public's expectation that a health professional will be in a position to assist them in a medical emergency situation.

3.2. Oral health practitioners have a legal and ethical responsibility to provide good care to the public within their level of competence and to put patient safety first at all times.

3.3. The Code of Health and Disability Services Consumers' Rights provides that every consumer has the right to have services provided with reasonable care and skill (Right 4(1)) and that comply with legal, professional, ethical, and other relevant standards (Right 4(2)).

3.4. Council expects oral health practitioners to attend to a medical emergency within their competence and skill levels, supported by their current training to the level prescribed in the practice standard.

3.5. Failure to respond to a medical emergency is a significant departure from the standard of care expected of oral health practitioners.

3.6. Instant decisions may have to be made in an emergency situation, and would be taken into account when deciding whether there had been a failure to meet the appropriate professional standard.

4. Preparation for medical emergencies

4.1. The New Zealand Resuscitation Council (NZRC), as the guideline and standard setting body for resuscitation in New Zealand, publishes national guidelines and policy statements to provide all those involved in resuscitation education and practice with treatment recommendations based, where possible, on scientific evidence. These documents are reviewed and amended as new evidence comes to hand.

4.2. The guidelines and policy statements are available on the NZRC website at the following link: www.nzrc.org.nz/guidelines

4.3. The management of some medical emergencies prevalent in the clinical practice of oral health practitioners, are not specifically covered in the resuscitation training that oral health practitioners undertake. To assist practitioners keeping up to date with guidelines on specific responses for these medical emergencies, the New Zealand Dental Association's *Medical Emergency Situations: Specific Responses* is included as Appendix A in the practice standard. A *Quick Reaction Guide* for medical emergencies is provided as Appendix B.

4.4. Practitioners must read the *Medical Emergency Situations: Specific Responses* information, provided as Appendix A, prior to attending resuscitation training. It is anticipated that oral-health practitioner specific CORE Immediate or equivalent courses would reinforce this information.

Medical History

4.5. A comprehensive medical history is fundamental in the prevention and management of a medical emergency, and must be recorded and regularly updated for all patients.

4.6. Patients who have a severe medical condition/s or an increased risk of a medical problem arising should be identified. An assessment should be made to determine if any additional precautions should be taken, or if referral is required to a more suitably qualified practitioner or a more appropriate medical environment, such as a hospital-based dental practice. The detailed requirements of practitioners undertaking a medical history are contained in the Dental Council *Patient Information and Records Practice Standard*.

Resuscitation training

4.7. The NZRC provides graduated levels of resuscitation training. CORE Immediate has been developed as the foundation level of resuscitation training appropriate for New Zealand's health professionals.

4.8. Oral health practitioners must successfully complete the following minimum levels of resuscitation training:

Professions	Resuscitation Training Levels
Dentists/Dental Specialists - not performing sedation	CORE[4] Immediate or equivalent
Dentists/Dental Specialists performing ANY form of sedation, with the exception of relative analgesia (RA)	NZRC CORE Advanced From 1 October 2019 onwards this course must include in the scenario training one or more scenarios relevant to the management of sedation-related complications.
Dental Therapists, Dental Hygienists, Orthodontic Auxiliaries, Clinical Dental Technicians	CORE Immediate or equivalent
Dental Technicians undertaking restricted activities	CORE Immediate or equivalent
Dental Technicians	Basic Life Support Skills

[4] Certificate of Resuscitation and Emergency Care

4.9. The Certificate of Resuscitation and Emergency Care (CORE) Immediate or equivalent course must contain the following modules to meet the minimum standards:

Airway management	Adult collapse	Childhood collapse
Manual airway opening	Adult collapse management plan	Childhood collapse management plan
Airway suction	Team scenario practice for adult collapse	Team scenario practice for childhood collapse
Oropharyngeal airway insertion	Use of Automatic External Defibrillation	Use of Automatic External Defibrillation
Mouth to mask ventilation	*Choking/ Airway obstruction*	*Choking/ Airway obstruction*
One person bag-mask ventilation	*Management of anaphylaxis*	*Management of anaphylaxis*
Two person bag-mask ventilation	*Syncope*	*Asthma*
Oxygen delivery	*Maternal collapse*	

4.10. Childhood collapse is **not required** for clinical dental technicians and dental technicians undertaking restricted activities, because of the low prevalence of treating children.

4.11. The italicised modules in the above table may not be covered in full in NZRC CORE Immediate or equivalent courses, and the *Medical Emergencies – Information and Specific responses* must be read prior to attending the resuscitation course.

4.12. Practitioners requiring NZRC CORE Immediate resuscitation training can still attend a course equivalent to the NZRC CORE Immediate course.

4.13. All practitioners providing sedation, with the exception of RA, must successfully complete a NZRC CORE Advanced course. From 1 October 2019, the scenario training included in the course must include one or more scenarios relevant to the management of sedation-related complications; for dentists/dental specialists providing sedation.

4.14. The resuscitation training must be revalidated every two years, and evidence of this must be available for verification, if requested by Council, from time to time.

4.15. Council does not have any legal jurisdiction over non-registered practice staff (such as dental assistants and administrative staff). However, it strongly recommends that all non-registered practice staff should be trained in Basic Life Support Skills.

4.16. A team approach to management of medical emergencies must be developed. Written protocols must be in place in the dental practice so that all staff members know their role in managing emergency situations.

4.17. Council recommends a six monthly practice review, involving all staff, of the management of medical emergencies through:

- discussion of the practice policy – including staff members' particular roles, specific response procedures and algorithms developed and/or adopted; and their continuing suitability for the practice, and
- checking the availability and expiry dates of medical emergency equipment and drugs.

4.18. This approach aims to reinforce the particular role of each staff member in the management of a medical emergency and ensure an appropriate and co-ordinated emergency response.

International training courses

4.19. Practitioners practising and completing their emergency training in Australia must successfully complete courses provided by Australian Resuscitation Council accredited course centres:

- Courses equivalent to NZRC CORE[5] Immediate : Advanced Life Support Level 1 - Immediate Life Support (ALS1/ILS)
- Courses equivalent to NZRC CORE Advanced: Advanced Life Support Level 2 - Advanced Life Support (ALS2/ALS)
- Courses for Basic Life Support Skills course by a credible provider.

4.20. The Australian Resuscitation Council maintains the list of accredited course centres in Australia, and this can be accessed on their website[6].

4.21. Practitioners practising and completing their emergency training in other overseas jurisdictions must successfully complete their emergency training at an accredited emergency training provider/course centre, where applicable. If providers/courses are not accredited or approved, the practitioner must complete their emergency training at a credible provider.

4.22. Training courses equivalent to NZRC CORE Immediate must contain the relevant training modules, specified in section 4.9.

4.23. The practice standard's training requirements do not replace any additional requirements of other regulatory authorities.

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[5] Certificate of Resuscitation and Emergency Care

[6] http://www.resus.org.au/

Equipment

4.24. The following age appropriate equipment must be readily available for dentists, dental specialists, dental therapists, dental hygienists, orthodontic auxiliaries, and clinical dental technicians:

- Oxygen cylinder, regulator and associated equipment suitable for delivering high flow oxygen
- Bag mask device with oxygen reservoir
- Basic airway adjuncts (oropharyngeal airways)

4.25. The following age appropriate equipment must *additionally* be readily available for dentists and dental specialists:

- Syringes and needles for drawing up and administering drugs
- Spacer device to deliver Salbutamol.

4.26. The equipment must be checked monthly to ensure it is fully operational. Staff must have training in the use of the equipment in their respective roles.

4.27. Early defibrillation of casualties who are in ventricular fibrillation/tachycardia dramatically improves prospects of survival. An AED must be available when administering sedation, with the exception of relative analgesia (RA). An automated external defibrillator (AED) is not mandatory for all oral health practitioners. Where an AED is not available, on-site practitioners should familiarise themselves with the location of the nearest available AED as part of their management of medical emergencies protocol.

Drugs

4.28. Drugs must be readily available and not be beyond their expiry date.

4.29. They must be stored to facilitate easy access, identification, and in dosages that are easy to administer in an emergency situation.

4.30. Oxygen must be available for dentists, dental specialists, dental therapists, dental hygienists, orthodontic auxiliaries and clinical dental technicians

4.31. The following drugs must be available for dentists and dental specialists:

- Glyceryl trinitrate
- Aspirin
- Adrenaline (1:1000)
- Salbutamol.

4.32. In settings where there is a reliance on crash response units, such as hospitals and Universities, factors such as accessibility to these emergency services and response time will determine the appropriate emergency equipment and drugs to be held at dental department level.

Additional training, equipment and drugs required for dentists/ dental specialists administering sedation (excluding RA)

4.33. Practitioners administering sedation (excluding RA) must undertake a higher level (NZRC CORE Advanced) of resuscitation training, due to the higher risks of a medical emergency associated with the activity.

4.34. A more complete range of equipment and drugs is required when sedation is performed. Further information regarding the safe use of sedation within dental practice is contained within the Dental Council Sedation practice standard.

4.35. The following *additional*, age appropriate equipment must be readily available when sedation (excluding RA) is performed:

- Advanced airway adjuncts - oropharyngeal and supraglottic airway devices
- Associated equipment for gaining and securing IV access and administering IV fluids and medication
- Automated external defibrillator (AED)

4.36. The following drugs must be readily available when sedation (excluding RA) is performed:

- Appropriate antagonists for sedative drugs being administered, where required
- Dextrose 10%
- Glucagon
- Normal saline 1000ml
- Hydrocortisone injection.

Scheduling of appointments

4.37. Scheduling of appointments should be made to ensure that two staff members are immediately available, with the appropriate level of training, to assist in a medical emergency.

Checklist

For all oral health practitioners -

- ☐ Do you record and regularly update the medical history of all patients?
- ☐ Do you have current resuscitation training to the minimum prescribed level?
- ☐ Does your CORE Immediate or equivalent course contain the following modules:
  - ☐ Airway management?
  - ☐ Adult collapse?
  - ☐ Childhood collapse (not required for clinical dental technicians and dental technicians undertaking restricted activities)?
- ☐ Do you revalidate your resuscitation training every two years, and have the necessary documentation to support this, if requested?
- ☐ Does your practice have written protocols describing the staff members' roles in management of a medical emergency?

For dentists, dental specialists, dental therapists, dental hygienists, orthodontic auxiliaries and clinical dental technicians -

- ☐ Do you have the following age appropriate equipment readily available where you practice:
  - ☐ Oxygen cylinder, regulator and associated equipment suitable for delivering high flow oxygen?
  - ☐ Bag mask device with oxygen reservoir?
  - ☐ Oro-pharyngeal airways?

  Additionally for dentists and dental specialists:
  - ☐ Syringes and needles?
  - ☐ Spacer device?
- ☐ Is the equipment checked monthly to ensure its operations?
- ☐ Are staff in the practice trained how to use the equipment in an emergency?
- ☐ Is oxygen readily available where you practise?

For dentists and dental specialists -

- ☐ Are the following emergency drugs readily available to you?
  - ☐ Adrenaline (1:1000)?
  - ☐ Salbutamol?
  - ☐ Glyceryl trinitrate?
  - ☐ Aspirin?
- ☐ Are the emergency drugs not beyond their expiry date?
- ☐ Are the emergency drugs easily accessible?
- ☐ Are the emergency drugs easily identifiable?
- ☐ Are the emergency drugs available in dosages that are easy to administer?

For dentists and dental specialists performing sedation (excluding RA) -

- ☐ Do you have the following equipment readily available where you practice:
  - ☐ advanced airway adjuncts - oropharyngeal and supraglottic airway devices?
  - ☐ associated equipment for gaining and securing IV access and administering IV fluids and medication?
  - ☐ automated external defibrillator (AED)?
- ☐ If you are performing intravenous sedation - do you have the following emergency drugs readily available where you practice:
  - ☐ Appropriate antagonists for the sedative drugs being administered?
  - ☐ Dextrose 10%?
  - ☐ Glucagon?
  - ☐ Normal saline 1000ml?
  - ☐ Hydrocortisone injection?

This checklist act as a guide only, and can be further developed for the specific drugs, equipment and associated expiry dates of the stock.

Appendix A

Medical emergency situations: specific responses

New Zealand Dental Association Code of Practice – Medical Emergencies in Dental Practice 2012

Anaphylaxis *(See Appendix B for a Quick Reaction Guide)*

Anaphylaxis is a severe potentially life threatening hypersensitivity reaction to AN ANTIGEN. In the dental setting anaphylaxis may follow administration of a drug or contact with substances used during care.

Presentation: Upper airway (laryngeal) oedema and bronchospasm and low blood pressure may develop. Symptoms may be severe leading to in collapse and cardiac arrest. There are a wide range of potential presenting symptoms which may include:

General	A sense of impending doom
Skin / mucosa	Wheals and itching (urticaria), flushing (erythema), runny nose (rhinitis), conjunctivitis
Breathing	Difficulty with breathing, noisy breaths (stridor), wheezing and/or hoarse voice, respiratory arrest
Cardiovascular	Low blood pressure (vasodilation mediated hypovolaemia), rapid pulse (tachycardia), cardiac arrest
Gastrointestinal	Abdominal pain, vomiting, diarrhoea

Management If an anaphylactic reaction is suspected the administration of any intravenous medications should cease and Basic Life Support procedures (Drs ABCD) should commence immediately. The airway, breathing and the maintenance of blood pressure are crucial. The patient should be laid flat, feet / legs elevated and oxygen administered at a rate of 8-10 litres per minute delivered via a mask and reservoir bag. If available administer isotonic saline intravenously.

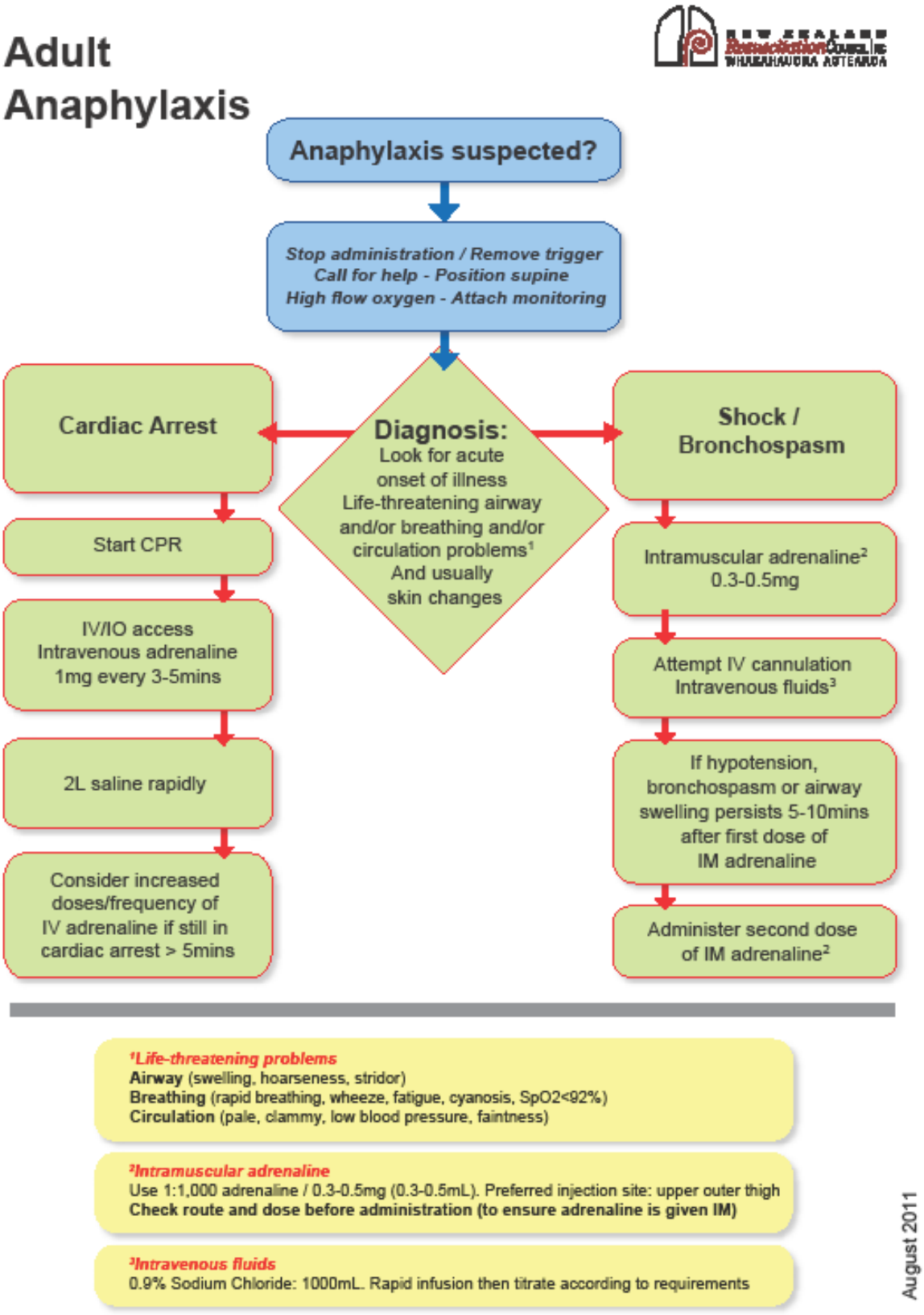
If there are marked airway, breathing or circulation symptoms such as rapid breathing, stridor, wheezing, hoarseness, cyanosis, and/or confusion, pallor, clammy skin, drowsy, confused OR coma then 1:1000 adrenaline should be administered intramuscularly (anteriolateral aspect of the centre of the thigh):

1:1000 Adrenaline emergency doses[1]:

Adult and children over 12 years of age:	0.5 mL (500 micrograms)
Child 6 to 12 years of age	0.3mL (300 micrograms)
Child less than 6 years of age	0.15mL (150 micrograms)

Repeat adrenaline administration if there has been no improvement in the symptoms (hypotension, airway swelling or bronchospasm), at 5 minute intervals depending on respiratory function, pulse and blood pressure.

Maintain Basic Life Support procedures (Drs ABCD) until help arrives.



From: NZ Resuscitation Council – Policies and Guidelines. Adult Anaphylaxis

Angina and myocardial infarction

See Appendix B for a Quick Reaction Guide

Presentation Symptoms vary depending on the cause and severity and may include; pallor, 'cold sweat', chest pain, shortness of breath, changes in heart rate (slow of fast), increased respiratory rate, low blood pressure, confusion, loss of consciousness.

Severe symptoms (indicative of a myocardial infarction) may include severe, crushing pain in the centre and across the front of the chest, pain may radiate into shoulders, arms, neck and jaw. Shortness of breath, weak pulse, falling blood pressure and nausea and vomiting may also be observed.

Management: **For undiagnosed chest pain seek urgent medical assistance**

For mild symptoms in patients previously diagnosed with angina administer *glyceryl trinitrate*, 400 micrograms (spray or tablet). If there is no (or only partial) resolution of symptoms repeat glyceryl trinitrate, 400 micrograms (spray or tablet), after 5 minutes. If symptoms persist treat as for 'severe symptoms'.

If symptoms are severe assume myocardial infarction and call for medical help immediately. Position the patient for their comfort, keep warm and provide reassurance and support. Administer glyceryl trinitrate, 400 micrograms (spray or tablet) and if possible administer aspirin 300 milligrams orally. Administer oxygen (15 litres per minute) if the patient is cyanosed or if their level of consciousness deteriorates. If the patient loses consciousness commence Basic Life Support procedures (Drs ABCD).

When medical assistance arrives advise them of the drugs you have administered.

Asthma

See Appendix B for a Quick Reaction Guide

Asthma is a chronic inflammatory disease of the airways with spasm and narrowing leading to obstruction to air flow.

Presentation: The patient will usually have a history of asthma. Symptoms depend on the severity of the attack and include rapid breathing (> 25 breaths per minute), shortness of breath (unable to compete a sentence in a single breath), racing pulse (tachycardia) rate over 110 beats per minute. In severe asthma attacks the breathing rate slows (less than 8 breathes per minute), heart rate slows (less than 50 beats per minute) and the patient may be cyanosed, may be confused, and may have a decreased level consciousness.

Management: The patient should administer their own asthma bronchodilator medication usually a few 'puffs'. If the patient does not have their inhaler or is unable to deliver their own medication a dose (up to 10 activations) of salbutamol should be given using a large volume spacer device.

If the patient does not respond rapidly or if the symptoms worsen (breathing rate slow (<10), heart rate slows (<50), cyanosis develops, patient only able to speak 2-3 words without taking a breath etc) help should be summoned, a further dose of salbutamol administered (10 activations) from the salbutamol inhaler through the large volume spacer device and oxygen (8-10 litres per minute delivered via a mask and reservoir bag.) given. The salbutamol should be repeated at 10 minute intervals until assistance arrives. If the patient becomes unresponsive Basic Life Support procedures (Drs ABCD) should commence immediately.

Choking and aspiration

See Appendix B for a Quick Reaction Guide

Presentation depends on the location and extent of the obstruction. Symptoms include; difficulty breathing, breathing may be noisy (wheeze or high pitch 'crowing' sounds), coughing and/or spluttering, may be unable to breath, speak or cough, cyanosis, loss of consciousness.

Management: Remove any visible obstruction. Allow the patient to cough or spit out the obstruction. If the object remains and/or the symptoms persist the patient should be referred to a hospital as an emergency for a chest x-ray and further care. If there is uncertainty regarding a possible aspiration or not the patient should be referred for further investigations as a priority.

Where coughing in a conscious patient fails to dislodge the obstruction back blows (5 sharp blows between the shoulder blades) should be delivered. If back-blows fail to dislodge the obstruction five chest thrusts should be delivered. And these measures repeated until the obstruction is cleared.

If the patient loses consciousness CPR should commence.

Diabetes

See hypoglycaemia and hyperglycaemia. Assume any diabetic patient with impaired consciousness has hypoglycaemia until proven otherwise.

Epilepsy

See Appendix B for a Quick Reaction Guide

A group of syndromes characterized by disturbance of the electrical activity of the brain that may manifest as episodic impairment or loss of consciousness, abnormal motor phenomena or psychic or sensory disturbances.

Presentation: Symptoms can vary dramatically and may include; sudden muscle spasm and rigidity, jerking movements of the limbs, jaw and tongue, sudden loss of consciousness, frothing from the mouth, urinary incontinence. Seizures can last several minutes and may be followed by unconsciousness.

Management: During any seizures ensure that the patient is protected from harming themselves by falling to the floor or impacting on objects around them. Do not attempt to restrain them and do not attempt to place anything between their teeth. If possible administer oxygen at 8-10 litres per minute delivered via a mask and reservoir bag. When seizures cease, check that the patient is breathing before placing the patient in the recovery position and actively monitor them. If the patient is unconscious commence Basic Life Support procedures (Drs ABCD).

As the patient recovers they may be confused and will need active supervision and support. Additional medical assistance should be sought if this is a 'first episode', if seizures last more than 5 minutes, if the individual is in a constant or near-constant state of having seizures (status epilepticus), if they remain confused after five minutes or if it is difficult to monitor the patient's condition.

> **Note**: Seizure activity can be a sign of other conditions and these (as follows) should be considered even in known epileptics.
>
> - Seizures can occur in the early stages of cardiac arrest
> - Seizures can occur as a symptom of hypoglycaemia
> - Seizures can occur as a symptom of a faint (through a drop in blood pressure and transient cerebral hypoxia).

Faint (Syncope)

See Appendix B for a Quick Reaction Guide

Transient loss of consciousness due to inadequate cerebral oxygenation (perfusion).

Presentation Feeling of light headedness or dizziness, pallor, 'cold sweat', slowing of pulse, low blood pressure, nausea and vomiting, loss of consciousness.

Management: Lay the patient down flat and elevate the legs. Loosen tight clothing around the neck. Administer oxygen (8-10 litres per minute delivered via a mask and reservoir bag.). Reassure patient when they regain consciousness. If the patient does not regain consciousness promptly commence Basic Life Support procedures (Drs ABCD).

Hypoglycaemia

See Appendix B for a Quick Reaction Guide

Blood glucose concentrations below levels satisfactory to support the body's need for energy usually defined a blood glucose levels below 3.0mmol per litre. Acute hypoglycaemia may clinically occur in patients who have diabetes and who fail to eat after taking insulin.

Presentation: Symptoms can be non-specific and include; hunger, trembling, sweating, slurring of speech, difficulty concentrating, agitation and confusion, headache, with progressive drowsiness, seizures and unconsciousness.

Management: Hypoglycaemia in conscious patients can usually be reversed with rapid acting oral glucose (eg. glucose powder dissolved in water, sugar – sucrose) which can be repeated after 10 minutes. The oral glucose should be followed by food high in carbohydrate as the patient recovers. The patient should be actively supervised until fully recovered, they should not drive and they should be accompanied home.

If the patient is unable to take oral glucose due to depressed consciousness or lack of cooperation, glucagon (if available can be given via the IM route – 1mg for adults and children over 8 years of age of who weigh more than 25kg or 0.5mg for children under 8 years or weighing less than 25kg.) should be administered. If glucose cannot be administered or if the administration of glucose is ineffective then Basic Life Support procedures (Drs ABCD) should commence immediately.

Hyperglycaemia

Blood glucose concentrations higher than normal. Hyperglycaemia may occur in patients. In what situations?

Presentation: Symptoms include thirst, increased urine output and dehydration. As glucose levels rise hypotension, a progressive reduction in consciousness and coma may result.

Management: Basic Life Support procedures (Drs ABCD) should commence immediately with a view to getting the patient to a medical facility.

Hyperventilation (anxiety associated)

See Appendix B for a Quick Reaction Guide

Prolonged rapid breathing resulting in a fall in arterial carbon dioxide leading to acute respiratory alkalosis and potentially cerebral vasoconstriction and loss of consciousness. High respiration rates can indicate more serious illness (eg. acute myocardial infarction, pulmonary embolism etc), it is therefore essential that an accurate diagnosis as to the cause of the rapid breathing is made and this may require medical assistance.

Presentation: Tingling in fingers or lips, involuntary spasm of peripheral musculature, dizziness, loss of consciousness.

Management: Reassure and calm the patient. For conscious patients with clinical signs of or actual low oxygen saturations administer oxygen at 8-10 litres per minute delivered via a mask and reservoir bag. If the patient loses consciousness commence Basic Life Support procedures (DRS ABCD).

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Appendix B

Emergency situations – Quick reaction guide

New Zealand Dental Association Code of Practice – Medical Emergencies in Dental Practice 2012

Anaphylaxis

Cease intravenous drug administration

Commence Basic Life Support procedures (Drs ABCD)

Patient laid flat, feet / legs elevated

Oxygen administered at a rate of 8-10 litres per minute delivered via a mask and reservoir bag.

Administer 1:1000 adrenaline intramuscularly

Adult and children over 12 years of age:	0.5 mL (500 micrograms)
Child 6 to 12 years of age	0.3mL (300 micrograms)
Child less than 6 years of age	0.15mL (150 micrograms)

Repeat adrenaline if no improvement of hypotension, airway swelling or bronchospasm, as necessary at 5 minute intervals depending on respiratory function, pulse and blood pressure.

Maintain Basic Life Support procedures (Drs ABCD) until help arrives.

Asthma

Patient administered bronchodilator medication

If the patient is unable to deliver their own medication give salbutamol through a large volume spacer.

No response to medications or symptoms worsen (breathing rate slowed, heart rate slowed, cyanosis developed etc)

Summon help

Administer salbutamol (10 activations) through the large volume spacer device, repeat at 10 minute intervals as necessary

Give oxygen (8-10 litres per minute delivered via a mask and reservoir bag). The salbutamol should be repeated at 10 minutes until assistance arrives.

If the patient becomes unresponsive commence Basic Life Support procedures (Drs ABCD)

Cardiac conditions

Mild symptoms

Administer glyceryl trinitrate, 400 micrograms (spray or tablet). Repeat glyceryl trinitrate, 400 micrograms (spray or tablet) after 5 minutes if there is no (or only partial) resolution of symptoms

If symptoms persist treat as for 'severe symptoms'.

Severe symptoms

Call for medical help immediately.

Position the patient for their comfort and reassure

Administer glyceryl trinitrate, 400 micrograms (spray or tablet)

Administer aspirin 300 milligrams orally.

Administer oxygen (8-10 litres per minute delivered via a mask and reservoir bag.) if the patient is cyanosed or if level of consciousness deteriorates.

If loss of consciousness commence Basic Life Support procedures (Drs ABCD).

When medical assistance arrives advise them of the drugs you have administered.

Choking and aspiration

Remove any visible obstruction.

Encourage patient to cough

Hospital referral if the object remains and/or the symptoms persist.

Failure to dislodge object - conscious patient back-blows / chest thrust

Unconscious CPR and call for help.

Epilepsy

Protect patient

Do not attempt to restrain them or attempt to place anything between their teeth.

Administer oxygen at 8-10 litres per minute delivered via a mask and reservoir bag per minute.

Post-seizure place in the recovery position and monitor

If unconscious commence Basic Life Support procedures (Drs ABCD).

During recovery active supervision and support.

Seek additional medical assistance if:

- this is a 'first episode',
- seizures lasts more than 5 minutes,
- the individual is in a constant or near-constant state of having seizures (status epilepticus),
- they remain confused after five minutes
- it is difficult to monitor the patient's condition, or
- you are uncertain

Note: Fitting can be a sign of hypoglycaemia so this should be considered even in know epileptics. A faint (through a drop in blood pressure and transient cerebral hypoxia) can also lead to a seizure which tend to be short in duration.

Faint (Syncope)

Lay the patient down flat and elevate the legs.

Administer oxygen (8-10 litres per minute delivered via a mask and reservoir bag.).

Reassure patient when they regain consciousness.

If the patient does not regain consciousness promptly commence Basic Life Support procedures (Drs ABCD).

Hypoglycaemia

Conscious patients administer oral glucose

Provide food high in carbohydrate as the patient recovers.

Actively supervise patient during recovery

Depressed consciousness or lack of cooperation administer glucagon via the IM route

1mg for adults and children over 8 years of age of who weigh more than 25kg

0.5mg for children under 8 years or weighing less than 25kg.)

If glucose cannot be administered or if patient is unresponsive to administration of glucose Basic Life Support procedures (Drs ABCD) should commence immediately.

Hyperventilation

Reassure and calm the patient.

For conscious patients with clinical signs of or actual low oxygen saturations administer oxygen

If the patient loses consciousness commence Basic Life Support procedures (DRS ABCD).

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Te Kaunihera Tiaki Niho

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New Zealand

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Appendix 2

Dental Council application to change the classification of articaine, lidocaine, prilocaine and felypressin

List of organisations consulted

The Dental Council has discussed this classification application with the following organisations, with letters attached from each:

- New Zealand Dental Association
- Department of Oral Health, Auckland University of Technology
- The Faculty of Dentisty, The University of Otago
- Te Aō Marama, The NZ Māori Dental Association
- Lumino
- New Zealand Dental and Oral Health Therapists Association
- The Clinical Directors and Senior Dentists of District Health Board child oral health services
- New Zealand Dental Hygienists' Association

All are in agreement with this proposal.

We have also consulted with the Ministry of Health, which will provide a submission once the application has been published.

We have also discussed adverse events with local anaesthetics with Dr Michael Tatley, NZ Pharmacovigilance Centre.

Marie Warner
Chief Executive Officer
Dental Council of New Zealand
Dental Council
PO Box 10 – 448
Wellington 6143

New Zealand Dental Assoc.

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New Zealand
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fax. +64 9 580 0010

21st December 2016

sent via email & post

Dear Marie

The New Zealand Dental Association (NZDA) has a membership of approximately 98% of New Zealand's practicing dentists and this membership is inclusive of general and specialist practitioners, private practitioners and those from the public sectors such as the Faculty of Dentistry, Defence and District Health Boards.

NZDA supports the application being made to the medicines classification committee for the reclassification of anaesthetic agents for use by oral health therapists.

The Council's application will request reclassification of anaesthetic agents from a prescription medicine, to allow oral health therapists registered with the Dental Council to use these agents without the need for a prescription or a standing order—within their scope of practice, and commensurate with their approved education, training and competence. This will be within the context of oral health therapy being practised within a consultative professional relationship with one or more dentists and/or dental specialists.

The NZDA supports this view.

Kind regards

Susan Gorrie
President
New Zealand Dental Association

Auckland University of Technology
Private Bag 92006, Auckland 1142, NZ
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www.aut.ac.nz

15 December 2016

Dr Robin Whyman
Chair
Dental Council
PO Box 10-448
Wellington 6143

Dear Dr Whyman

Application for medicine reclassification for oral health therapists

On December 8 2016, I participated in a teleconference in which Marie Warner, the Chief Executive, discussed the Council's intention to apply for the reclassification of specific local anaesthetic agents, currently prescription medicines, to enable oral health therapists to administer these without the need for a prescription or a standing order.

The specific local anaesthetics discussed were Articaine, Prilocaine, and Lignocaine; and Felypressin, as vasoconstrictors used in conjunction with local anaesthetics.
In my capacity as Head of Department for Oral Health at AUT University, I wish to offer my support for the Council's application.

The administration of local anaesthetic is a core activity of oral health therapy practice. I believe the reclassification of these prescription medicines is necessary to enable oral health therapists to provide appropriate care for their patients, in a more seamless manner than under a standing order or obtaining a prescription from a dentist.

I can confirm that AUT oral health graduates are competent in administering local anaesthetics for their patients. The oral health programme provides students with the necessary education and training to enable them to administer local anaesthetic for their patients competently, safely and appropriately.
More specifically—students learn the pharmacology of local anaesthetic solutions (absorption, distribution, metabolism and excretion); indications and contraindications for their use; the local and systemic complications; and adverse effects, including toxicity, syncope and anaphylaxis. Oral health graduates have the knowledge to identify when a local anaesthetic is indicated or not according to the patient's needs. Oral health graduates learn the different types of local anaesthetic injection techniques that are used in dentistry. However, they are only competent in the injection techniques, within the oral health therapy scope of practice.

As an additional safety measure, put in place by the Council to protect the safety of the public, the oral health therapy scope of practice is to be practised within a consultative professional relationship with a dentist or dental specialist. This is with the stated purpose of providing professional advice in relation to the treatment and management of patients, when needed.

Our graduates are oral health professionals, with a strong sense of professional responsibility to their patients and the profession. If in any doubt whether it is safe to administer local anaesthetic for a particular patient, we would expect our graduates would consult with the dentist or dental specialist in the consultative professional relationship for advice.

In the event of a medical emergency related to the administration of local anaesthesia, oral health students receive resuscitation training at the same level as other oral health practitioners (excluding dental technicians, and dentists/dental specialists providing sedation). That is, NZRC CORE Immediate training (previously named CORE Level 4), or equivalent, during the programme.

This training includes management of anaphylaxis, and prepares the students to provide initial management of a resuscitation event.

Please feel free to contact me for further information regarding oral health graduates' capabilities in these practice areas, if needed.

I hope to hear of a positive response to the Council's application for reclassification of the local anaesthetic medicines for use by oral health therapists.

Regards

Daniel Fernandez
Head of Department
Oral Health
AUT University

UNIVERSITY of OTAGO
Te Whare Wānanga o Otāgo
NEW ZEALAND

17 December 2016

Robin Whyman
Chair
Dental Council
PO Box 10-448
WELLINGTON 6143

Dear Robin

Re: Support for the Dental Council Medicine Reclassification Application

The Faculty of Dentistry University of Otago offers the Bachelor of Oral Health programme; a Dental Council-accredited programme that is a gazetted, prescribed qualification for registration in the dental hygiene and dental therapy scope of practice[1]. Since 2009 the oral health programme has delivered 312 graduates, including the 2016 cohort.

The Faculty was actively engaged, and contributed extensively throughout the Council's development of the newly gazetted oral health therapy scope of practice, that comes into effect on 1 November 2017. The Faculty supported the Council's principle of ensuring the oral health therapy scope of practice is underpinned by the education delivered and competencies attained by oral health graduates.

The Council has advised its stakeholders in the consultation outcome letter of its intent, and reasoning, to apply for reclassification of the local anaesthetic agents (Articaine, Prilocaine, Lignocaine), Felypressin and Fluoride. These agents are commonly used in practice by oral health graduates.

The Faculty supports the Council's application for the reclassification of these agents from a prescription medicine, to allow oral health therapists registered with the Dental Council to use these agents without the need for a prescription or a standing order—within their scope of practice, and commensurate with their approved education, training and competence. Oral health therapy will be practised within a consultative professional relationship with one or more dentists and/or dental specialists.

University of Otago oral health graduates are educated to safely and competently use the abovementioned agents. They are taught to seek advice from a dentist where necessary, e.g. known contraindications or precautions to local anaesthetic use; or refer appropriately if

[1] The programme is gazetted as a prescribed qualification for the oral health therapy scope of practice, coming into effect on 1 November 2017. From 1 November 2017 the oral health prescribed qualification for the dental hygiene and dental therapy scopes of practice will be closed.

Faculty of Dentistry — Office of the Dean
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www.otago.ac.nz/dentistry

needed. The programme includes the necessary didactic education related to the pharmacological aspects of these medicines, including contraindications and potential side effects. Oral health graduates are well versed in the techniques of administering local anaesthetics. Taking and considering the medical history of the patient, keeping of patient records, and informed consent are all covered in the programme. Oral health graduates are also trained to handle potential adverse events including anaphylaxis, with completion of resuscitation training to CORE Level 4 during the programme.

The Faculty supports this application to ensure ongoing access of these agents for oral health therapists. Their use form a major part of the practice of oral health therapy in providing quality oral health care to the public of New Zealand.

Yours sincerely

Paul A Brunton
Dean

Te Aō Marama
The NZ Māori Dental Association
13 Tawhara Place
Edgecumbe, 3120

22 December 2016

Ms Marie Warner, CEO
Dental Council of New Zealand
PO Box 10-448
Wellington 6143
New Zealand

Dear Marie

On behalf of the members of Te Aō Marama, the New Zealand Māori Dental Association, we would like to thank DCNZ for meeting with us recently to explain its proposal for a reclassification, by the Medicines Classification Committee, of lignocaine, prilocaine, articaine and felypressin, to include an exemption for Oral Health Therapists.

We understand that the result of this change will see access to local anaesthetics for Oral Health Therapists being the same as that which currently exists for Dental Therapists. We also think this change will ensure access to care for patients, especially those living in our most vulnerable communities.

We support the proposed addition of Oral Health Therapists to the prescriber exemption for lignocaine, prilocaine, articaine and felypressin, as being both safe and in the public interest.

Noho ora mai rā

L.Waaka
Leeann Waaka

Rudi Johnson

Kelly Larkins

Johanna Wilson

Samuel Carrington

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2nd January 2017

Suzanne Bornman
Standards and Accreditation Manager
New Zealand Dental Council

Dear Suzanne,
I write in support of your application for Medicine Reclassification, in reference to the new scope of practice for Oral Health Therapists. The application applies to specific local anaesthetic agents, namely Articaine, Prilocaine, Lignocaine and Felypressin, a vasoconstrictor. These drugs are currently prescription drugs and as such are presently only available to Oral Health Therapists through standing orders.

Lumino currently operates 105 practices, with a total of 113 clinicians in the scopes of dental therapy, dental hygiene and oral health graduates. Operating under standing orders is not standard practice within our clinics and would not be a pragmatic solution for Oral Health Therapists. This would be particularly difficult when providing oral health care to large numbers of children, as seen with our Health Board contracts, where we operate from mobile facilities. The cumbersome nature and lack of understanding around standing orders are more likely to limit access to appropriate care and pain relief.

Lumino supports the establishment of the oral health therapy scope of practice. We believe that the consultative professional relationship for the oral health scope of practice is appropriate, based on the tertiary education and training of these graduates, and is practical for providing oral health care.

This scope will facilitate a comprehensive model of care, with oral health therapists being able to treat patients within their full scope of practice at all times. The new scope allows oral health therapists to practice in a single dental practice, which offers patients continuity of care also. It will provide practitioners a greater opportunity to maintain competence and confidence across the full oral health therapy scope of practice, because they are able to operate comprehensively and appropriately at all times. It is essential that they are able to readily access the noted prescription drugs to provide this level of care, particularly when the risk assessment and use of these drugs have been part of their undergraduate training. Oral health graduates have the same resuscitation capabilities as other oral health practitioners, including dentists not performing sedation. The ability to provide pain relief readily and appropriately while undertaking operating procedures is an integral part of clinical practice. Standing orders will not facilitate access to this level of care.

Lumino trusts oral health graduates' professional judgment in the risk assessment for administering local anaesthetic, when to seek advice from the dentist, and when to refer the patient. Lumino places great emphasis on patient safety, mentoring new graduates to build confidence and communication skills, to foster professionalism and to be part of the dental team.

Please do not hesitate to contact me if you require any further support on this matter. Lumino is looking forward to engaging oral health graduates and for them to assist in providing high quality and comprehensive oral health care in a safe environment.

Kind regards
Cathrine Lloyd MA, BDS (Hons), FICD, FADI, FNZDA
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PO Box 5450, Wellington , New Zealand

NZ Dental & Oral Health Therapists
Nga Kaihaumanu Hauora a-Niho, a-Waha hoki

15 December 2016

Attention: Dr Robin Whyman
Dental Council of New Zealand - Chair

Dear Robin,

Re: Reclassification of local anaesthetic for the practice of oral health therapy

Our association represents and supports dental and oral health therapists and dental hygienists on professional issues. We have 650 members including over 100 recent graduates and students.

Our purpose is to promote the interests of our profession and the importance of oral health. We have been advocating for the creation of the oral health therapy scope of practice since 2008 and we are very pleased that it is being introduced in 2017.

With the change in scope, it is necessary to change the local anaesthetic and associated vasoconstrictors classifications to include oral health therapy. The medicines requiring reclassification include: articaine, lignocaine, prilocaine, and felypressin.

As dental therapists already have access to these local anaesthetic medicines, with no known concerns in the provision of local anaesthetic to children, the classification should be extended to include the new scope of oral health therapy, which incorporates the dental therapy and dental hygienist qualifications.

The reclassification is essential to ensure the continued, uninterrupted access by oral health therapists to local anaesthesia currently available to dental therapists. This is fundamental to the practice of oral health therapy and, if the reclassification does not occur, patient access to care will likely be negatively impacted.

We have full confidence in the competence of oral health graduates to safely and competently use these medicines and, importantly, to know when not to administer local anaesthetic and when to seek advice from dentists/dental specialists or to refer.

We believe that reclassifying these medicines is in line with the ethical obligation to put the patient's interests first, do no harm and provide good quality and safe oral health care. We are in full support of the reclassification of these medicines to ensure on-going patient access to a high standard of oral health care.

Kind regards,

Arish Naresh

Chair - NZDOHTA

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Canterbury
District Health Board
Te Poari Hauora ō Waitaha
Community Dental Service

14 December, 2016

Ms Marie Warner
CEO
Dental Council of New Zealand

Dear Marie

On behalf of the clinical directors and senior dentists of District Health Board child oral health services, we'd like to thank the DCNZ for meeting with us to explain its proposal for a reclassification, by the Medicines Classification Committee, of lignocaine, prilocaine, articaine and felypressin to include an exemption for oral health therapists.

We understand that the result of this change will see access to local anaesthetics for oral health therapists being the same as currently exists for dental therapists where the treatment falls into the dental therapy scope. An alternative arrangement through the issuing and maintaining of standing orders is available however this comes with a significant administrative burden and offers no improvement in safety.

We support the proposed addition of oral health therapists to the prescriber exemption for lignocaine, prilocaine, articaine and felypressin as being both safe and in the public interest.

Kind regards,

Dr Martin Lee, Specialist in Public Health Dentistry

on behalf of: Drs Ellen Clark, Northland; Sathananthan Kanagaratnam, Auckland Regional Dental Service; Rob Aitken, Waikato; Rudi Johnson, Bay of Plenty; David O'Brian, Lakes; David Edgar, Tairawhiti; Andrea Kelsen, Taranaki; Phil Marshall, Mid-Centra; Kathy Fuge Hutt/Capital & Coast; Tule Misa, Canterbury; Angela Benn, Southern; Tim Mackay, Southern.

ref: document4

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New Zealand
Dental Hygienists' Association
(est. 1993)

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www.nzdha.co.nz

12 December 2016

Marie Warner
Chief Executive
Dental Council
PO Box 10-448
Wellington 6143

Support for the Dental Council medicine reclassification application

The New Zealand Dental Hygienists Association (NZDHA) is the professional association for dental hygienists in New Zealand, and represents 400 dental hygienists.

The NZDHA is a key stakeholder of the Dental Council, and has received, and responded to the two consultations on the development of the oral health therapy scope of practice. The NZDHA supports the new scope of practice as reflecting the qualification and capabilities of the oral health graduates.

The Council has discussed its intent and the nature of its medicine reclassification with me during a teleconference on 8 December 2017. I was advised that the Council's application will include widening of the classification of the following agents to allow use by an oral health therapist without requiring supervision by a dentist/dental specialist: Articaine, Prilocaine, Lignocaine, and Felypressin. This widened access is consistent with work that dental therapists (previously known as school dental nurses) have been doing for a great many years.

Dental hygienists, dental therapists and graduates of the oral health three-year Bachelor qualification all use local anaesthetics in their practice frequently and have strong capabilities. Dental therapists use local anaesthetics in treating children with no dentist present or supervising. Dental hygienists use local anaesthetics when a dentist/dental specialist is on the premises. It is reasonable for oral health therapists to use local anaesthetics without requiring a dentist/dental specialist to be there. The alternative of standing orders for oral health therapists would be burdensome to district health boards, dentists, and oral health therapists, and provide no additional safety to the public than the proposal.

IFDH Association Member

The burden of standing orders might potentially impact negatively on access to care. We therefore strongly support the change. We would note that for the future this same consideration could be applied to dental hygienists given their vast experience with these medicines.

Oral health therapy will be practised within a consultative professional relationship with one or more dentists and/or dental specialists. In our experience to date, oral health graduates have the insight and ethical obligation, to seek advice in cases that fall outside of the own competence or scope of practice; or refer appropriately.

The combined dental hygiene and dental therapy programmes were introduced in New Zealand in 2006 by Auckland University of Technology, followed by the University of Otago in 2007. Since then, these oral health graduates have become our colleagues. The NZDHA believes that the oral health therapists, similar to its own members, put patients' interest first, and strive to always deliver good quality and safe oral health care to the public of New Zealand.

The NZDHA wishes to reconfirm its request for the Council to consider a similar change to the dental hygiene scope of practice, allowing the administration of local anaesthetics under clinical guidance within the working relationship of a dentist/dental specialist; rather than under direct clinical supervision. This will acknowledge the significant experience of practising dental hygienists, and provide an equal practising environment for the administration of local anaesthetics. The NZDHA acknowledges the Council's current workplan with the implementation of the oral health therapy scope of practice, and the need for such a change to undergo the normal consultation processes.

Yours sincerely

Paula Palmer

President NZDHA

IFDH Association Member

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
108789	OCT13	2 2 FAINTNESS	* MEPIVACAINE	DE	[redacted]				1-59 mins
		2 2 HEADACHE	* ARTICAINE w/ADRENALINE	DE					1-59 mins
		2 2 SHAKING							
		2 2 DROWSINESS							
		5 2 APNOEA							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge :
Seriousness : Not Serious

Patient Age: 51 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
113660	SEP14	2 2 RASH ERYTHEMATOUS	* ARTICAINE w/ADRENALINE	DE	[redacted]				< 12 hours
		2 2 BRONCHOSPASM	METHYLPHENIDATE	PO					

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Not Serious

Patient Age: 14 Date of Birth: [redacted]
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
091918	SEP10	2 1 ANAPHYLACTIC SHOCK	* ARTICAINE w/ADRENALINE	DE	[redacted]				instantaneous
		2 1 CARDIAC ARREST	METOPROLOL	PO					
		1 1 SKIN TEST POSITIVE	ACETYLSALICYLIC ACID	PO					
			GLYCERYL TRINITRATE	SL					

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : Recurrence of symptoms
Seriousness : Life threatening

Patient Age: 44 Date of Birth: [redacted]
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
110534	MAR14	2 2 RASH ERYTHEMATOUS 2 2 HYPOTENSION 2 2 STRIDOR	* ARTICAINE w/ADRENALINE CITALOPRAM	DE PO	[redacted]			[redacted]	1-59 mins

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Life threatening

Patient Age: 56 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
073801	NOV06	2 2 LIPS SWELLING NON-SPECIFIC	* ARTICAINE w/ADRENALINE	BU	[redacted]			[redacted]	< 12 hours

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Not Serious

Patient Age: 59 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
109771	JAN14	3 2 LIPS SWELLING NON-SPECIFIC	* 00000 * ARTICAINE w/ADRENALINE * QUINAPRIL OMEPRAZOLE SIMVASTATIN	DE DE PO PO PO	[redacted]			[redacted]	< 12 hours < 12 hours

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Unknown
Rechallenge : No rechallenge performed
Seriousness : Not Serious

Patient Age: 89 Date of Birth: [redacted]
Sex: Male
Reporter: [redacted]
Outcome: Not yet recovered

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
084840	JUN09	2 2 URTICARIA	* ARTICAINE w/ADRENALINE	DE	[redacted]			[redacted]	
		2 2 OEDEMA PERIORBITAL							
		2 2 NAUSEA							
		2 2 HYPERKINESIA							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Life threatening
Patient Age: 10 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
104018	SEP12	1 2 PRURITUS	BENZOCAINE	DE	[redacted]			[redacted]	1-59 mins
		1 2 FLUSHING	TETRACAINE	DE					1-59 mins
		1 2 OEDEMA PERIORBITAL	LIGNOCAINE	DE					1-59 mins
		1 2 SKIN TEST POSITIVE	* ARTICAINE w/ADRENALINE	DE					1-59 mins
			LEVLEN ED	PO	[redacted]				1-5 years

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : Recurrence of symptoms
Seriousness : Not Serious
Patient Age: 41 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
111558	APR14	1 1 ANAPHYLACTIC REACTION	* LIGNOCAINE	DE	[redacted]			[redacted]	1-59 mins
		1 1 SKIN TEST POSITIVE							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : Recurrence of symptoms
Seriousness : Life threatening
Patient Age: 30 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
009786	JAN81	1 1 ANAPHYLACTIC SHOCK	* LIGNOCAINE	DE				[redacted]	< 1 week
			* ADRENALINE	DE				-	< 1 week
			TERBUTALINE	IH	[redacted]			-	1-5 years
			DIGOXIN	PO				-	1-5 years
			THEOPHYLLINE	PO				-	1-5 years

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Not Serious

Patient Age: 65 Date of Birth:
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
041738	JUN99	2 2 ANAPHYLACTIC SHOCK	* LIGNOCAINE	DE	[redacted]			[redacted]	< 12 hours
			* ACETYLSALICYLIC ACID	PO					< 12 hours

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Hospitalisation

Patient Age: 57 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
034163	APR97	2 2 ANGIOEDEMA	* LIGNOCAINE	IV	1	DF	[redacted]	[redacted]	< 12 hours
		2 2 RASH							
		2 2 BULLOUS ERUPTION							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Not Serious

Patient Age: 11 Date of Birth: [redacted]
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
008800	SEP79	1 1 BRONCHOSPASM	* LIGNOCAINE	DE				[redacted]	1-59 mins
		1 1 RASH							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Not Serious

Patient Age: 38 Date of Birth:
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
015914	APR87	2 1 CONVULSIONS	* LIGNOCAINE	DE	[redacted]			[redacted]	1-59 mins

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Unknown
Rechallenge : Unknown
Seriousness : Not Serious

Patient Age: 9 Date of Birth:
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
085183	JUL09	1 2 PRURITUS	* LIGNOCAINE	DE	[redacted]			[redacted]	1-59 mins
		2 2 VOMITING	SALBUTAMOL	IH					
		2 2 CONVULSIONS	FLUTICASONE	IH					
		1 2 SKIN TEST POSITIVE							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : Recurrence of symptoms
Seriousness : Hospitalisation

Patient Age: 24 Date of Birth: [redacted]
Sex: Preg. Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
000541	JUN66	1 1 CONVULSIONS GRAND MAL	* LIGNOCAINE w/ADRENALINE	DE				[redacted]	1-59 mins
		1 1 COMA	* ADRENALINE	DE					1-59 mins
			DIPHENHYDRAMINE	TO	[redacted]				

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Not Serious

Patient Age: 31 Date of Birth:
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
010896	MAY82	1 1 FACE OEDEMA	* LIGNOCAINE	DE				[redacted]	< 24 hours
		1 1 EYELID OEDEMA							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Intervention

Patient Age: 15 Date of Birth:
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
011468	DEC82	1 2 FACE OEDEMA	* LIGNOCAINE	DE	[redacted]				< 12 hours
		1 2 DYSPNOEA							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) :
Dechallenge :
Rechallenge :
Seriousness : Not Serious

Patient Age: 36 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
011946	JUN83	1 1 FACE OEDEMA 1 1 RASH ERYTHEMATOUS	* LIGNOSPAN	DE	[redacted]			[redacted]	< 12 hours

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Intervention

Patient Age: 14 Date of Birth: [redacted]
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
013950	SEP85	1 2 FACE OEDEMA	* PROCAINE	DE				[redacted]	Unknown
			* LIGNOCAINE	DE				[redacted]	Unknown
			* BUPIVACAINE	DE				[redacted]	Unknown

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Not Serious

Patient Age: 16 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
020076	MAR90	1 2 CONFUSION 1 2 FACE OEDEMA	* LIGNOCAINE	DE	[redacted]			[redacted]	

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Not Serious

Patient Age: 6 Date of Birth: [redacted]
Sex: Male
Reporter: [redacted]
Outcome: Unknown outcome

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
103160	JUL12	4 2 URTICARIA	* LIGNOCAINE w/ADRENALINE	DE			[redacted]	[redacted]	< 12 hours
		4 2 PRURITUS							
		4 2 BULLOUS ERUPTION							
		4 2 FACE OEDEMA							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Not Serious
Patient Age: 75 Date of Birth: [redacted]
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

002595	MAY71	1 1 SYNCOPE	* LIGNOCAINE	DE				[redacted]	1-59 mins
		1 1 HYPERKINESIA	* ADRENALINE	DE					1-59 mins
		1 1 HYPOTENSION							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Not Serious
Patient Age: 41 Date of Birth:
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

095944	JUN11	1 1 THROAT TIGHTNESS	* LIGNOCAINE	DE			[redacted]	-	instantaneous
		1 2 RASH							
		1 1 SKIN TEST POSITIVE							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) :
Dechallenge : Definite improvement
Rechallenge : Recurrence of symptoms
Seriousness : Life threatening
Patient Age: Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
025357	DEC93	2 1 DYSPHAGIA	* LIGNOCAINE	DE	[redacted]			[redacted]	< 12 hours
		2 1 ANGIOEDEMA	* MEPIVACAINE	DE					< 12 hours
		2 1 URTICARIA							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Not Serious

Patient Age: 48 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
034162	APR97	2 2 URTICARIA	* LIGNOCAINE	DE	[redacted]			[redacted]	< 12 hours

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Not Serious

Patient Age: 33 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
038848	AUG98	3 2 URTICARIA	* LIGNOCAINE	DE	[redacted]			[redacted]	1-59 mins
			* ADRENALINE	DE					1-59 mins

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Intervention

Patient Age: 25 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Not yet recovered

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
109400	JAN14	1 1 SKIN TEST POSITIVE 1 1 ANAPHYLACTIC REACTION	* PRILOCAINE w/FELYPRESSIN	DE		[redacted]		[redacted]	1-59 mins

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : Recurrence of symptoms
Seriousness : Life threatening

Patient Age: 48 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
005890	AUG76	1 1 ANAPHYLACTOID REACTION	* PRILOCAINE	DE	[redacted]			[redacted]	1-59 mins

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Intervention

Patient Age: 24 Date of Birth:
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
017848	OCT88	1 1 ANAPHYLACTOID REACTION	* PRILOCAINE	DE				[redacted]	1-59 mins

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Not Serious

Patient Age: 74 Date of Birth: [redacted]
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
077648	FEB08	1 1 ANAPHYLAXIS	* PRILOCAINE	DE	[redacted]			[redacted]	< 12 hours

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : Recurrence of symptoms
Seriousness : Hospitalisation
Patient Age: 15 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

032669	NOV96	2 1 RHINITIS	* PRILOCAINE	DE	[redacted]			[redacted]	1-59 mins
		2 1 BRONCHOSPASM							
		2 1 VOMITING							
		2 1 DIARRHOEA							
		2 1 URINARY INCONTINENCE							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Not Serious
Patient Age: 57 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

020854	NOV90	1 1 HYPOTENSION	* PRILOCAINE	DE				-	
		1 1 CONVULSIONS							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) :
Dechallenge : Definite improvement
Rechallenge : No rechallenge performed
Seriousness : Not Serious
Patient Age: 10 Date of Birth: [redacted]
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
094515	MAR11	2 1 CONVULSIONS	* PRILOCAINE w/FELYPRESSIN	DE	[redacted]				1-59 mins
		2 1 CEREBRAL HAEMORRHAGE	PAROXETINE	PO					
		2 1 VOMITING	SIMVASTATIN	PO					
		2 1 DYSPNOEA	METOPROLOL	PO					
		2 1 HYPERTENSION	FRUSEMIDE	PO					< 1 week

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Unknown
Rechallenge : No rechallenge performed
Seriousness : Life threatening

Patient Age: 87 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Not yet recovered

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
009633	OCT80	1 2 FACE OEDEMA	* PRILOCAINE	DE				[redacted]	1-59 mins

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Not Serious

Patient Age: 30 Date of Birth:
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
008471	MAY79	1 1 RESPIRATORY DEPRESSION	* PRILOCAINE	DE	[redacted]			[redacted]	1-59 mins

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Intervention

Patient Age: 23 Date of Birth:
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases
Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
070021	JAN06	2 2 URTICARIA	* PRILOCAINE	DE	[redacted]			[redacted]	< 12 hours
		2 2 TONGUE OEDEMA							
		2 2 AMNESIA							

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge : Definite improvement
Rechallenge :
Seriousness : Not Serious

Patient Age: 63 Date of Birth: [redacted]
Sex: Female
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
004813	SEP74	1 1 VOMITING	CODEINE	PO	[redacted]			[redacted]	< 12 hours
		1 1 URTICARIA	* PRILOCAINE	DE				-	< 12 hours
		1 1 ANGIOEDEMA	PRACTOLOL	PO				-	< 1 month
		1 1 RASH	PRAZOSIN	PO				-	< 1 month

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Not Serious

Patient Age: 55 Date of Birth:
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION
011858	MAY83	1 1 URTICARIA	* PRILOCAINE	DE	[redacted]			[redacted]	< 24 hours

OTHER RELEVANT INFORMATION:
Onset (DDMMYY) : [redacted]
Dechallenge :
Rechallenge :
Seriousness : Intervention

Patient Age: 40 Date of Birth:
Sex: Male
Reporter: [redacted]
Outcome: Recovered without sequelae

REACTIONS REPORTED to CARM - Local Anaesthetics - Selected cases

Severity : 1 = Severe 2 = Not Severe

REPORT	DATE	REL/SEVERITY/REACTIONS	DRUGS	ROUTE	DOSE	UNIT	FREQ	ADMINISTRATION	DURATION

Detail for Articaine between 1 Jan 2000 and 01 dec 2016

Number of reports for Articaine: 12

Number reports where death was reported: 0

Number of reactions: 32

Report	Date	Gender	Age	Medicine(s)	Reaction(s)
73801	Nov 2006	Female	59	Articaine with adrenaline injection (Suspect)	Lip swelling
83862	Apr 2009	Female	48	Articaine with adrenaline injection (Suspect)	Hypoaesthesia
84840	Jun 2009	Female	10	Articaine with adrenaline injection (Suspect)	Hyperkinesia Nausea Periorbital oedema Urticaria
87226	Nov 2009	Female	49	Articaine with adrenaline injection (Suspect)	Hypoaesthesia
91273	Aug 2010	Female	49	Articaine with adrenaline injection (Suspect)	Depressed level of consciousness Dizziness Nausea Tremor
91918	Sep 2010	Male	44	Articaine with adrenaline injection (Suspect) Metoprolol oral (Concomitant) Aspirin oral (Concomitant) Glyceryl trinitrate spray (Concomitant)	Anaphylactic shock Cardiac arrest Skin test positive
104018	Sep 2012	Female	41	Benzocaine oral topical (Concomitant) Tetracaine topical (Concomitant) Lidocaine with adrenaline dental injection (Concomitant) Articaine with adrenaline injection (Suspect) Levlen ED oral (Concomitant)	Flushing Periorbital oedema Pruritus Skin test positive
108789	Oct 2013	Female	51	Mepivacaine injection (Suspect) Articaine with adrenaline injection (Suspect)	Apnoea Dizziness Headache Somnolence Tremor
110393	Mar 2014	Female	55	Xylestesin-A injection (Suspect)	Rash Skin test positive

				Articaine with adrenaline injection (Suspect) Bupivacaine injection (Concomitant)	
110534	Mar 2014	Female	56	Articaine with adrenaline injection (Suspect) Citalopram oral (Concomitant)	Hypotension Rash erythematous Stridor
113660	Sep 2014	Male	14	Articaine with adrenaline injection (Suspect) Methylphenidate oral (Concomitant)	Bronchospasm Rash erythematous
121455	Jul 2016	Female	26	Articaine with adrenaline injection (Suspect) Norimin oral (Concomitant)	Nausea Paraesthesia oral

Detail for Felypressin between 1 Jan 2000 and 1 dec 2016

Number of reports for Felypressin: 4

Number reports where death was reported: 0

Number of reactions: 12

Report	Date	Gender	Age	Medicine(s)	Reaction(s)
46224	Nov 2000	Female	38	Citanest 3% with Octapressin injection (Suspect) Adrenaline; Lidocaine injection (Concomitant) Diazepam oral (Suspect) Paracetamol oral (Concomitant)	Dizziness Headache Sedation Somnolence
62101	Sep 2004	Female	49	Citanest 3% with Octapressin injection (Suspect)	Rash pruritic
94515	Mar 2011	Female	87	Citanest 3% with Octapressin injection (Suspect) Paroxetine oral (Concomitant) Simvastatin oral (Concomitant) Metoprolol oral (Concomitant) Furosemide oral (Concomitant)	Cerebral haemorrhage Dyspnoea Hypertension Seizure Vomiting
109400	Jan 2014	Female	48	Citanest 3% with Octapressin injection (Suspect)	Anaphylactic reaction Skin test positive

Detail for Lidocaine

Number of reports for Lidocaine: 109

Number reports where death was reported: 0

Number of reactions: 218

Report	Date	Gender	Age	Medicine(s)	Reaction(s)
43546	Feb 2000	Male	32	Lidocaine with adrenaline dental injection (Suspect) Bupivacaine injection (Suspect)	Malaise Rash macular
43592	Feb 2000	Female	5	Lidocaine topical (Suspect)	Application site reaction Burning sensation Dermatitis exfoliative
44873	Jul 2000	Female	41	Methylprednisolone; Lidocaine injection (Suspect) Cilazapril oral (Concomitant)	Anaphylactic reaction
45230	Aug 2000	Female	18	Strepsils Numbing lozenge (Suspect)	Dyspnoea Rash Throat tightness
47311	Apr 2001	Female	47	Lidocaine with adrenaline dental injection (Suspect) Citanest 3% with Octapressin injection (Concomitant)	Affect lability Dizziness Tachycardia
47663	May 2001	Male	7	Lignospan injection (Suspect)	Dizziness Pallor
47814	Jun 2001	Female	23	Lidocaine with adrenaline dental injection (Suspect)	Urticaria
47961	Jun 2001	Male	42	Lidocaine injection (Suspect)	Anaphylactoid reaction
48181	Jul 2001	Female	36	Lidocaine injection (Suspect)	Anaphylactic reaction
48938	Oct 2001	Female	54	Xyloproct rectal (Suspect)	Application site reaction Oedema genital Pruritus
49235	Nov 2001	Male	77	Povidone-iodine (Suspect) Lidocaine injection	Angioedema Pruritus

				(Suspect) Atenolol oral (Concomitant) Furosemide oral (Concomitant)	
49376	Nov 2001	Female	53	Xylestesin-A injection (Suspect) Salmeterol inhalation (Concomitant) Fluticasone inhalation (Concomitant) Salbutamol inhalation (Concomitant) Claratyne oral (Concomitant)	Muscle contractions involuntary Paraesthesia
52579	Aug 2002	Male	5	Lidocaine injection (Suspect) Adrenaline injection (Suspect) Sodium sulfate (Suspect)	Urticaria
52852	Sep 2002	Male	78	Dalteparin injection (Suspect) Visipaque injection (Suspect) Lidocaine injection (Suspect)	Conjunctivitis Face oedema Urticaria
53016	Sep 2002	Male	68	Chlorhexidine; Lidocaine topical (Suspect)	Dysuria Oedema Rash erythematous
53035	Sep 2002	Male	78	Chlorhexidine; Lidocaine topical (Suspect) Cefoxitin injection (Concomitant)	Anaphylactic shock Atrial fibrillation Hyperhidrosis Rash
53577	Nov 2002	Male	70	Lidocaine injection (Suspect)	Anaphylactic reaction
53599	Nov 2002	Male	54	Lidocaine injection (Suspect) Codeine oral (Concomitant)	Rash macular
53809	Nov 2002	Female	29	Lidocaine topical (Suspect)	Anaphylactoid reaction
53837	Nov 2002	Female	44	Lidocaine injection (Suspect) Diclofenac oral (Concomitant)	Anaphylactic shock Injection site reaction

53937	Dec 2002	Female	41	Adrenaline; Lidocaine injection (Suspect)	Fatigue Hypoaesthesia Muscular weakness
53948	Dec 2002	Female	30	Cophenylcaine nasal (Suspect)	Conjunctivitis Rhinitis
55022	Feb 2003	Female	42	Adrenaline; Lidocaine injection (Suspect)	Seizure Syncope
55343	Mar 2003	Female	52	Paraderm Plus topical (Suspect)	Dermatitis contact
55358	Mar 2003	Male	75	Chlorhexidine; Lidocaine topical (Suspect)	Rash pruritic Tongue oedema
56065	May 2003	Male	79	Chlorhexidine; Lidocaine topical (Suspect)	Anaphylactic shock
56517	Jun 2003	Female	33	Adrenaline; Lidocaine injection (Suspect)	Dizziness Injection site pain Nausea
59425	Feb 2004	Female	50	Methylprednisolone; Lidocaine injection (Suspect)	Anaphylactic reaction
60867	Jun 2004	Female	82	Methylprednisolone; Lidocaine injection (Suspect) Atenolol oral (Concomitant)	Dizziness Flushing Tachycardia
61293	Jul 2004	Male	34	Lidocaine injection (Suspect) Alprazolam oral (Concomitant) Metoprolol oral (Concomitant) Omeprazole oral (Concomitant) Amiodarone oral (Concomitant)	Rash pruritic
61473	Jul 2004	Male	56	Lidocaine injection (Suspect) Simvastatin oral (Concomitant) Omeprazole oral (Concomitant) Felodipine oral (Concomitant) Flucloxacillin injection (Concomitant)	Anaphylactic reaction

61596	Aug 2004	Male	67	Lidocaine injection (Suspect) Hyalase injection (Concomitant) Tetracaine topical (Concomitant)	Pruritus Rash pruritic
62605	Oct 2004	Unknown	0	Lidocaine oral (Suspect)	Disorientation Dyskinesia Hyperacusis Somnolence Tremor
62621	Oct 2004	Female	49	Lorazepam oral (Suspect) Lidocaine injection (Suspect)	Delirium Paralysis
62779	Nov 2004	Male	55	Propofol injection (Suspect) Remifentanil injection (Suspect) Lidocaine oral (Suspect) Rocuronium injection (Suspect) Cyclophosphamide oral (Concomitant)	Hypotension Rash erythematous
62974	Nov 2004	Female	54	Dalteparin injection (Suspect) Lidocaine injection (Suspect)	Anaphylactic reaction Flushing Malaise Paraesthesia
63120	Nov 2004	Female	61	Adrenaline; Lidocaine injection (Suspect) Salbutamol inhalation (Suspect) Amoxicillin; Clavulanic acid oral (Concomitant) Nicotinic acid oral (Concomitant) Thompson's organic magnesium oral (Concomitant)	Pruritus Rash
64396	Feb 2005	Female	82	Lidocaine oral (Suspect) Mylanta oral (Suspect) Omeprazole oral (Concomitant) Glyceryl trinitrate oral (Concomitant)	Anaphylactic reaction

68406	Sep 2005	Female	56	Adrenaline; Lidocaine injection (Suspect) Warfarin oral (Concomitant)	Ataxia Headache Hyperhidrosis Tremor
70375	Feb 2006	Female	50	Propofol injection (Suspect) Fentanyl injection (Suspect) Lidocaine injection (Suspect) Loratadine oral (Concomitant) Salbutamol inhalation (Concomitant)	Anaphylactic shock Bradycardia
71634	May 2006	Male	35	Medijel topical (Suspect)	Dysaesthesia Tongue oedema
71651	May 2006	Male	36	Chlorhexidine; Lidocaine topical (Suspect) Cefazolin injection (Suspect) Midazolam injection (Concomitant) Rocuronium injection (Concomitant) Fentanyl injection (Concomitant)	Bronchospasm Urticaria
72123	Jun 2006	Female	5	Tegaderm dressing (Suspect) Lidocaine; Prilocaine topical (Suspect)	Urticaria
72224	Jun 2006	Male	36	Latex (Suspect) Lidocaine injection (Suspect)	Rash
72838	Jul 2006	Female	45	Lidocaine injection (Suspect) Triamcinolone injection (Concomitant)	Flushing Headache
74146	Dec 2006	Male	63	Lidocaine topical (Suspect)	Dermatitis bullous
74658	Feb 2007	Male	15 months	Measles, Mumps, Rubella vaccine injection (Suspect) Lidocaine; Prilocaine topical (Suspect) Hiberix vaccine injection (Concomitant)	Urticaria

74711	Mar 2007	Female	13	Lidocaine; Prilocaine topical (Suspect) Omnipaque injection (Concomitant)	Dermatitis contact
75517	Jun 2007	Male	22	Xylestesin-A injection (Suspect)	Abdominal pain Hyperhidrosis Nausea Pyrexia Vomiting
75630	Jun 2007	Male	14	Lidocaine injection (Suspect)	Anaphylactoid reaction
76518	Sep 2007	Male	75	Xylestesin-A injection (Suspect)	Anaphylactic reaction
77195	Dec 2007	Female	39	Lidocaine injection (Suspect)	Depressed level of consciousness
77477	Jan 2008	Female	70	Omperazole oral (Suspect) Midazolam injection (Suspect) Lidocaine topical (Suspect) Warfarin oral (Concomitant) Simvastatin oral (Concomitant)	Angioedema Urticaria
78250	Apr 2008	Male	67	Chlorhexidine; Lidocaine topical (Suspect) Bupivacaine injection (Concomitant) Morphine injection (Concomitant) Midazolam injection (Concomitant) Cefazolin injection (Concomitant)	Anaphylactic reaction
78253	Apr 2008	Female	9	Lidocaine; Prilocaine topical (Suspect)	Urticaria
79490	Jul 2008	Male	72	Chlorhexidine; Lidocaine topical (Suspect) Simvastatin oral (Concomitant) Aspirin oral (Concomitant) Colchicine oral (Concomitant) Quinapril oral (Concomitant)	Anaphylactic reaction

80558	Sep 2008	Female	24	Medijel topical (Suspect)	Anaphylactic reaction
81127	Sep 2008	Female	16	Lidocaine injection (Suspect) Mepivacaine injection (Suspect)	Anaphylactic reaction
82285	Dec 2008	Female	47	Lidocaine injection (Suspect) Chlorhexidine mouthwash (Suspect) Povidone-iodine (Concomitant) Pethidine oral (Concomitant) Contrast medium NOS injection (Concomitant)	Dysphonia Dyspnoea Rash Throat tightness
83177	Mar 2009	Female	35	Adrenaline; Lidocaine injection (Suspect)	Face oedema Flushing Paraesthesia oral Throat tightness
83330	Mar 2009	Male	66	Lidocaine topical (Suspect)	Application site reaction Blister
85096	Jul 2009	Male	23	Ibuprofen oral (Suspect) Paracetamol oral (Suspect) Lidocaine injection (Suspect) Bupivacaine injection (Suspect) Iodine topical (Suspect)	Periorbital oedema
85183	Jul 2009	Female	24	Lidocaine topical (Suspect) Salbutamol inhalation (Concomitant) Fluticasone inhalation (Concomitant)	Pruritus Seizure Skin test positive Vomiting
87132	Nov 2009	Male	0	Chlorhexidine; Lidocaine topical (Suspect)	Anaphylactic reaction
87133	Nov 2009	Male	69	Chlorhexidine; Lidocaine topical (Suspect) Latex (Suspect)	Anaphylactic reaction
87303	Nov 2009	Male	75	Lidocaine oral (Suspect) Fentanyl injection (Suspect) Midazolam oral (Suspect)	Respiratory arrest Stridor

87708	Dec 2009	Male	89	Chlorhexidine; Lidocaine topical (Suspect)	Bradycardia Hypotension Nausea Presyncope
88947	Mar 2010	Male	64	Adrenaline; Lidocaine injection (Suspect) Digoxin oral (Concomitant) Colecalciferol oral (Concomitant) Zinc oral (Concomitant) Aspirin oral (Concomitant)	Hypoaesthesia Vasospasm
89157	Mar 2010	Male	86	Chlorhexidine; Lidocaine topical (Suspect) Leuprorelin injection (Suspect)	Urticaria
92050	Sep 2010	Female	54	Lidocaine injection (Suspect)	Application site reaction Skin test positive
93492	Jan 2011	Female	31	Fentanyl injection (Suspect) Lidocaine injection (Suspect) Misoprostol oral (Concomitant) Diclofenac oral (Concomitant) Midazolam oral (Concomitant)	Agitation Flushing Pruritus
95446	May 2011	Female	69	Bupivacaine injection (Suspect) Lidocaine injection (Suspect) Adrenaline injection (Suspect) Fluoxetine oral (Concomitant) Atorvastatin oral (Concomitant)	Circulatory collapse Seizure
95944	Jun 2011	Female	0	Lidocaine with adrenaline dental injection (Suspect)	Rash Skin test positive Throat tightness
96297	Jul 2011	Female	22	Lidocaine injection (Suspect) Benzathine benzylpenicillin injection (Concomitant)	Hypoaesthesia Rash Vomiting

97136	Sep 2011	Male	74	Lidocaine injection (Suspect)	Dermatitis contact
99870	Feb 2012	Female	46	Triamcinolone injection (Suspect) Lidocaine injection (Suspect)	Urticaria
100047	Feb 2012	Female	50	Triamcinolone injection (Suspect) Chlorhexidine; Lidocaine topical (Suspect)	Chest discomfort Pruritus Throat tightness
100592	Mar 2012	Male	71	Lidocaine topical (Suspect)	Drug level increased Seizure
100701	Apr 2012	Male	54	Chlorhexidine; Lidocaine topical (Suspect)	Anaphylactic reaction
101602	May 2012	Male	69	Lidocaine injection (Suspect) Bupivacaine injection (Concomitant) Ropivacaine injection (Concomitant)	Skin test positive
101851	May 2012	Male	77	Ropivacaine injection (Suspect) Lidocaine injection (Suspect) Cefazolin injection (Suspect) Dexamethasone ophthalmic (Suspect) Acetazolamide injection (Suspect)	Anaphylactic reaction
101860	May 2012	Male	44	Visipaque injection (Suspect) Lidocaine injection (Suspect)	Headache Rash
101938	Jun 2012	Male	14 months	Lidocaine; Prilocaine topical (Suspect)	Application site rash
102136	Jun 2012	Female	47	Triamcinolone injection (Suspect) Adrenaline; Lidocaine injection (Suspect)	Infection
104244	Oct 2012	Male	22	Chlorhexidine; Lidocaine topical (Suspect) Fentanyl injection (Concomitant)	Anaphylactic reaction Skin test positive

				Propofol injection (Concomitant) Dexamethasone injection (Concomitant) Gentamicin injection (Concomitant)	
106377	Apr 2013	Male	75	Medijel topical (Suspect) Metoprolol oral (Concomitant) Atorvastatin oral (Concomitant) Pantoprazole oral (Concomitant) Aspirin oral (Concomitant)	Rash Syncope Vomiting
107306	Jun 2013	Female	0	Adrenaline; Lidocaine injection (Suspect)	Hypersensitivity
107513	Jul 2013	Male	45	Lidocaine topical (Suspect)	Urticaria
108424	Sep 2013	Female	56	Lidocaine injection (Suspect) Streptokinase injection (Concomitant)	Dysgeusia Dyspnoea Hypotension Pharyngeal oedema Skin test negative
108657	Oct 2013	Female	42	Lidocaine injection (Suspect)	Anaphylactic reaction
109387	Jan 2014	Female	32	Lidocaine topical (Suspect)	Face oedema Oedema mouth Urticaria
110393	Mar 2014	Female	55	Xylestesin-A injection (Suspect) Articaine with adrenaline injection (Suspect) Bupivacaine injection (Concomitant)	Rash Skin test positive
111148	Apr 2014	Male	76	Chlorhexidine; Lidocaine topical (Suspect) Midazolam injection (Concomitant) Atorvastatin oral (Concomitant) Levothyroxine oral (Concomitant) Warfarin oral (Concomitant)	Anaphylactic shock Skin test negative

111460	Apr 2014	Female	10	Xylestesin-A injection (Suspect)	Angioedema Rash Skin test negative
111558	Apr 2014	Female	30	Lidocaine with adrenaline dental injection (Suspect)	Anaphylactic reaction Skin test positive
112056	May 2014	Male	86	Adrenaline; Lidocaine injection (Suspect) Triamcinolone injection (Suspect)	Dizziness Myocardial infarction
112321	Jun 2014	Female	61	Cophenylcaine nasal (Suspect)	Dizziness Nausea Tachycardia
112485	Jun 2014	Female	37	Lidocaine injection (Suspect)	Anaphylactic reaction Skin test positive
113123	Aug 2014	Male	89	Latex (Suspect) Chlorhexidine; Lidocaine topical (Suspect) Bupivacaine injection (Concomitant) Amoxicillin oral (Concomitant) Fentanyl injection (Concomitant)	Anaphylactic reaction Angioedema
113997	Oct 2014	Female	38	Adrenaline; Lidocaine injection (Suspect)	Bronchospasm Skin test positive Tachycardia
114209	Nov 2014	Female	46	Triamcinolone injection (Suspect) Lidocaine injection (Suspect) Valproic acid oral (Concomitant)	Back pain
115024	Jan 2015	Male	78	Chlorhexidine; Lidocaine topical (Suspect) Fentanyl injection (Concomitant) Propofol injection (Concomitant) Rocuronium injection (Concomitant) Remifentanil injection (Concomitant)	Anaphylactic reaction

115772	Mar 2015	Male	33	Ceftriaxone injection (Suspect) Lidocaine injection (Suspect)	Urticaria
116776	Jun 2015	Female	25	Tetracaine topical (Suspect) Oral contraceptive (Concomitant) Lidocaine; Prilocaine topical (Suspect)	Application site rash Application site warmth Skin test positive
116899	Jun 2015	Male	27	Methylprednisolone; Lidocaine injection (Suspect)	Chest discomfort Dysphonia Skin burning sensation Stridor
117636	Aug 2015	Female	0	Xylestesin-A injection (Suspect) Levothyroxine oral (Concomitant)	Bronchospasm Skin test negative Throat tightness
118195	Oct 2015	Male	54	Cortisone oral (Suspect) Lidocaine injection (Suspect)	Paraesthesia oral Pharyngeal oedema
118475	Oct 2015	Female	68	Lidocaine injection (Suspect)	Anaphylactic reaction
119301	Jan 2016	Female	24	Adrenaline; Lidocaine injection (Suspect)	Rash Urticaria

Detail for Prilocaine between 1 Jan 2000 and 1 dec 2016

Number of reports for Prilocaine: 17

Number reports where death was reported: 0

Number of reactions: 32

Report	Date	Gender	Age	Medicine(s)	Reaction(s)
46224	Nov 2000	Female	38	Citanest 3% with Octapressin injection (Suspect) Adrenaline; Lidocaine injection (Concomitant) Diazepam oral (Suspect) Paracetamol oral (Concomitant)	Dizziness Headache Sedation Somnolence
60061	Apr 2004	Male	57	Prilocaine injection (Suspect) Doxazosin oral (Concomitant)	Blepharospasm Laryngospasm Vocal cord paralysis
62101	Sep 2004	Female	49	Citanest 3% with Octapressin injection (Suspect)	Rash pruritic
70021	Jan 2006	Female	63	Prilocaine injection (Suspect)	Amnesia Tongue oedema Urticaria
72123	Jun 2006	Female	5	Tegaderm dressing (Suspect) Lidocaine; Prilocaine topical (Suspect)	Urticaria
73877	Nov 2006	Female	21	Prilocaine injection (Suspect)	Bronchospasm
74658	Feb 2007	Male	15 months	Measles, Mumps, Rubella vaccine injection (Suspect) Lidocaine; Prilocaine topical (Suspect) Hiberix vaccine injection (Concomitant)	Urticaria
74711	Mar 2007	Female	13	Lidocaine; Prilocaine topical (Suspect) Omnipaque injection (Concomitant)	Dermatitis contact
77648	Feb 2008	Female	15	Prilocaine injection (Suspect)	Anaphylactic reaction

78253	Apr 2008	Female	9	Lidocaine; Prilocaine topical (Suspect)	Urticaria
87507	Dec 2009	Female	46	Prilocaine injection (Suspect)	Rash
94515	Mar 2011	Female	87	Citanest 3% with Octapressin injection (Suspect) Paroxetine oral (Concomitant) Simvastatin oral (Concomitant) Metoprolol oral (Concomitant) Furosemide oral (Concomitant)	Cerebral haemorrhage Dyspnoea Hypertension Seizure Vomiting
101938	Jun 2012	Male	14 months	Lidocaine; Prilocaine topical (Suspect)	Application site rash
108634	Oct 2013	Male	16	Prilocaine injection (Suspect) Morphine injection (Concomitant) Ibuprofen oral (Concomitant) Paracetamol oral (Concomitant)	Hypoaesthesia oral Urticaria
109400	Jan 2014	Female	48	Citanest 3% with Octapressin injection (Suspect)	Anaphylactic reaction Skin test positive
116776	Jun 2015	Female	25	Tetracaine topical (Suspect) Oral contraceptive (Concomitant) Lidocaine; Prilocaine topical (Suspect)	Application site rash Application site warmth Skin test positive
120969	Jun 2016	Male	21	Bupivacaine injection (Concomitant) Prilocaine injection (Suspect)	Methaemoglobinaemia

Data Sheet

3% Citanest® DENTAL with Octapressin®

Prilocaine 30 mg/mL, felypressin 0.54 µg/mL

Presentation

3% Citanest® DENTAL with Octapressin® solution for injection is a sterile isotonic aqueous solution. The pH of the solution is 3.5-5.2. The ampoules and cartridges are free from preservatives and are intended for single use only.

Uses

Actions

Prilocaine is a local anaesthetic of the amide type with a potency and duration similar to lidocaine (lignocaine).

Prilocaine, like other local anaesthetics, causes a reversible blockade of impulse propagation along nerve fibres by preventing the inward movement of sodium ions through the nerve membrane. Local anaesthetics of the amide type are thought to act within the sodium channels of the nerve membrane.

Local anaesthetic medicines may also have similar effects on excitable membranes in the brain and myocardium. If excessive amounts of medicine reach the systemic circulation rapidly, symptoms and signs of toxicity will appear, emanating mainly from the central nervous and cardiovascular systems.

Central nervous system toxicity (see "Overdose") usually precedes the cardiovascular effects as it occurs at lower plasma concentrations. Direct effects of local anaesthetics on the heart include slow conduction, negative inotropism and eventually cardiac arrest.

Felypressin is a suitable alternative to adrenaline as a localising agent, provided that local ischaemia is not essential.

Felypressin is a synthetic hormone with similar properties to vasopressin. In contrast to adrenaline, felypressin does not produce ischaemia distal to or at the injection site. 3% Citanest® DENTAL with Octapressin® is therefore indicated for routine use. It is particularly suitable for use in patients for whom the use of solutions containing sympathomimetic agents is contraindicated.

Pharmacokinetics

Prilocaine has a pKa of 7.9 and an N-heptane/pH 7.4 buffer partition coefficient of 0.9.

Prilocaine is between 40% and 55% protein bound in plasma, mainly to alpha 1-acid glycoprotein.

Prilocaine redistributes rapidly from the blood and it has a large apparent distribution volume of between 190 L and 260 L.

The terminal elimination half-life of prilocaine is 1.6 h.

Prilocaine readily passes through the placenta and free plasma concentrations are similar in both foetus and mother. In the presence of fetal acidosis, they may be slightly higher in the foetus, due to ion trapping. Information concerning the elimination half-life of prilocaine in neonates is not available.

In the liver, prilocaine is primarily metabolized by amide hydrolysis to σ-toluidine and N-propylamine. σ-Toluidine is subsequently hydroxylated to 2-amino-3-hydroxytoluene and 2-amino-5-hydroxytoluene, metabolites which are believed to be responsible for the occurrence of methaemoglobinaemia.

Only a small proportion of prilocaine (less than 5%) is excreted unchanged in the urine. *In vitro* and animal studies have shown metabolism of prilocaine by lung and kidney tissues.

Indications

- Infiltration anaesthesia in dentistry, where there is no need for profound ischaemia in the injected area.
- Regional nerve block anaesthesia in dentistry.

Dosage and Administration

3% Citanest® DENTAL with Octapressin® has a rapid onset of action after infiltration anaesthesia, with an average of 2-3 minutes. Inferior alveolar nerve block requires 5 minutes or more to take full effect. The duration of effective anaesthesia varies in individuals and depends on the type of block. The average duration of useful anaesthesia after infiltration is 45 minutes. After successful regional block, e.g. inferior alveolar nerve block, anaesthesia lasts for 2 hours or longer.

Injections should always be made slowly with careful aspiration before and intermittently during injection to avoid inadvertent intravascular injection, which may have toxic effects.

The lowest dose that results in effective anaesthesia should be used. The dose will also depend on the area of the oral tissues to be anaesthetised, the vascularity of the oral tissues and the technique of anaesthesia. The total dose must be adjusted to the age, size and physical status of the patient.

For effective local anaesthesia in most dental procedures, an adequate dose of 3% Citanest® DENTAL with Octapressin® solution injected into the tissue is:

In normally healthy adults: 1-5 mL (equivalent to 30-150 mg prilocaine hydrochloride). For routine dental procedures, a dose of 10 mL (equivalent to 300 mg prilocaine hydrochloride) 3% Citanest® DENTAL with Octapressin® should not be exceeded.

Children under 10 years of age: 1-2 mL (equivalent to 30-60 mg prilocaine hydrochloride).

A rapid rate of injection may lead to complications due to the high concentration (see OVERDOSAGE) even after the injection of small amounts. This is more likely following accidental intravascular injection. The injected medicine could be transported in a retrograde manner along a blood vessel and, in cases of intra-arterial injection in the head and neck area, reach the brain.

Contraindications

- Known history of hypersensitivity to local anaesthetic agents of the amide type.
- Congenital or idiopathic methaemoglobinaemia.

Warnings and Precautions

The safety and effectiveness of the local anaesthetic agent, prilocaine hydrochloride, depends on the proper dosage, the correct injection technique, adequate precautions and readiness for emergencies.

Although largely free of side-effects, as an additive to prilocaine, felypressin may cause a rise in blood pressure or coronary constriction if an overdose is given.

Before administering a local anaesthetic medicine, make sure that resuscitative equipment, such as equipment required for oxygenation and assisted ventilation, and medicine for the treatment of toxic reactions are immediately available.

The patient should be advised to exert caution to avoid inadvertent trauma to the lips, tongue, cheek mucosa or soft palate when these structures are anaesthetised. The ingestion of food should therefore be postponed until normal function and sensation returns.

In the head and neck area, due to the proximity of the CNS, the intravascular injection of even small doses of local anaesthetics may cause systemic adverse reactions similar to those seen after the inadvertent intravascular injection of larger doses in other parts of the body.

Even if the dose of 3% Citanest® DENTAL with Octapressin® used in dental practice is generally small, some patients may require special attention to reduce the risk of dangerous side effects:

- Patients with partial or complete heart block due to the fact that local anaesthetics may depress myocardial conduction.
- Patients with advanced liver disease or severe renal dysfunction.
- The elderly and patients in poor general condition.

Local anaesthetics should be administered with caution to patients with severe or untreated hypertension, severe heart disease, severe anaemia or circulatory failure from whatever cause, or any other pathological condition. Local anaesthetics should be avoided when there is infection in the region of the proposed injection.

Regarding methaemoglobin formation see ADVERSE REACTIONS.

Pregnancy and Lactation

It is reasonable to assume that 3% Citanest® DENTAL with Octapressin® has been administered to a large number of pregnant women and women of child-bearing age. No specific disturbances to the reproductive process have so far been reported, e.g. an increased incidence of malformations or other direct or indirect harmful effects on the foetus.

Methaemoglobinaemia in the neonate has been reported after the administration of prilocaine to the mother in doses exceeding 600 mg.

Prilocaine may enter the mother’s milk, but in such small amounts that there is generally no risk of this affecting the neonate. It is not known whether felypressin is excreted in breast milk.

Effect on Ability to Drive and Use Machines

Depending on dosage, local anaesthetics may have a very mild effect on mental function and may temporarily impair locomotion and co-ordination.

Adverse Effects

Reactions to 3% Citanest® DENTAL with Octapressin® are very rare in the doses used in dental procedures. If adverse reactions occur, they are similar in character to those observed with other local anaesthetics.

Allergic Reactions

Allergic reactions (in the most severe instances anaphylactic shock) to local anaesthetics of the amide type are rare.

Neurological Complications

The incidence of adverse neurological reactions (e.g. persistent neurological deficit) associated with the use of local anaesthetics is very low. Neurological reactions may be dependent upon the particular medicine used, the route of administration and the physical status of the patient. Many of these effects may be linked to the injection techniques, with or without a contribution by the medicine. Neurological reactions following regional nerve blocks have included persistent numbness, paraesthesia and other sensory disturbances.

Acute Systemic Toxicity

Prilocaine can cause acute toxic effects if high systemic levels occur due to accidental intravascular injection, fast absorption or overdosage. (See ACTIONS and OVERDOSAGE.)

Methaemoglobinaemia

Methaemoglobinaemia may occur after the administration of prilocaine. The repeated administration of prilocaine, even in relatively small doses, can lead to clinically overt methaemoglobinaemia (cyanosis).

The conversion of haemoglobin to methaemoglobin is caused by the prilocaine metabolite, σ-toluidine, which has a long half-life and tends to accumulate, and in turn, by its conversion to 4- and 6-hydroxytoluidine. Methaemoglobin has risen to clinically significant levels in patients receiving high doses of prilocaine. Cyanosis occurs when the methaemoglobin concentration in the blood reaches 1-2 g/100 mL (6-12% of the normal haemoglobin concentration). Methaemoglobin oxidises slowly back to haemoglobin, but this process can be greatly accelerated by giving methylene blue IV (see OVERDOSAGE).

The reduction in the oxygen-carrying capacity in normal patients is marginal, hence the cyanosis is usually symptomless. However, in severely anaemic patients it may cause significant hypoxaemia. It is important to rule out other more serious causes of cyanosis such as acute hypoxaemia and/or heart failure. With the dental dosage of prilocaine (1-5 mL 3% Citanest® DENTAL with Octapressin®, i.e. 30-150 mg prilocaine hydrochloride 3% with felypressin 0.54 µg/mL), the occurrence of methaemoglobinaemia in dental practice appears remote. However, gross overdosage in dental practice has been reported to cause methaemoglobinaemia.

Note. Even low concentrations of methaemoglobin may interfere with pulse oximetry readings, indicating a false low oxygen saturation.

Interactions

Prilocaine should be used with caution in patients receiving agents structurally related to local anaesthetics, since the toxic effects are additive.

Medicines which may predispose to methaemoglobin formation, e.g. sulphonamides, antimalarials and certain nitric compounds, could potentiate this adverse effect of prilocaine.

Due to its very low acute toxicity, felypressin does not increase the toxicity of a prilocaine solution.

Overdosage

Since prilocaine is the least toxic of the amino-amide local anaesthetics, it is particularly useful in situations where a high dosage of the local anaesthetic may be needed. This advantage, however, should be weighed against the risk of causing methaemoglobinaemia.

Acute emergencies are, in general, dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption (i.e. rate of increase of plasma concentration) or unintentional intravascular injection, or may result from hypersensitivity or diminished tolerance on the part of the patient.

Acute Systemic Toxicity

CNS reactions are excitatory or depressant and may be characterised by nervousness, tinnitus, twitching, euphoria, drowsiness, blurred or double vision, dizziness, convulsions, unconsciousness and possibly respiratory arrest. The excitatory reactions may be very brief or may not occur at all, in which case the first manifestation of toxicity is drowsiness merging into unconsciousness and even respiratory arrest.

Cardiovascular reactions are depressant and may be characterised by hypotension, myocardial depression, bradycardia and possibly cardiac arrest. Signs and symptoms of depressed cardiovascular function may commonly result from a vasovagal reaction, particularly if the patient is in an upright position. Less commonly, they may occur as a direct effect of the medicine. Failure to recognise premonitory signs such as sweating, a feeling of faintness, changes in pulse or sensorium may result in progressive cerebral hypoxia and seizure or serious cardiovascular collapse.

Cardiovascular effects are usually only seen in the most severe cases and are generally preceded by signs of toxicity in the central nervous system.

Acidosis or hypoxia in the patient may increase the risk and severity of toxic reactions. Such reactions involve the central nervous system and the cardiovascular system.

Treatment of Overdosage

The immediate treatment of acute systemic toxicity is as follows:

1. Put the patient in a supine position. Raise the legs 30°-45° above the horizontal level.

2. Ensure a patent airway. If ventilation is inadequate, ventilate the patient, with oxygen if available. This is important since toxicity increases with acidosis.

3. The treatment of convulsions consists of ensuring a patent airway and arresting convulsions. Should convulsions persist despite adequate ventilation, diazepam 0.1 mg/kg or thiopentone sodium 1-3 mg/kg should be administered intravenously to arrest the convulsions. Since this treatment may also depress respiration, a means of mechanically supporting or controlling ventilation should be available.

4. Supportive treatment of circulatory depression may require the administration of intravenous fluids and, when appropriate, a vasopressor (e.g. ephedrine 5-10 mg IV and repeated, if necessary, after 2-3 min), as governed by the clinical situation.

5. If the patient is unresponsive and the carotid pulse rate is totally absent, start external cardiac massage and mouth to mouth resuscitation.

Treatment of Acute Methaemoglobinaemia

If clinical methaemoglobinaemia occurs, it can be rapidly treated by a single intravenous injection of a 1% methylene blue solution, 1 mg/kg body weight, over a 5-minute period. Cyanosis will disappear in about 15 minutes. This dose should not be repeated as methylene blue in high concentrations acts as a haemoglobin oxidant.

Pharmaceutical Precautions

Storage Conditions

Store below 25°C. Protect from light.

Shelf-Life

3% Citanest® DENTAL with Octapressin® Glass Cartridges 24 months

Medicine Classification

Prescription Medicine

Package Quantities

3% Citanest® DENTAL with Octapressin®

- Glass Aspirating Dental Cartridge 100 x 2.2 mL
- Glass Standard Dental Cartridge 100 x 2.2 mL
- Glass Aspirating Dental Cartridge 100 x 1.8 mL
- Glass Standard Dental Cartridge 100 x 1.8 mL

Further Information

Additions to 3% Citanest® DENTAL with Octapressin® used in conjunction with dental procedures are not recommended.

Instructions for Use/Handling

Surface sterilisation using pure, undiluted isopropyl alcohol (91%) or 70% ethyl alcohol may be carried out if desired. Do not soak or autoclave.

The solutions which are free from preservative should be used immediately after opening of the container. Any unused solution should be discarded.

Aspiration (preferably by the use of passive-type aspiration systems) prior to injection is recommended since this reduces the possibility of intravascular injection, thereby keeping the incidence of side effects and anaesthetic failure to a minimum.

In order to avoid traumatic nerve injuries leading to paraesthesia in conjunction with dental nerve blocks, an atraumatic technique should be used. Dental cartridge systems may generate high pressures during injection, leading to local anaesthetics distributing in a retrograde manner along a nerve in cases of intraneural injection.

Excipients

- Sodium Chloride
- Sodium Hydroxide
- Hydrochloric Acid
- Water for Injections

Name and Address

Sponsor:
Dentsply (N.Z.) Limited
11 Marshall Road
Katikati 3129
New Zealand

Freephone: 0800 33 68 77

Date of Preparation

17 June 2014

Data Sheet

2% Xylocaine® DENTAL with Adrenaline 1:80,000

(lignocaine 2% with adrenaline 1:80,000)

Presentation

2% Xylocaine® DENTAL with Adrenaline 1:80,000 solution for injection is a sterile, isotonic aqueous solution. It contains sodium metabisulphite as an antioxidant. The pH of the solution is 3.3-5.0.
The cartridges are free from preservatives and are intended for single use only.

Uses

Actions

Lignocaine, like other local anaesthetics, causes a reversible blockade of impulse propagation along nerve fibres by preventing the inward movement of sodium ions through the nerve membrane. Local anaesthetics of the amide type are thought to act within the sodium channels of the nerve membrane.

The addition of adrenaline decreases the rate of absorption of lignocaine from the site of injection, increasing the duration of effect.

Local anaesthetic medicines may have similar effects on excitable membranes in the brain and myocardium. If excessive amounts of medicine reach the systemic circulation rapidly, symptoms and signs of toxicity will appear, emanating mainly from the central nervous and cardiovascular systems.

Central nervous system toxicity (see OVERDOSAGE) usually precedes the cardiovascular effects since it occurs at lower plasma concentrations. Direct effects of local anaesthetics on the heart include slow conduction, negative inotropism and eventually cardiac arrest.

Pharmacokinetics

Lignocaine has a pKa of 7.9, an oil/water partition coefficient of 2.9, and is 65% protein-bound (mainly to alpha-1-acid glycoprotein) in plasma.

Lignocaine has a total plasma clearance of 0.95 L/min, a volume of distribution at steady state of 91 L, an elimination half-life of 1.6 h and an estimated hepatic extraction ratio of 0.65. The clearance of lignocaine is almost entirely due to liver metabolism, and depends both on liver blood flow and the activity of metabolising enzymes.

The elimination half-life in neonates (3.2 h) is approximately twice that of adults.

Lignocaine readily crosses the placenta and equilibrium in regard to free, unbound medicine will be reached. Because the degree of plasma protein binding in the foetus is less than in the mother, the total plasma concentration will be greater in the mother, but the free concentrations will be the same.

Lignocaine is excreted in breast milk, but in such small quantities that there is no risk of affecting the child with therapeutic doses.

Only 2% of lignocaine is excreted unchanged. Most is metabolised first to monoethylglycinexylidide (MEGX) and then to glycinexylidide (GX) and 2,6-xylidine. Up to 70% appears in the urine as 4-hydroxy-2,6-xylidine.

Indications

Lignocaine solutions are indicated for the production of local nerve anaesthesia in routine dental procedures and oral surgery by means of infiltration and nerve block techniques.

Lignocaine solutions with adrenaline are recommended for oral surgery requiring prolonged duration of anaesthesia and haemostasis.

Dosage and Administration

2% Xylocaine® DENTAL with Adrenaline 1:80,000 has a rapid onset of action after infiltration, averaging 2-3 minutes. Inferior alveolar nerve block requires 5 minutes or more to take full effect. The duration of effective anaesthesia varies in individuals and depends on the type of anaesthetic technique. The average duration of useful anaesthesia after infiltration is 60 minutes. After successful regional anaesthesia, e.g. inferior alveolar nerve block, anaesthesia lasts for 2 hours or longer.

Injections should always be made slowly, with careful aspiration before and intermittently during injection, to avoid inadvertent intravascular injection, which may have toxic effects.

The lowest dose that results in effective anaesthesia should be used. The dose will also depend on the area of the oral tissues to be anaesthetised, the vascularity of the oral tissues and the technique of anaesthesia. The total dose must be adjusted to the age, size and physical status of the patient.

For effective local anaesthesia in most dental procedures, an adequate dose of 2% Xylocaine® DENTAL with Adrenaline 1:80,000 solution injected into the tissues is as follows.

Adults

In normal healthy adults: 1-5 mL (equivalent to 20-100 mg lignocaine hydrochloride). For routine dental procedures, a dose of 10 mL (equivalent to 200 mg lignocaine hydrochloride) should not be exceeded.

Children under 10 years of age

1-2 mL (equivalent to 20-40 mg lignocaine hydrochloride)

A rapid rate of injection may lead to complications due to the high concentration (see OVERDOSAGE) even after injection of small amounts. This is more likely following accidental intravascular injection. The injected medicine could be transported in a retrograde manner along a blood vessel and, in cases of intra-arterial injection in the head and neck area, reach the brain.

Contraindications

Known hypersensitivity to local anaesthetics of the amide type, or other components of the solution, e.g. sodium metabisulphite in solutions containing adrenaline.

Warnings and Precautions

The safety and effectiveness of the local anaesthetic agent, lignocaine hydrochloride, depends on the proper dosage, correct injection technique, adequate precautions and readiness for emergencies.

Before administering a local anaesthetic medicine, make sure that resuscitative equipment, such as equipment required for oxygenation and assisted ventilation, and medicines for the treatment of toxic reactions are immediately available.

The patient should be advised to exert caution to avoid inadvertent trauma to the lips, tongue, cheek mucosa or soft palate when these structures are anaesthetised. The ingestion of food should therefore be postponed until normal function and sensation returns.

In the head and neck area, due to the proximity of the CNS, the intravascular injection of even small doses of local anaesthetics may cause systemic adverse reactions similar to those seen after the inadvertent intravascular injection of larger doses in other parts of the body.

Even if the dose of 2% Xylocaine® DENTAL with Adrenaline 1:80,000 used in dental practice is generally small, some patients may require special attention to reduce the risk of dangerous side effects:

- Patients with partial or complete heart block, due to the fact that local anaesthetics may depress myocardial conduction.
- Patients with advanced liver disease or severe renal dysfunction.
- The elderly and patients in poor general condition.

Local anaesthetics, especially those containing adrenaline, should be administered with caution to patients with severe or untreated hypertension, severe heart disease, advanced diabetes, severe anaemia or circulatory failure from whatever cause, thyrotoxicosis or any other pathological condition that might be aggravated by the effects of adrenaline. Adrenaline may induce anginal pain in patients suffering from ischaemic heart disease. Local anaesthetics should be avoided when there is infection in the region of the proposed injection.

2% Xylocaine® DENTAL with Adrenaline 1:80,000 contains sodium metabisulphite, a sulphite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulphite sensitivity in the general population is unknown and probably low. Sulphite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Use in Pregnancy and Lactation

It is reasonable to assume that a large number of pregnant women and women of child-bearing age have been given lignocaine with or without adrenaline. No specific disturbances to the reproductive process have so far been reported, e.g. no increased incidence of malformations, or other direct or indirect harmful effects on the foetus.

Lignocaine may enter the mother's milk, but in such small amounts that there is generally no risk of this affecting the neonate. It is not known whether adrenaline enters breast milk or not, but it is unlikely to affect the breast-fed child.

Effects on Ability to Drive and Use Machines.

Depending on dosage, local anaesthetics may have a very mild effect on mental function and may temporarily impair locomotion and co-ordination.

Adverse Effects

Reactions to 2% Xylocaine® DENTAL with Adrenaline 1:80,000 are very rare in the doses used in dental procedures. If adverse reactions occur, they are similar in character to those observed with other local anaesthetics.

Allergic Reactions

Allergic reactions (in the most severe instances anaphylactic shock) to local anaesthetics of the amide type are rare. However, other constituents of the solutions, e.g. sodium metabisulphite, may cause this type of reaction.

Neurological Complications

The incidence of adverse neurological reactions (e.g. persistent neurological deficit) associated with the use of local anaesthetics is very low. Neurological reactions may be dependent upon the particular medicine used, the route of administration and the physical status of the patient. Many of these effects may be linked to the injection techniques, with or without a contribution by the medicine (see INSTRUCTIONS FOR USE/HANDLING). Neurological reactions following regional nerve blocks have included persistent numbness, paraesthesia and other sensory disturbances.

Acute Systemic Toxicity

Lignocaine may cause acute toxic effects if high systemic levels occur due to accidental intravascular injection or overdosage. (See ACTIONS and OVERDOSAGE.)

Interactions

Lignocaine should be used with caution in patients receiving agents structurally related to local anaesthetics e.g tocainide, since the toxic effects are additive.

Solutions containing adrenaline should generally be avoided or used with care in patients receiving tricyclic antidepressants since severe, prolonged hypertension may be the result. In addition, the concurrent use of adrenaline-containing solutions and oxytocic medicines of the ergot type may cause severe, persistent hypertension and possibly cerebrovascular and cardiac accidents. Phenothiazines and butyrophenones may reduce or reverse the pressor effect of adrenaline, giving rise to hypertensive response and tachycardia.

Non-cardioselective betablockers such as propranolol enhance the pressor effects of adrenaline, which may lead to severe hypertension and bradycardia.

Serious cardiac arrhythmias may occur if preparations containing a vasoconstrictor, such as adrenaline, are employed during or following the administration of volatile inhalation anaesthetics such as halothane.

Overdosage

Acute emergencies are, in general, dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption (i.e. rate of increase of plasma concentration) or unintentional intravascular injection, or may result from hypersensitivity or diminished tolerance on the part of the patient.

Acute Systemic Toxicity

CNS reactions are excitatory or depressant and may be characterised by nervousness, twitching, tinnitus, euphoria, drowsiness, blurred or double vision, dizziness, convulsions, unconsciousness and possibly respiratory arrest. The excitatory reactions may be very brief or may not occur at all, in which case the first manifestation of toxicity is drowsiness merging into unconsciousness and even respiratory arrest.

Cardiovascular reactions are depressant and may be characterised by hypotension, myocardial depression, bradycardia and possibly cardiac arrest. Signs and symptoms of depressed cardiovascular function may commonly result from a vasovagal reaction, particularly if the patient is in an upright position. Less commonly, they may occur as a direct effect of the medicine. Failure to recognise premonitory signs such as sweating, a feeling of faintness, changes in pulse or sensorium may result in progressive cerebral hypoxia and seizure or serious cardiovascular collapse.

Cardiovascular effects are usually only seen in the most severe cases and are generally preceded by signs of toxicity in the central nervous system.

Acidosis or hypoxia in the patient may increase the risk and severity of toxic reactions. Such reactions involve the central nervous system and the cardiovascular system.

Treatment of Acute Toxicity

1. Put the patient in a supine position. Raise the legs 30°-45° above the horizontal level.

2. Ensure a patent airway. If ventilation is inadequate, ventilate the patient, with oxygen if available. This is important since toxicity increases with acidosis.

3. The treatment of convulsions consists of ensuring a patent airway and arresting convulsions. Should convulsions persist despite adequate ventilation, diazepam 0.1 mg/kg or thiopentone sodium 1-3 mg/kg should be administered intravenously to arrest the convulsions. Since this treatment may also depress respiration, a means of mechanically supporting or controlling ventilation should be available.

4. Supportive treatment of circulatory depression may require the administration of intravenous fluids and, when appropriate, a vasopressor (e.g. ephedrine 5-10 mg IV and repeated, if necessary, after 2-3 min), as governed by the clinical situation.

5. If the patient is unresponsive and the carotid pulse rate is totally absent, start external cardiac massage and mouth to mouth resuscitation.

Pharmaceutical Precautions

Shelf-life and Storage Conditions

2% Xylocaine® DENTAL with Adrenaline 1:80,000
Glass Cartridges: 24 months.
Store at 2°C to 8°C (Refrigerate. Do not freeze.). Protect from light.
Once removed from refrigeration for use, store below 25°C and use within 4 weeks. Do not return to refrigerator.
Excursions outside the recommended storage temperature are permitted during transport.

Medicine Classification

Prescription Medicine.

Package Quantities

2% Xylocaine® DENTAL with Adrenaline 1:80,000

Glass Aspirating Dental Cartridge 100 x 2.2 mL
Glass Standard Dental Cartridge 100 x 2.2 mL

Further Information

Instructions for Use/Handling

Adequate precautions should be taken to avoid prolonged contact between local anaesthetic solutions containing adrenaline (low pH) and metal surfaces (e.g. needles or metal parts of syringes) since dissolved metal ions, particularly copper ions, may cause severe local irritation (swelling, oedema) at the site of injection and accelerate the degradation of adrenaline.

Surface sterilisation using pure, undiluted isopropyl alcohol (91%) or 70% ethyl alcohol may be carried out if desired. Do not soak or autoclave.

The solutions which are free from preservative should be used immediately after opening of the container. Any unused solution should be discarded.

Aspiration (preferably by the use of passive-type aspiration systems) prior to injection is recommended since this reduces the possibility of intravascular injection, thereby keeping the incidence of side effects and anaesthetic failure to a minimum.

In order to avoid traumatic nerve injuries leading to paraesthesia in conjunction with dental nerve block, an atraumatic technique should be used. Dental cartridge systems may generate high pressures during injection, leading to local anaesthetics distributing in a retrograde manner along a nerve in cases of intraneural injection. If an accidental traumatic nerve injury has occurred, the adrenaline content in 2% Xylocaine® DENTAL with Adrenaline 1:80,000 may aggravate the local neurotoxicity by decreasing the intraneural blood circulation.

Name and Address

Sponsor:
Dentsply (N.Z.) Limited
11 Marshall Road
Katikati 3129
New Zealand

Date of Preparation

28 January 2014

Data Sheet

UBISTESIN
4% Articaine with Adrenaline 1/200 000
UBISTESIN FORTE
4% Articaine with Adrenaline 1/100 000

Presentation
UBISTESIN and UBISTESIN FORTE are sterile isotonic aqueous solutions for injection. They contain sodium sulphite as an antioxidant. The pH of the solutions is 3.6-4.4. The cartridges are free from preservatives and are intended for single-use only.

Uses
Actions
Articaine is a local anaesthetic of the amide type. Local anaesthetics produce reversible loss of sensation by preventing or diminishing the conduction of sensory nerve impulses by decreasing the permeability of the nerve cell membrane to sodium ions. Articaine is thought to act by blocking the voltage dependent Na^+ channels on the membrane of the nerve fibre.

Adrenaline is a vasoconstrictor added to retard diffusion and limit absorption of the local anaesthetic, thereby prolonging the duration of effect and lessening the danger of toxicity.

Complete anaesthesia can be achieved within 1-3 minutes of administration. The mean duration of effect in pulpal anaesthesia is 48-54 minutes for UBISTESIN and at least 75 minutes for UBISTESIN FORTE. For surgical interventions in soft tissue the mean duration of effect is 120-240 minutes.

Pharmacokinetics
Articaine is rapidly and almost completely absorbed. The maximum plasma level from intraoral injection is achieved after approximately 10-15 minutes. The volume of distribution is 1.67L/kg, and the elimination half-life is approximately 20 minutes. Upto 95% of Articaine is bound to plasma proteins. Articaine is rapidly hydrolysed by plasma cholinesterases to its primary metabolite articainic acid, which is further metabolised to articainic glucuronide. Excretion is via the kidneys.

Adrenaline undergoes rapid enzymatic degradation in the liver and other body tissues. The metabolites are excreted in the urine.

Indications
Infiltration anaesthesia and nerve block anaesthesia in dentistry. UBISTESIN FORTE is especially indicated for more complex dental procedures requiring prolonged anaesthesia.

Dosage and Administration

The following dosage instructions apply:
The smallest possible volume of solution that will lead to effective anaesthesia should be used.

For extraction of maxillary teeth, 1.7mL UBISTESIN or UBISTESIN FORTE per tooth suffices in most cases, thereby avoiding painful palatal injections. A smaller injection volume is often possible for serial extractions of neighbouring teeth.

If a cut or suture is required in the palate, a palatal injection of approximately 0.1mL per puncture is indicated.

For smooth extractions of mandibular premolar teeth, infiltration anaesthesia of 1.7mL UBISTESIN or UBISTESIN FORTE per tooth is mostly sufficient; in single cases a buccal re-injection of 1 to 1.7mL is required. In rare cases an injection into the mandibular foramen can be indicated.

Vestibular injections of 0.5-1.7mL per tooth enable cavity and crown stump preparations.

Nerve-block anaesthesia should be used in the treatment of mandibular molar teeth.

Generally, in children weighing about 20-30kg, doses of 0.25-1mL are sufficient; and in children weighing 30-40kg, 0.5-2mL. UBISTESIN and UBISTESIN FORTE must not be used in children under the age of 4 years.

Increased plasma levels can occur in older patients due to diminished metabolic processes and lower distribution volume. The risk of accumulation is increased, in particular after repeated administration (eg re-injection). A similar effect can ensue where the general condition of the patient is poor, and in severely impaired hepatic and renal function (see *Warnings and Precautions*). In these cases a lower dose range (minimum quantity for sufficient anaesthetic depth) is recommended

The dose should also be reduced in patients with certain pre-existing diseases (angina pectoris, arteriosclerosis) (see *Warnings and Precautions*).

Maximum Recommended Dosage
Adults: For healthy adults the maximum dose is 7mg/kg body weight articaine (500mg for a 70kg patient), equivalent to 12.5mL UBISTESIN or UBISTESIN FORTE. The maximum dose represents 0.175mL of solution per kg.
Children: The quantity to be injected should be determined by the age and weight of the child and the magnitude of the operation. Do not exceed the equivalent of 7mg articaine/kg (0.175mL/kg) of body weight.

UBISTESIN FORTE may be more appropriate for procedures of longer duration and when there is a risk of significant bleeding into the operative field (see *Uses/Actions* for information on duration of analgesia). The duration of anaesthesia during which an operation can be performed using UBISTESIN FORTE is up to 75 minutes.

Method of Administration

For injection / oromucosal use in dental anaesthesia only.

To avoid intravascular injection, aspiration control in at least two planes (rotation of the needle by 180^{o}) must always be carefully undertaken, although a negative aspiration result does not rule out an unintentional and unnoticed intravascular injection.

The injection rate should not exceed 0.5mL in 15 seconds ie 1 cartridge per minute.

Major systemic reactions resulting from accidental intravascular injection can in most cases be avoided by the injection technique: after aspiration slow injection of 0.1-0.2mL followed by slow injection of the remainder no sooner than 20-30 seconds later.

Opened cartridges must not be used in other patients. Residues must be discarded.

Contraindications

Use in children under the age of 4 years. Hypersensitivity to any ingredients. In general patients with demonstrated hypersensitivity to articaine and other amides should receive an ester-group local anaesthetic for subsequent procedures.

Due to the local anaesthetic ingredient articaine, do not use in the event of:

- known allergy or hypersensitivity to local anaesthetics of the amide type;
- severe impairment of the nerve impulses and conduction system of the heart (eg grade II and III AV block, pronounced bradycardia);
- acutely decompensated cardiac insufficiency;
- severe hypotension;
- patients who are known to have a deficiency in plasma cholinesterase activity;
- haemorrhagic diatheses, particularly with nerve-block anaesthesia.

Do not inject into inflamed or infected areas.

Due to the content of adrenaline as a vasoconstrictor admixture, do not use in the event of:

- heart disease such as unstable angina pectoris, recent myocardial infarction, recent coronary artery bypass surgery, refractory arrhythmias and paroxysmal tachycardia or high-frequency continuous arrhythmia, untreated or uncontrolled hypertension, untreated or uncontrolled congestive heart failure;
- concomitant treatment with monoamine oxidase (MAO) inhibitors or tricyclic antidepressants (see *Interactions).*

UBISTESIN and UBISTESIN FORTE must not be used in persons who are allergic or hypersensitive to sulphite, as well as in persons with severe bronchial asthma. UBISTESIN and UBISTESIN FORTE can provoke acute allergic reactions with anaphylactic symptoms (eg bronchospasm).

Warnings and Precautions

Use with particular caution in the event of:

- severe impairment to renal function;
- angina pectoris (see *Dosage and Administration* and *Contraindications)*;
- arteriosclerosis;
- considerably impaired blood coagulation (see *Interactions)*;
- thyrotoxicosis;
- narrow-angle glaucoma;

- diabetes mellitus;
- lung diseases, particularly allergic asthma;
- pheochromocytoma.

Accidental intravenous injection may be associated with convulsions, followed by central nervous system or cardiorespiratory arrest. Resuscitative equipment, oxygen and other resuscitative drugs should be available for immediate use.

Since amide-type local anaesthetics are metabolised in the liver, use with caution in patients with hepatic disease. Patients with severe hepatic disease are at greater risk of developing toxic plasma levels.

Administer with caution in patients with impaired cardiovascular function since they may be less able to compensate for functional changes associated with the prolongation of A-V conduction produced by these drugs.

Administer with caution to patients with a history of epilepsy.

There is the possibility of a positive doping test result.

Inadvertent vasopuncture can lead to serious bleeding during treatment with anticoagulants (eg heparin or acetylsalicylic acid), and in general haemorrhagic tendency is increased.

Avoid inadvertent intravascular injection (see *Dosage and Administration).*

In the case of cavity or crown preparations the risk of overlooking an opened pulp must be taken into account since adrenaline reduces blood flow in the pulp tissue.

Precautions for Use
Before a local anaesthetic is used the following drugs/therapy should be available: anti-convulsant medicines (benzodiazepines or barbiturates), myorelaxants, atropine and vasopressors or adrenaline for a severe allergic or anaphylactic reaction; resuscitating equipment (in particular a source of oxygen) enabling artificial ventilation if necessary.

Cardiovascular and respiratory vital signs and the patient's state of consciousness should be monitored after each local anaesthetic injection. Restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness may be early signs of central nervous system toxicity and require rapid corrective measures to prevent possible worsening (see *Overdose*).

Patients taking phenothiazines:
Phenothiazines may reduce or reverse the pressor effect of adrenaline. Concurrent use of these agents should generally be avoided. In situations where concurrent therapy is necessary, careful patient monitoring is essential.

Patients taking non-selective beta-blockers:
The concomitant administration of non-cardioselective beta-blockers can lead to an increase in blood pressure due to adrenaline (see Interactions).

The administration of large doses of articaine may produce methaemoglobinaemia in patients with subclinical methaemoglobinaemia.

Use in Pregnancy and Lactation

No clinical experience of use in pregnant and lactating women is available. Safe use of local anaesthetics during pregnancy with respect to adverse effects on foetal development has not been established. The medicine should only be used if the expected benefit to the patient outweighs the risk to the foetus.

The excretion of articaine and its metabolites in human milk is unknown. Preclinical safety data suggests that the amount of articaine in breast milk does not reach clinically relevant levels. It is recommended that nursing mothers express and discard the first mother's milk following anaesthesia with articaine.

Effect on ability to Drive and Use Machines

Although trial patients have shown no impairment of their normal reactions when driving, possible impairment on the ability to drive or operate machinery should be assessed. The patient should not leave the dental surgery earlier than at least 30 minutes after the injection.

Adverse Effects

The following adverse effects can occur as a result of the local anaesthetic ingredient articaine or to the content of adrenaline, and are presented at a frequency of:

Rare: ≥1/10,000 and <1/1000
Very Rare <1/10,000

Cardiovascular disorders: *Rare:* Bradycardia, hypotension, cardiac impulse conduction disorders, asystole, cardiovascular arrest, heat sensation, sweating, heart racing, migraine-like headache, hypertension, anginal disorders, tachycardia, tachyarrhythmia, cardiovascular arrest and acute oedematous thyroid swelling.
Central Nervous System disorders: *Rare:* Metallic taste, tinnitus, dizziness, nausea, vomiting, restlessness, anxiety, yawning, shaking, nervousness, nystagmus, headache, hyperventilation, paraesthesia of the lip and/or tongue. More severe symptoms are drowsiness, confusion, tremor, muscular twitching, seizures, coma and respiratory paralysis.
Respiratory disorders: *Rare:* Tachypnea, then bradypnea, which could lead to apnoea.
Allergic Reactions: *Very Rare:* Rash, oedema, pruritis, eythema; nausea, diarrhoea, wheezing and anaphylaxis as a result of hypersensitivity to articaine. Methaemoglobinaemia (see *Warnings and Precautions).* Allergic or hypersensitivity reactions to sulphite, particularly in bronchial asthmatics, are manifested as vomiting, diarrhoea, wheezing, acute asthma attacks, clouding of consciousness or shock.

2 Weeks delayed onset of facial nerve paralysis has been described with articaine/ adrenaline, the event still occurring after 6 months.

Interferences in the clinical picture can result from the simultaneous occurrence of various complications and adverse effects.

Interactions

The sympathomimetic effect of adrenaline can be intensified by the simultaneous intake of MAO inhibitors or tricyclic antidepressants (see *Contraindications).*

Adrenaline can inhibit insulin release in the pancreas and thus diminish the effect of oral anti-diabetics. The concomitant administration of non-cardioselective beta-blockers can lead to an increase in blood pressure due to the adrenaline in UBISTESIN and UBISTESIN FORTE.

Certain inhalational anaesthetics, such as halothane, can sensitise the heart to catecholamines and therefore induce arrhythmias following administration of UBISTESIN or UBISTESIN FORTE.

Haemorrhagic tendency is increased during treatment with anti-coagulants (see *Warnings and Precautions)*.

Cross-reactivity to articaine has been reported in a patient with delayed hypersensitivity to prilocaine.

Overdosage

Symptoms and Signs

Toxic effects may occur either immediately, caused by unintentional intravascular injection or rapid absorption eg in inflamed or intensive vascularised tissue, or delayed caused by excessive dosage, and manifest themselves as CNS and/or cardiovascular symptoms.

Milder CNS symptoms include metallic taste, tinnitus, dizziness, nausea, vomiting, restlessness, anxiety, initial hyperventilation. More severe symptoms are drowsiness, confusion, tremor, muscular twitching, seizures, coma and respiratory paralysis. Cardiovascular symptoms are characterised by heat sensation, sweating, migraine-like headache, angina pectoris disorders, tachycardia and tachyarrhythmias. Severe cardiovascular episodes are seen in the form of hypotension, cardiac impulse conduction disorders, bradycardia and cardiovascular arrest.

General Basic Measures:

Diagnostics (respiration, circulation, consciousness), maintenance/restoration of the vital functions of respiration and circulation, oxygen administration, intravenous access.

Special Measures:

- Hypertension: Elevation of the upper body, sublingual nifedipine if necessary.
- Convulsions: Protect patients from concomitant injuries, diazepam i.v if necessary.
- Hypotension: Horizontal position, intravascular infusion of an electrolyte solution if necessary, vasopressors (eg etilefrine i.v).
- Bradycardia: Atropine i.v.
- Anaphylactic Shock: Contact emergency physician. In the interim shock positioning, generous infusion of an electrolyte solution, if necessary adrenaline i.v, cortisone i.v.
- Cardiac shock: Elevation of the upper body, contact emergency physician.
- Cardiovascular arrest: Immediate cardiopulmonary resuscitation, contact emergency physician.

Pharmaceutical Precautions

Store below 25^{o}C. Store in the original package in order to protect from light.

Medicine Classification

Prescription Medicine

Package Quantities
50 cartridges of 1.7mL each.

Further Information
Keep out of reach of children.

Name and Address
3M New Zealand Limited
PO Box 33246
Takapuna
North Shore City 0740
Telephone: (09) 477 4040
Facsimile: (09) 4776699

Date of Preparation
11 May 2010

SEPTANEST
Articaine hydrochloride 4% with adrenaline 1:100,000
Injection for local and regional dental anaesthesia

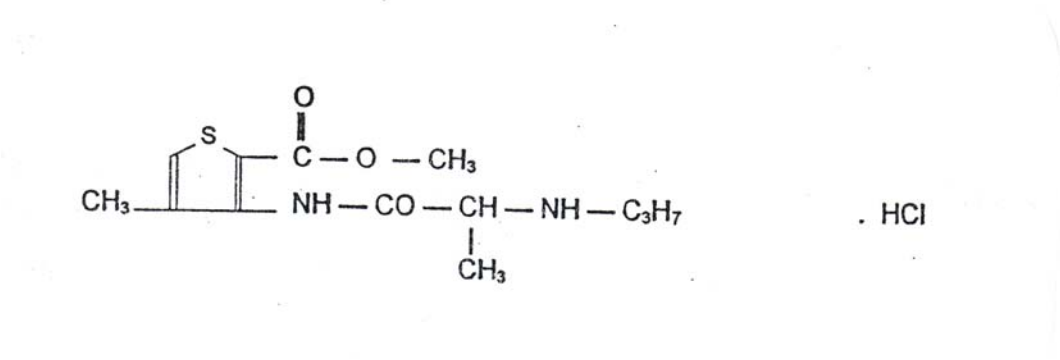
DESCRIPTION

SEPTANEST is a sterile aqueous solution that contains articaine hydrochloride 4% (40 mg/mL) with adrenaline acid tartrate in a 1:100,000 strength.

Articaine hydrochloride

CAS [23964-57-0] MW: 320.84

(±)-4-methyl-3-[2-(propylamino)-propionamido]-2-thiophene-carboxylic acid, methyl ester hydrochloride.



$C_{13}H_{20}N_2O_3S.HCl$

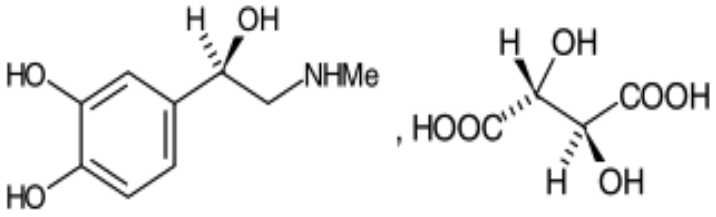
White to almost white powder, odourless.

Articaine hydrochloride is a local anaesthetic and is a racemic mixture. Articaine hydrochloride has a partition coefficient in n-octanol/ Soerensen buffer (pH : 7.35) of 17 and a pKa of 7.8.

Adrenaline acid tartrate

CAS[51-42-3] MW: 333.3

(R)-1-(3,4-di-hydroxyphenyl)-2-methylamino-ethanol hydrogen tartrate



$C_9H_{13}NO_3 . C_4H_6O_6$

White or greyish-white or light brownish grey, odourless, crystalline powder, which slowly darkens on exposure to air and light. Adrenaline acid tartrate 1.8 mg is approximately equivalent to 1 mg of adrenaline.

Adrenaline acid tartrate is a vasoconstrictor.

Qualitative and Quantitative Composition

	Per 1.7 mL cartridge	Per 2.2 mL cartridge
SEPTANEST 1:100,000		
Articaine hydrochloride (INN)	68.0 mg	88.0 mg
Adrenaline (as acid tartrate)	17.0 µg	22.0 µg
Other ingredients		
Sodium chloride	2.72 mg	3.52 mg
Sodium metabisulfite	0.85 mg	1.1 mg
Sodium hydroxide solution (to adjust pH)		
Water for injection q.s ad	1.7 mL	2.2 mL

For single patient use only. Contains no antimicrobial agent.
Discard unused contents after use.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Articaine is a local anaesthetic of the amide type. Preclinical pharmacodynamic studies show that the mechanism of action of articaine is similar to that of other commonly used anaesthetics (lidocaine, procaine, prilocaine). Inhibition of the generation and the conduction of the action potential but no change in resting potential is shown.
Articaine blocks sodium channels and, with lower sensitivity, potassium channels at neutral pH. Inhibition of muscle activation after nerve stimulation and depression of cardiac electrophysiologic measurements demonstrate that articaine has the same pharmacologic activities as other local anaesthetics. When injected close to sensitive nerve filaments, articaine has the reversible effect of blocking the conduction of painful sensations.
Adrenaline added to the solution reduces bleeding during surgery, slows down the passage of articaine into the general circulation and thus ensures the prolonged maintenance of an active tissue concentration.
Adrenaline acts on both adrenergic receptors of tissue innervated by sympathetic nerves, except for the sweat glands and arteries of the face. It is the most important alpha receptor activator.
Adrenaline stimulates the heart to increase output, raises the systolic blood pressure, lowers the diastolic blood pressure, relaxes bronchial spasm and mobilises liver glycogen, resulting in hyperglycaemia and possibly glycosuria.
The mean time to onset of anaesthesia after administration of articaine 4% with adrenaline 1:100,000 is about 3.5 minutes with a range of 1 to 6 minutes, and the mean duration of anaesthesia is about 68 minutes with a range of 20 to 175 minutes. The pulpal analgesia lasts 75 minutes and the bleeding during surgery is significantly reduced.

PHARMACOKINETICS

Absorption:

Following dental injection by the submucosal route of a 4% articaine solution containing 1:200,000 adrenaline, articaine reaches peak blood concentration about 25 minutes after a single dose injection and 48 minutes after three doses. Peak plasma levels of articaine achieved after 68 minutes and 204 mg doses are 385 and 900 ng/mL, respectively.

Distribution:

Approximately 60 to 80 % of articaine hydrochloride is bound to human serum albumin and γ-globulins at 37°C in vitro.

Metabolism:
Articaine HCl is rapidly metabolized by plasma carboxyesterase to its primary metabolite, articainic acid which is inactive. Articainic acid concentration reaches its peak about 30 to 60 minutes following the peak in articaine concentration. In vitro studies show that the human liver microsome P450 isoenzyme system metabolises approximately 5% to 10% of the available articaine with nearly quantitative conversion to articainic acid.

Excretion:
The elimination half-life of articaine is about 1.8 hours and that of articainic acid is about 1.5 hours. Articaine is excreted primarily through urine with 53 - 57% of the administered dose eliminated in the first 24 hours following submucosal administration. Articainic acid is the primary metabolite in urine. A minor metabolite, articainic acid glucuronide, is also excreted in urine. Articaine constitutes only 2% of the total dose in excreted urine.

Special Populations
Effect of Age **:** No pharmacokinetic data is available in the following populations: elderly, children.
Race : No pharmacokinetic data is available for different racial groups.
Renal and Hepatic Insufficiency : No pharmacokinetic data is available for patients with hepatic or renal impairment.

CLINICAL TRIALS

Three randomized, double-blind, active-controlled studies were designed to evaluate effectiveness of Septanest 1:100,000 as a dental anaesthetic. A total of 882 patients received Septanest 1:100,000. Of these, 7% were between 4 and 16 years old, 87% were between 17 and 65 years old, and 6% were at least 65 years old. In addition, 53% of patients were female and 47% were male, with a racial/ethnic distribution of 73% white, 11% Hispanic, 8% black, 5% Asian and 3% 'other' races/ethnicities. These patients underwent simple dental procedures, single apical resections and single crown procedures, and complex dental procedures such as multiple extractions, multiple crowns and/or bridge procedures, multiple apical resections, alveolectomies, muco-gingival operations, and other surgical procedures on the bone. Septanest 1:100,000 was administered as submucosal infiltration and/or nerve block. Efficacy was measured immediately following the procedure by having the patient and investigator rate the patient's procedural pain using a 10 cm visual analog scale (VAS), in which a score of zero represented no pain, and a score of 10 represented the worst pain imaginable. Mean patient and investigator VAS pain scores were 0.3 - 0.4 cm for simple procedures and 0.5 - 0.6 cm for complex procedures. These values are summarized in Table 1 below.

Table 1. Summary of VAS Pain Scores.

	Septanest 1:100,000 (articaine HCl 4% with adrenaline acid tartrate 1:100,000)	
	Simple procedures	Complex procedures
Number of patients	674	207
Investigator score (cm)		
Mean	0.3	0.5
Median	0.0	0.2
Range	0 – 9.0	0 – 7.3
Patient score (cm)		
Mean	0.4	0.6
Median	0.0	0.2
Range	0 – 8.0	0 – 8.7

In clinical trials, 61 pediatric patients between the ages of 4 and 16 years received Septanest 1:100,000. Among these pediatric patients, doses from 0.76 mg/kg to 5.65 mg/kg (0.9 to 5.1 mL) were administered safely to 51 patients for simple procedures and doses between 0.37 mg/kg and 7.48 mg/kg (0.7 to 3.9 mL) were administered safely to 10 patients for complex procedures. However, there was insufficient exposure to Septanest 1:100,000 at doses greater than 7.00 mg/kg in order to assess its safety in pediatric patients. No unusual adverse events were noted in these patients. Approximately 13% of these pediatric patients required additional injections of anaesthetic for complete anaesthesia.

In the clinical trials 54 patients between the ages of 65 and 75 years, and 11 patients 75 years and over received Septanest 1:100,000. Among all patients between 65 and 75 years, doses from 0.43 mg/kg to 4.76 mg/kg (0.9 to 11.9 mL) were administered safely to 35 patients for simple procedures and doses from 1.05 mg/kg to 4.27 mg/kg (1.3 to 6.8 mL) were administered safely to 19 patients for complex procedures. Among the 11 patients ≥ 75 years old, doses from 0.78 mg/kg to 4.76 mg/kg (1.3 to 11.9 mL) were administered safely to 7 patients for simple procedures and doses of 1.12 mg/kg to 2.17 mg/kg (1.3 to 5.1 mL) were administered to 4 patients for complex procedures

INDICATIONS

SEPTANEST 1:100,000 is indicated for local or regional anaesthesia for both simple and complex dental procedures in adults, adolescents and children 4 years of age and older.
SEPTANEST 1:100,000 is indicated only for dental procedures.

CONTRAINDICATIONS

These may be of the following types:

a. Contraindications to articaine:
   - specific allergies to articaine or to other anaesthetics of amide type,
   - hypersensitivity to any local anaesthetic agent.
b. Contraindications to the vasoconstrictor:
   - arterial hypertension,
   - coronary disease,
   - valvular cardiac disease (particularly sequelae to acute rheumatic fever).
   - thyrotoxicosis, untreated,
   - known sensitivity to sympathomimetic amines.
c. Hypersensitivity to sulfites (sodium metabisulfite is present in the formula as an antioxidant).
d. Injection by intravenous route.
e. Inflammation or sepsis in the region of the proposed injection.
f. Patients who have experienced bronchospasm after administration of any product, which contains sulfites, should not be given SEPTANEST.
g. Hypersensitivity to any other component of SEPTANEST.
h. Patients who are known or who have a history, which suggests a deficiency in plasma cholinesterase activity (see section Pharmacokinetic properties).
i. Patients receiving monoamine oxidase inhibitors (or who have received such an agent within two weeks), or tricyclic antidepressants.
j. Patients in whom there is a possibility that general anaesthesia might be required to complete the procedure.
k. Do not use under 4 years of age.

PRECAUTIONS

General precautions

WHEN ANY LOCAL ANAESTHETIC AGENT IS USED, RESUSCITATIVE EQUIPMENT AND RESUSCITATIVE DRUGS, INCLUDING OXYGEN, SHOULD BE IMMEDIATELY

AVAILABLE IN ORDER TO MANAGE POSSIBLE ADVERSE REACTIONS INVOLVING THE CARDIOVASCULAR, RESPIRATORY OR CENTRAL NERVOUS SYSTEMS. Because of the possibility of hypotension and bradycardia following major blocks, an IV cannula should be inserted before the local anaesthetic is injected. Delay in proper management of dose-related toxicity, under ventilation from any cause and/or altered sensitivity may lead to the development of acidosis, cardiac arrest and death.

INJECTION SHOULD ALWAYS BE MADE SLOWLY WITH FREQUENT ASPIRATIONS TO AVOID INADVERTENT INTRAVASCULAR INJECTION, WHICH CAN PRODUCE CEREBRAL SYMPTOMS EVEN AT LOW DOSES.
Note, however, that the absence of blood in the syringe does not assure that intravascular injection will be avoided. There should be careful monitoring of cardiovascular and respiratory vital signs after each injection.
Intravascular injection is strictly contraindicated. An accidental injection into a blood vessel may be associated with systemic adverse effects due to the circulating levels of adrenaline and/or articaine. Therefore, it is imperative to ensure that the needle being used for the injection does not go into a vessel.

Since amide-type local anaesthetics are also metabolised by the liver, SEPTANEST should be used with caution in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolise local anaesthetics normally, are at greater risk of developing toxic plasma concentration.
Due to the presence of adrenaline, the product is not advised for diabetic subjects and for patients with thyrotoxicosis.

Use with caution in the following circumstances:
- The lowest dosage that results in effective anaesthesia should be used to avoid high plasma levels and serious adverse effects. Repeated doses may cause significant increases in blood levels with each repeated dose due to slow accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients, acutely ill patients and children should be given reduced doses commensurate with their age and physical condition. SEPTANEST should also be used with caution in patients with heart block.
- Local anaesthetic solutions containing a vasoconstrictor should be used with caution in areas of the body supplied by end arteries or having otherwise compromised blood supply. Patients with peripheral vascular disease and those with hypersensitive vascular disease may exhibit exaggerated vasoconstrictor response. Ischaemic injury or necrosis may result. SEPTANEST containing a vasoconstrictor should be used with caution in patients during or following the administration of potent general anaesthetic agents, since cardiac arrhythmias may occur under such conditions.
- Many drugs used during the conduct of anaesthesia are considered potential triggering agents for familial malignant hyperthermia. Since it is not known whether amide-type local anaesthetics may trigger this reaction, and since the need for supplemental general anaesthesia cannot be predicted in advance, it is suggested that a standard protocol for management should be available.
- Solutions containing adrenaline should be used with caution in patients with hypertension, cardiac disease, and / or cerebrovascular insufficiency.
- Prostatic hypertrophy.
- SEPTANEST should be administered with caution to subjects with cardiovascular disease, abnormalities of cardiac conduction, or a history of epilepsy.
- SEPTANEST should not be used in patients with a deficiency of plasma cholinesterase activity.

Systemic absorption of local anaesthetics can produce effects on the central nervous and cardiovascular systems. At blood concentrations achieved with therapeutic doses, changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance are minimal. However, toxic blood concentrations depress cardiac conduction and excitability, which may lead to atrioventricular block, ventricular arrhythmias, and cardiac arrest, sometimes resulting in fatalities. In addition, myocardial contractility is depressed and peripheral vasodilation occurs, leading to decreased cardiac output and arterial blood pressure.

Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be accomplished after each local anaesthetic injection. It should be kept in mind at such times that restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression, or drowsiness may be early warning signs of central nervous system toxicity.

In vitro studies show that about 5% to 10% of articaine is metabolised by the human liver microsomal P450 isoenzyme system. However because no studies have been performed in patients with liver dysfunction, caution should be used in patients with severe hepatic disease. SEPTANEST should also be used with caution in patients with impaired cardiovascular function since they may be less able to compensate for functional changes associated with the prolongation of A-V conduction produced by these drugs.

Small doses of local anaesthetics injected in dental blocks may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. Confusion, convulsions, respiratory depression and/or respiratory arrest, and cardiovascular stimulation or depression have been reported. These reactions may be due to intra-arterial injection of the local anaesthetic with retrograde flow to the cerebral circulation. Patients receiving these blocks should be observed constantly. Resuscitative equipment and personnel for treating adverse reactions should be immediately available. Dosage recommendations should not be exceeded.

Information for Patients:
The patient should be informed in advance of the possibility of temporary loss of sensation and muscle function following infiltration and nerve block injections.

Carcinogenicity and Mutagenicity:
Studies to evaluate the carcinogenic potential of articaine hydrochloride in animals have not been conducted. Articaine was negative in bacterial and mammalian assays for gene mutation and a chromosomal aberration test in Chinese hamster ovary cells. *In vivo* clastogenicity (mouse micronucleous) assays with articaine alone and with adrenaline were negative at a low subcutaneous dose (same as the maximal recommended clinical dose on a mg/m^2 basis).

Impairment of Fertility:
No effects on male or female fertility were observed in rats given articaine hydrochloride with adrenaline subcutaneously from prior to mating until mating (males) or early gestation (females) at doses up to 80 mg/kg/day (approximately twice the maximum recommended human dose on a mg/m^2 basis).

Use in pregnancy (Category B3):
No clinical experience of the use in pregnancy and lactating women is available. Safe use of local anaesthetics during pregnancy has not been established with respect to adverse effects on foetal

development. The product should only be used in pregnancy when the benefits are considered to outweigh the risks.

No effects on embryofetal development were observed when articaine hydrochloride with adrenaline was administered subcutaneously throughout organogenesis at doses up to 40 mg/kg/day in rabbits and 80 mg/kg/day in rats (approximately 2 times the maximum recommended human dose on a mg/m^2 basis). In rabbits, fetal death and increased fetal skeletal variations were observed at the maternotoxic dose of 80 mg/kg (approximately 4 times the maximum recommended human dose on a mg/m^2 basis).

When articaine hydrochloride alone was administered subcutaneously to rats throughtout gestation and lactation, 80 mg/kg/day (approximately 2 times the maximum recommended human dose on a mg/m^2 basis) increased the number of stillbirths, delayed eye opening, and adversely affected passive avoidance, a measure of learning, in pups, along with maternal toxicity were observed. A dose of 40 mg/kg/day (approximately the maximum recommended human dose on a mg/m^2 basis) did not produce these effects. A similar study using articaine hydrochloride with adrenaline produced maternal toxicity, but no effects on the offspring.

Use during lactation:
The excretion of articaine or its metabolites in human milk is unknown. As many drugs are excreted in human milk, caution should be exercised when SEPTANEST is administered to a nursing woman. If administered, nursing women should not breast feed for at least 48 hours following anaesthesia with SEPTANEST.
For effects of articaine hydrochloride in rat pups being suckled see *Use in pregnancy.*

Use in Children and Adolescents
SEPTANEST 1:100,000 should not be used in children younger than 4 years of age as safety and effectiveness has not been established in this age group.
See CLINICAL TRIALS for description of studies in children and adolescents (4 years of age to 16 years of age). See DOSAGE and ADMINISTRATION.

Use in the Elderly

No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Approximately 6% of patients between the ages of 65 and 75 years and none of the 11 patients 75 years of age or older required additional injections of anaesthetic for complete anaesthesia compared with 11% of patients between 17 and 65 years old who required additional injections.
See CLINICAL TRIALS for description of studies in the Elderly.

Effects on ability to drive and use machines:
In a controlled study on healthy volunteers articaine was shown to have no effect on the level of attentiveness, reaction time to visual stimulations or motor co-ordination.
Patients who experience systemic adverse effects during or immediately following administration of SEPTANEST should be advised to avoid driving or operating machinery until resolution of signs or symptoms.

INTERACTIONS

No drug interaction studies have been performed.
Due to the possibility that clinically significant increases in circulating adrenaline concentrations may occur post-injection, SEPTANEST should be administered with caution to any patient receiving drugs with sympathomimetic properties or with agents whose therapeutic actions may be antagonised by adrenaline.

The administration of local anaesthetic solutions containing adrenaline to patients receiving monoamine oxidase inhibitors, tricyclic antidepressants or phenothiazines may produce severe prolonged hypotension or hypertension. Phenothiazines and butyrophenones may reduce or reverse the pressor effect of adrenaline. Concurrent use of these agents should generally be avoided. In situations when concurrent therapy is necessary, careful patient monitoring is essential. Concurrent administration of vasopressor drugs and ergot-type oxytocic drugs may cause severe, persistent hypertension or cerebrovascular accidents.

SEPTANEST should be administered with caution to patients under the following treatments:

- Hypoglycaemics: adrenaline-induced hyperglycaemia may lead to loss of blood sugar control in diabetic patients treated with hypoglycaemics.
- Anti-arrhythmic agents (e.g. procainamide, mexilitine, disopyramide).
- Antiepileptic skeletal muscle relaxant.
- Cardiac glycosides (e.g. digoxin): adrenaline may interact with cardiac glycosides resulting in cardiac arrhythmias.
- Adrenergic neuron blocking agents (e.g. guanethidine) since the product contains adrenaline.
- Quinidine: combination with adrenaline may lead to cardiac arrhythmias.
- Cimetidine.
- Amiodarone.
- Phenytoin and other antiepileptic drugs such as phenobarbitone, primidone and carbamazepine
- Inhalational anaesthetics: serious cardiac arrhythmias may occur if preparations containing adrenaline are employed in patients following the administration of inhalational anaesthetics.
- Beta adrenoreceptor antagonists - Propranolol and metoprolol, timolol. Administration of adrenaline may result in dose-dependent hypertension and bradycardia with possible heart block.
- Thyroid hormones: may potentiate the actions of adrenaline.

Incompatibilities

None reported.

ADVERSE REACTIONS

Articaine and adrenaline may reach sufficient concentrations in blood to provoke systemic adverse effects. Reactions to SEPTANEST are characteristic of those associated with other amide-type local anaesthetics. Adverse reactions to this group of drugs may also result from excessive plasma levels, which may be due to overdosage, unintentional intravascular injection, or slow metabolic degradation.

Adverse Reactions from Clinical Trials

The reported adverse events are derived from clinical trials in the US and UK.
Of the 1325 patients treated in the primary clinical trials, 882 were exposed to SEPTANEST.

Table 2. Adverse Events in controlled trials with an incidence of 1% or greater in patients administered SEPTANEST (articaine hydrochloride 4% (40 mg/mL) with epinephrine (adrenaline) 1:100,000 Injection).

Body system	SEPTANEST 1:100,000 N (%)
Number of Patients	882 (100%)
Body As A Whole	
Face Edema	13 (1%)
Headache	31 (4%)
Infection	10 (1%)
Pain	114 (13%)
Digestive System	
Gingivitis	13 (1%)
Nervous system	
Paresthesia	11 (1%)

The following list includes adverse and concurrent events that were recorded in 1 or more patients, but occurred at an overall rate of less than one percent, and were considered clinically relevant.

Body as a Whole - abdominal pain, accidental injury, asthenia, back pain, injection site pain, malaise, neck pain.
Cardiovascular System - hemorrhage, migraine, syncope, tachycardia.
Digestive System - constipation, diarrhea, dyspepsia, glossitis, gum hemorrhage, mouth ulceration, nausea, stomatitis, tongue edemas, tooth disorder, vomiting.
Hemic and Lymphatic System - ecchymosis, lymphadenopathy.
Metabolic and Nutritional System - edema, thirst.
Musculoskeletal System - arthralgia, myalgia, osteomyelitis.
Nervous System - dizziness, dry mouth, facial paralysis, hyperesthesia, increased salivation, nervousness, neuropathy, paresthesia, somnolence.
Respiratory System - pharyngitis, rhinitis.
Skin and Appendages - pruritis, skin disorder.
Special Senses - ear pain, taste perversion.
Urogenital System - dysmenorrhea.

Adverse Reactions Due to Articaine:
Toxic reactions (showing an abnormally high concentration of local anaesthetic in the blood) may appear either immediately, by accidental intravascular injection or later, by true overdose following an injection of an excessive quantity of anaesthetic solution.

Symptoms include:
- symptoms showing effects on the central nervous system: nervousness, shaking, yawning, trembling, apprehension, nystagmus, logorrhoea, headache, nausea, buzzing in the ears. These signs, when they appear, require rapid corrective measures to prevent possible worsening.
- Respiratory symptoms: tachypnoea, then bradypnoea, which could lead to apnoea.
- Cardiovascular signs: reduction in the contractile power of the myocardium, lowering of heart rate and drop in blood pressure.

Common ≥ 1% and <10%
Headache, facial oedema, gingivitis,

Disruption of nerve transmission (para-, hypo- and dysaesthesia) may appear after articaine administration. Resolution usually occurs within two weeks.

Uncommon ≥ 0.1% and <1%
Nausea

Other Adverse Reactions
Serious adverse experiences following the administration of articaine are similar in nature to those observed with other amide local anaesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption, unintended intravascular injection or may result from hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

Central nervous system
CNS manifestations are excitatory and/or depressant and may be characterised by light-headedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, agitation, difficulty in swallowing and slurred speech, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest which are **less common.**
The excitatory manifestations may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.

Cardiovascular system
Cardiovascular manifestations are usually depressant and are characterised by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest. Signs and symptoms of depressed cardiovascular function may commonly result from a vasovagal reaction, particularly if the patient is in an upright position.
Less commonly, they may result from a direct effect of the drug. Failure to recognize the premonitory signs such as sweating, a feeling of faintness, changes in pulse or sensorium may result in progressive cerebral hypoxia and seizure or serious cardiovascular catastrophe. Management consists of placing the patient in the recumbent position and ventilation with oxygen. Supportive treatment of circulatory depression may require the administration of intravenous fluids and resuscitative drugs as directed by the clinical situation.

Hypersensitivity
One may observe manifestations of hypersensitivity to articaine as rash, pruritis, urticaria or anaphylaxis.
The administration of large doses of articaine may produce methaemoglobinaemia in patients with subclinical methaemoglobinaemia.

Allergic reactions
Allergic reactions are characterised by cutaneous lesions, urticaria, oedema or anaphylactoid reactions.

Allergic reaction to sulfites
Allergic-type reactions may occur in patients with bronchial asthma due to hypersensitivity to the sulfite component and may be manifested by dermatologic reactions, oedema, urticaria and other allergy symptoms.

DOSAGE AND ADMINISTRATION
One or more cartridges should be used on a single patient on one occasion only during each session of treatment. If only a portion of a cartridge is used, the remainder must be discarded.

Use in Adults
Table 3 summarises the recommended volumes and concentrations of SETPANEST for various types of anaesthetic procedures. For most common operations, one infiltration with 1.7 mL SEPTANEST is sufficient. In all cases, the injection must be done slowly (about 1 mL/min). For an infiltration in the interdental septum, a quantity of 0.3 to 0.5 mL is generally sufficient. Higher volumes should rarely be required.
MAXIMUM RECOMMENDED DOSE for normal health adults of articaine hydrochloride administered by submucosal infiltration and/or nerve block should not exceed 7 mg/kg of body weight. This corresponds, for a subject weighing 60 kg, to six (6) standard 1.7 mL cartridges or five (5) standard 2.2 mL cartridges (doses of 7 mg/kg were not exceeded in clinical trials). Anaesthesia is obtained rapidly (1 to 6 minutes).

Table 3. Recommended Dosages

PROCEDURE	SEPTANEST INJECTION	
	Vol (mL)	Total Dose of Articaine HCl (mg)
Infiltration	0.5 – 2.5	20 – 100
Nerve Block	0.5 – 3.4	20 – 136
Oral Surgery	1.0 – 5.1	40 - 204
The above-suggested volumes serve only as a guide for normal health adults. Other volumes may be used provided that the total maximum recommended dose is not exceeded.		

The duration of the anaesthesia during which an operation can be performed is about one hour (pulpal analgesia) depending on the technique used, and on the procedure.

Use in Children
Safety and effectiveness in pediatric patients below the age of 4 years have not been established. Dosages in pediatric patients (over 4 years) should be reduced, commensurate with age, body weight, and physical condition. Please refer to the table 4 below. Use of SEPTANEST in children under 4 years of age is not recommended due to the absence of safety and efficacy data.
MAXIMUM RECOMMENDED DOSE for normal health children must not exceed 7mg/kg of body weight.

Table 4. Dosage Adjustments for Use in Children

	20 kg child		**40 kg child**	
Maximum Dose: 0.175 mL/kg	3.5 mL, i.e. ≈ 2 cartridges of 1.7 mL or ≈ 1.5 cartridge of 2.2 mL		7.0 mL, i.e. ≈ 4 cartridges of 1.7 mL or ≈ 3 cartridges of 2.2 mL	
Recommended dose : **0.06 mL/kg for simple procedure** **0.07 mL/kg for complex procedure**	**Procedure**		**Procedure**	
	Simple	Complex	Simple	Complex
	1.2 mL i.e. ≈ ¾ cartridge of 1.7 mL or ≈ ½ cartridge of 2.2 mL	1.4 mL i.e. ≈ ¾ cartridge of 1.7 mL or ≈ ½ cartridge of 2.2 mL	2.4 mL i.e. ≈ 1 ½ cartridge of 1.7 mL or ≈ 1 cartridge of 2.2 mL	2.8 mL i.e. ≈ 1 ½ cartridge of 1.7 mL or ≈ 1 cartridge of 2.2 mL

OVERDOSE

The most serious effects of articaine intoxication are on the CNS and cardiovascular system. The type of toxic reaction is unpredictable and depends on such factors as dosage, rate of absorption, and clinical status of the patient. Two types of reactions that effect stimulation and/or depression of the central cortex and medulla may result from systemic absorption.

Slow onset symptoms following overdose include stimulation leading to nervousness, dizziness, blurred vision, nausea, tremors, convulsions, hypotension, cardiovascular depression, and respiratory arrest.

Rapid onset symptoms following overdose include depression, leading primarily to respiratory arrest, cardiovascular collapse, and cardiac arrest. Since cardiac arrest symptoms may occur rapidly and with little warning, treatment should be readily available.

Treatment of overdose

For all symptoms: If acute toxicity occurs the injection should be stopped immediately. A patent airway should be established and maintained, oxygen should be administered, and assisted or controlled ventilation should be provided as required.

Circulatory collapse: toxic cardiovascular reactions can include peripheral vasodilation, hypotension, bradycardia and cardiac arrest. Immediately resuscitate with oxygen and commence cardiovascular resuscitation procedures as appropriate.

Convulsions: Appropriate medication for the management of convulsions should be used.

If not treated immediately, both convulsions and cardiovascular depression may result in hypoxia, acidosis, bradycardia, arrhythmia and cardiac arrest.

Supportive treatment should be given; standard cardiopulmonary resuscitative therapy, including respiratory support may be required to counter adverse effects on the cardiovascular and/or respiratory systems and to control convulsions. There is no specific antidote.

PHARMACEUTICAL PARTICULARS

Presentation

Box containing 5 blister trays of 10 x 1.7 mL (glass cartridge) with rubber closure

Box containing 5 blister trays of 10 x 2.2 mL (glass cartridge) with rubber closure.

Store below 25°C

Distributed by
Sponsor name: IVOCLAR VIVADENT Ltd
Sponsor address: 12 Omega Street, Rosedale, Auckland 0632, NEW ZEALAND
Medicine classification
Prescription Medicine
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