

Reclassification of a Medicine for consideration by the Medicine Classification Committee

Part A

1. International Non-proprietary Name of the medicine. Bupivacaine Hydrochloride

2. Proprietary name(s). Marcain Plain and Marcain with Adrenaline

3. Name and contact details of the company / organisation / individual requesting a reclassification.

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Note: Contact details will be removed from the form prior to publication on the Medsafe website.

4. Dose form(s) and strength(s) for which a change is sought.

Marcain Plain 0.25% and 0.5 % Solution for Injection and Marcain with Adrenaline 0.25% /1:400,000 Solution for Injection and Marcain with Adrenaline 0.5% /1:200,000 Solution for Injection

5. Pack size and other qualifications.

Marcain 0.25% Plain: 5 x 20mL

Marcain 0.5% with Adrenaline 1:400,000: 5 x 20mL

Marcain 0.5% Plain: 5 x 10mL

Marcain 0.5% with Adrenaline 1:200,000: 5 x 20mL

6. Indications for which change is sought.

Marcain to be exempt from prescription status when used by Podiatrists with the Scope of Practice (SoP) of Podiatric Surgeons when performing surgical anaesthesia (digital) and local infiltration.

7. Present classification of the medicine.

Marcain has prescription status.

8. Classification sought.

Marcain be exempt from prescription status for Podiatrists with the extended SoP of Podiatric Surgeons.

9. Classification status in other countries (especially Australia, UK, USA, Canada).

Podiatric Surgeons in Australia, UK and Canada have exemption to use Marcain, USA Podiatrists/Podiatric Physicians and Surgeons prescribe Marcain.

10. Extent of usage in New Zealand and elsewhere (eg, sales volumes) and dates of original consent to distribute.

Not applicable

11. Local data or special considerations relating to New Zealand (if applicable).

Marcain to be exempt from prescription status when used by Podiatric Surgeons when performing bone surgery and local infiltration.

12. Labelling or draft labelling for the proposed new presentation(s). Not applicable

13. Proposed warning statements (if applicable).

As per Marcain ± Adrenaline Data Sheet uploaded from Medsafe website which states the use of Marcain with adrenaline is not recommended for digital blocks.

14. Other products containing the same active ingredient(s) and which would be affected by the proposed change.

Not applicable

Part B

1. Indications and dose

What is the medicine indicated for, and for which indication(s) is the reclassification application for?

Marcain is indicated for surgical anaesthesia (local infiltration and digital block) and analgesia. Under the Scopes of Practice (SoP) of the Podiatrists Board of New Zealand, Podiatric Surgeons perform bone procedures and therefore Marcain's use for surgery will assist in the increased duration of surgical anaesthesia and analgesia when compared to Lignocaine.

Podiatrist registered with the Podiatry Board are permitted to use Lignocaine for minor surgical procedures. Podiatrists have demonstrated competence to safely and effectively administer Lignocaine (a restricted medicine classification).

Lignocaine has a faster onset, low lipid solubility, and shorter duration than Marcain. Balakrishnan et al. (2015) discusses the merits of using Marcain rather than Lignocaine. They found Marcain was more effective in relation to prolonged post-op analgesia and anaesthesia with minor surgical procedures when comparing it to Lignocaine.

Podiatrists have been using other local anaesthetics as indicated by the comments made by Mr Street Orthopaedic Surgeon in a submission made in 2009. "At present, Podiatry prescribing is limited to the use of local anaesthetic agents, with this right being gained under the Medicines Regulations by the Profession in 1975. Lignocaine was approved but the use of Pravacaine, Rapivacaine and Bupivacaine have been used commonly".

What is the evidence that the proposed indication is an OTC indication ie, that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?

The proposed indication for use of Marcain is indicated for surgical anaesthesia (local infiltration and digital block) and analgesia and does not fall under an OTC indication. Diagnosis and treatment are performed by registered healthcare practitioners, podiatrists with the SoP as Podiatric Surgeons perform surgical several procedures to the foot under local anaesthesia. Consumers are advised of the risks and benefits of the treatment including the use of local anaesthesia. This currently applies to Lignocaine that is exempt from prescription status when used by Podiatrists when performing minor surgery (digital) and local infiltration. Podiatrists have demonstrated competence to safely and effectively administer Lignocaine (a restricted medicine classification) to patients undergoing minor surgical procedures. This also applies to podiatric surgeons using other local anaesthetics since to 2009.

What is the treatment population for the indication (age; gender etc.)? – What is the dose and dose frequency of the medicine for this indication?

The general population that would require digital and/or infiltration of local anaesthesia for minor surgery or analgesia.

Adults: Recommended dosages for Marcain Plain and Marcain with Adrenaline solutions for anaesthetic procedures is based on the average healthy 70 Kg adult patient and is calculated based on 2mg/kg in a 24 hour period.

Bupivacaine Hydrochloride			
Surgical anaesthesia	Conc %	Volume mL	Dosage mg
Local infiltration in surgery	0.25	≤ 60	≤ 150
	0.5	≤ 30	≤ 150
Digital Block	0.25	1 - 5	2.5 – 12.5
NB adrenaline not recommended			

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Analgesia requirements for adults follows the local infiltration concentrations, volume and dosage above.

It is interesting to note that the maximum safe recommended doses (mg) are using the calculated 2mg/kg for a 70 Kg adult equates to 140mg for infiltration in 24 hours. The digital volume is based on the anatomy of the digit and the restriction of volume to be administered. 2.5mg- 12.5mg in 24 hours. Medsafe Data sheet for Bupivacaine

Paediatrics: The Data Sheet for Marcain and use in paediatrics states the experience in children under 12 is limited and recommends dosage to be calculated at 2mg/kg, this is in contrast to the American FDA access data sheet that does not recommend the use of Marcain.

Based on the FDA safety data sheet for Marcain, it is proposed that Marcain +/- adrenaline would not be recommended for use by Podiatrists under the age of 12.

Older Adult Use: Patients over 65 years, particularly those with hypertension, may be at increased risk for developing hypotension while undergoing anaesthesia with Marcain. Medsafe Data sheet for Bupivacaine

2. Presentation

What is the proposed dose form and strength of the medicine to be reclassified?

Marcain Plain 0.25% and 0.5 % Solution

Marcain with Adrenaline 0.25% /1:400,000 Solution and Marcain with Adrenaline 0.5% /1:200,000 Solution

Is this the same for all indications? No

Surgical Anaesthesia: Local infiltration in surgery, less than or equal to 150mg (Marcain with and without adrenaline). This type of anaesthesia would be used to perform a mayo block, a block around the first ray in order to perform bunion surgery.

Digital block 2.5-12.5mg (Marcain with adrenaline will not be used) in order to perform bony digital correction procedures. Medsafe Data sheet for Bupivacaine.

What is the proposed pack size for reclassification?

Marcain 0.25% Plain: 20mL

Marcain 0.5% with Adrenaline 1:400,000: 20mL

Marcain 0.5% Plain: 10mL

Marcain 0.5% with Adrenaline 1:200,000: 20mL

What is the proposed packaging for the reclassified medicine? Does it include child resistant containers for liquids; a dosing device etc?

Not applicable

What disposal considerations need to be made for the medicine?

The vials are intended for single use only, any unused portions of solutions should be discarded. The solution should be used immediately after opening. Solutions showing discolouration or containing particulate matter should be discarded. Medsafe Data sheet for Bupivacaine

What storage considerations need to be made for the medicine?

Unopened container Store below 30°C. Do not refrigerate or freeze. Protect from light. Opened container for immediate use only. Discard any residue. Medsafe Data sheet for Bupivacaine

How practical and easy to use is the proposed presentation? Very easy to use

3. Efficacy/benefits

What is the evidence for efficacy and the degree of efficacy for the proposed indication(s)?

Balakrishnan et al. (2015) discusses the merits of using Marcain rather than Lignocaine. They found Marcain was more effective in relation to prolonged post-op analgesia and anaesthesia with minor surgical procedures when comparing it to Lignocaine.

To what extent is this medicine used for the proposed indication(s) ie, duration of use; frequency of use?

The extent depends on the number of patients requiring surgical anaesthesia, when used will be used once with MSD determined in a 24hour period. Medsafe Data sheet for Bupivacaine.

What is the history of this medicine's use for the proposed indication(s) ie, number of users; number of countries used in? Endorsed podiatric prescribers in Australia, Canada and USA have access to use Marcain for surgical anaesthesia and analgesia. At 30 September 2018 there were 5,168 registered Podiatrists in Australia, 99 of whom were endorsed prescribers. In Australia, Podiatrists with prescribing endorsement have had access to Marcain since 2011.

What is the evidence that improved access is beneficial?

Active patient participation leads to more accessible and effective health services

What is the evidence of improved consumer involvement in their health?

Ethical reasons:

The addition of Marcain would create choice for the patient. In consultation with the podiatric surgeon they would be able to make an informed decision as to what is the most suitable form of anaesthesia and analgesia for the procedure. This would facilitate the decision-making process and supports an active role for the patients in managing their own health.

What are the benefits from a consumer viewpoint?

No extra cost to patient care as Marcain is being used part of the treatment.

Health:

Patients have a choice of the type of anaesthesia, rather than undergoing general anaesthesia and the associated risks, the procedure can be performed under local. Lignocaine is not suitable for bone procedures. Balakrishnan et al. (2015) discusses the merits of using Marcain rather than Lignocaine. They found Marcain was more effective in relation to prolonged post-op analgesia and anaesthesia with minor surgical procedures when comparing it to Lignocaine.

4. Contraindications and precautions

What are the contraindications for the medicine and how easy are they to identify and prevent?

Contraindications:

Patients that are allergic or hypersensitive to amide type local anaesthetics or to the excipients (methyl parahydroxybenzoate). Skin changes, itchy, hives, wheal and erythema to anaphylaxis. Treatment of anaphylaxis protocol.

Patients identified, and allergy/hypersensitivity maybe prevented as the patient undergoes an extensive questioning into their history which includes a known history of allergic reaction to any known medications and specifically asked about allergies or prior reactions to local anaesthesia. Medsafe Data sheet for Bupivacaine

Allergy or hypersensitivity to sodium metabisulphite in adrenaline-containing solutions. *Patients identified and prevented as the patient undergoes an extensive questioning into*

their history which includes a known history of allergic reaction to any known medications (sulphur) and specifically asked about allergies or prior reactions to local anaesthesia. Signs and symptoms as above. The overall prevalence of sulphite sensitivity in the general population is unknown but probably low; such sensitivity appears to occur more frequently in asthmatic than in non-asthmatic individuals. American Society of Health System Pharmacists; AHFS Drug Information 2009. Bethesda, MD. (2009), p. 3335

Bupivacaine is contraindicated in obstetric paracervical block, intravenous regional anaesthesia (Bier's block) and all intravenous infusions. *Podiatric surgeons do not perform intravenous infusions (Bier Blocks) within the SoP.*

Local anaesthetic techniques must not be used when there is inflammation and/or sepsis in the region of the proposed injection and/or in the presence of septicaemia.

Adrenaline is contraindicated in conditions where the production or exacerbation of tachycardia could prove fatal, such as thyrotoxicosis or severe heart disease or in obstetrics when maternal blood pressure exceeds 130/80 mm Hg. The through medical history would identify a patient with a history of cardiac disease including tachycardia, severe heart disease, signs and symptoms such as fatigue, heart palpitations, increased sweating, heat intolerance, irritability, changes in appetite thyrotoxicosis prior to the clinical decision to use Marcain with adrenaline. *Pre-operative history and physical, vital signs and monitoring patients using pulse-oximetry would identify at risk patients.*

What are the precautions for this medicine and how easy are these to understand?

The lowest dosage that results in effective anaesthesia should be used. Repeated injection of Marcain may cause accumulation of bupivacaine or its metabolites and result in toxic effects. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly or young patients, including those with partial or complete conduction block, advanced liver disease or severe renal impairment, should be given reduced doses commensurate with their age and physical condition. *Podiatric Surgeons determine the MSD for each patient and perform history and physicals to identify at risk patients and thus modify the amount of drug to be administered.*

In view of the risk of inadvertent intravascular injection bupivacaine should be given with great caution to patients with epilepsy, severe bradycardia, cardiac conduction disturbances, severe shock or severe digitalis intoxication. Injections should always be made slowly with frequent aspirations to avoid inadvertent intravascular injection which can produce toxic effects. *A detailed history would identify patients above.*

When any local anaesthetic agent is used, resuscitative equipment and medicines, including oxygen, should be immediately available to manage possible reactions involving the cardiovascular, respiratory or central nervous systems. *Podiatric surgeons must have a current Level 4 CPR certificate and anaphylaxis training to manage possible adverse reactions as part of their Annual Practising Certificate. The use of pulse-*

oximetry would alert the surgeon to cardiac changes, blood pressure, heart rate and oxygen saturation and then manage the situation accordingly.

Injections should always be made slowly with frequent aspirations to avoid inadvertent intravascular injection which can produce toxic effects. *This is taught and simulated as part of podiatric practice when injecting any local anaesthesia.*

The use of local anaesthetics for major peripheral nerve block may involve the administration of large volumes in highly vascularised areas, often close to large blood vessels. As such there is an increased risk of intravascular injection and/or rapid systemic absorption which can lead to high plasma concentrations. There have been reports of cardiac arrest or death during use of bupivacaine for epidural anaesthesia or peripheral nerve blockade. In some instances, resuscitation has been difficult or impossible despite apparently adequate preparation and management. *The treatment and management of cardiac arrest, seeking assistance, resuscitation and ventilation*

The safety and effectiveness of Marcain depend on proper dosage, correct technique and adequate precautions. *Podiatric Surgeons are taught advanced local anaesthetic techniques, calculating the MSD, the importance of aspirating to avoid accidental intravascular injection, injecting slowly are taught for all LA techniques.*

Bupivacaine is metabolised in the liver and excreted via the kidneys, the possibility of bupivacaine accumulation should be considered in patients with hepatic and/or renal impairment. *The medical history would identify patients with hepatic and/or renal impairment and dose would be adjusted prior to performing anaesthesia.*

Adrenaline-containing solutions should be used with extreme caution in patients with severe or untreated hypertension, poorly controlled hyperthyroidism, arteriosclerotic heart disease, cerebral vascular insufficiency, heart block, advanced diabetes, or any other pathological conditions that might be aggravated by the effects of adrenaline. *The podiatric medical history would identify patients with the above medical conditions and therefore adrenaline would not be indicated.* **Adrenaline** containing solutions should also be used cautiously and in carefully restricted quantities in areas of the body supplied by end arteries, such as digits, or otherwise having a compromised blood supply. Adrenaline may induce anginal pain in patients suffering from angina pectoris. Medsafe Data sheet for Bupivacaine.

Adrenaline will not be injected into the digital arteries and will not be used in patients with angina pectoris.

Solutions containing adrenaline should be used with extreme caution in patients receiving tricyclic antidepressants and monoamine oxidase (MAO) inhibitors since severe, prolonged hypertension may result. Neuroleptics such as phenothiazines and butyrophenones may reduce or reverse the pressor effects of adrenaline giving rise to hypotensive responses and tachycardia. Medsafe Data sheet for Bupivacaine.

Solutions containing **adrenaline** enhance the toxic effects of cardiac glycosides which may result in arrhythmias. *Podiatric medical history would identify patients on cardiac glycosides and Marcain with adrenaline would not be used.*

Solutions containing **adrenaline** and non-cardioselective betablockers such as propranolol enhance the pressor effects of adrenaline, which may lead to severe hypertension and bradycardia. *Podiatric medical history would identify patients on non-cardioselective betablockers and Marcain with adrenaline would not be used.*

Does the medicine have a low therapeutic index? Yes

What class effects need to be considered and what are the risks?

Reactions to Marcain are characteristic of those associated with other amide-type local anaesthetics. A major cause of adverse reactions to this group of drugs may be associated with excessive plasma levels, which may be due to overdosage, rapid absorption, unintentional intravascular injection or slow metabolic degradation. Medsafe Data sheet for Bupivacaine.

What are the risks of the medicine being used in an OTC environment? None as Marcain is prescription only.

What other drug interactions need to be considered?

Marcain should be used with caution in patients receiving agents structurally related to local anaesthetics, e.g. certain anti-arrhythmic agents, such as lignocaine, amiodarone, mexiletine, sotalol and tocainide, since the systemic toxic effects are additive. Alcohol, captopril, indomethacin, metoprolol, midazolam, prazosin, propranolol, risperidone, verapamil and ziconotide. Medsafe Data sheet for Bupivacaine.

What food and/or drink interactions need to be considered? No food interactions noted but patients who regularly drink large amounts of alcohol reduces the effect of Marcain. Medsafe Data sheet for Bupivacaine.

Are there any other restrictions when taking the medicine ie, driving restrictions or operating machinery?

Local anaesthetics may have a very mild effect on mental function and co-ordination even in the absence of overt central nervous system toxicity and may temporarily impair locomotion and alertness. Patients and carers should be advised to not undertake skilled tasks (including driving) if the anaesthetised region impairs individual's ability to operate this task safely. *Patients are advised at the time of scheduling surgery of the restrictions and are encouraged to bring a relative or family member to drive them home, not make any major decision or use of machinery until the next day.*

Are there any special populations where exposure to the medicine needs to be restricted? Yes

Paediatrics: The Data Sheet for Marcain and use in paediatrics states the experience in children under 12 is limited and recommends dosage to be calculated at 2mg/kg, this is in contrast to the American FDA safety data sheet that does not recommend the use of Marcain. Medsafe Data sheet for Bupivacaine.

Pregnancy: Dose restricted in the late stages of pregnancy

Debilitated and elderly patients: Debilitated and elderly patients and those with partial or complete heart block, advanced liver disease or severe renal dysfunction should be given reduced dose. Medsafe Data sheet for Bupivacaine.

Breast feeding: amount too small to be harmful.

5. Undesirable effects

What are the known undesirable effects and the frequencies of these?

Very common events (>10%) Vascular: Hypotension. Gastrointestinal: Nausea

Common events (>1%<10%) Cardiac: Bradycardia. Vascular: Hypertension. CNS: Paraesthesia, dizziness. Gastrointestinal: Vomiting. Renal: Urinary retention.

Uncommon events (>0.1% <1%) CNS: CNS toxicity eg paraesthesia, convulsions, circumoral, numbness of the tongue, hyperacusis, visual disturbances, loss of consciousness, tremor, light headedness, tinnitus, dysarthria

Rare ($\leq 0.1\%$) Cardiac arrest, cardiac arrhythmias; Allergic reactions (anaphylactoid reactions, angioneurotic oedema and urticaria), diplopia, neuropathy, peripheral nerve injury. Medsafe Data sheet for Bupivacaine.

Do these vary for special populations?

No

What are the risks and consequences of known undesirable effects?

Local anaesthesia toxicity results in central nervous system excitation and then depression as well as cardiovascular affects of bradycardia and death. Cardiovascular effects may lead to cardiac arrest. Neurological consequences depend type of anaesthetic procedure/block. Allergy to the class of amide-type local anaesthetics is very rare. Reactions to sodium metabisulphite which is contained in adrenaline solutions can occur. Medsafe Data sheet for Bupivacaine.

Are there any significant safety concerns for the medicine under review? No

Have there ever been any withdrawals of the medicine or other regulatory actions taken for safety reasons (during a time period or in a specific jurisdiction)? No

Are there any withdrawal effects following cessation of use of the medicine? No

6. Overdose

Is there a potential for overdose of the medicine?

Yes, if maximum safe dose is not correctly calculated and administers too much. or clinician, inadvertent intravenous injection. Systemic toxicity would be low due to low dose administration but could be seen within 1-3 minutes of injecting. Toxicity may be delayed based on the site and peak plasma concentration resulting in CNS and cardiovascular effects. Medsafe Data sheet for Bupivacaine.

What are the consequences of overdose of the medicine? Systemic toxicity will affect the Central nervous system depression and Cardiovascular collapse resulting in death. Medsafe Data sheet for Bupivacaine.

Are there any reports of overdose of the medicine? There have been reports of cardiac arrest and death during the use of Bupivacaine Hydrochloride (Marcain) for intravenous regional anaesthesia (Bier Block). Medsafe Data sheet for Bupivacaine.

7. Medication errors and abuse/misuse potential

Would reclassification affect the risk of unnecessary use?

No reclassification would not affect the risk of unnecessary use as only podiatrists with to SoP of Podiatric Surgeons would have the use of Marcain which currently number four in New Zealand.

Is the medicine be provided with necessary tools to allow correct dosing eg, liquids supplied with a measuring device?

The tool to ensure correct dosing is the calculation of maximum safe dose for and adult and child as discussed in section B part I.

What are the reported medication errors post-market?

To date there are no reported post-market errors.

What are the reported cases of abuse/misuse/accidental overdose?

There have been reports of cardiac arrest and death during the use of Bupivacaine Hydrochloride for intravenous regional anaesthesia (Bier Block). Information on safe dosages and techniques of administration of Bupivacaine Hydrochloride in this

procedure is lacking. Therefore, Bupivacaine Hydrochloride is not recommended for use in this technique. Medsafe Data sheet for Bupivacaine.

How would reclassification affect import considerations?

Not applicable

What is the addiction potential of the medicine?

Not applicable

8. Communal harm and / or benefit

What are the possibilities of community harm resulting from wider use of the medicine in question (eg, the development of antibiotic resistance in bacteria or increased immunisation rates)?

Not applicable

What are the possibilities of community benefit resulting from wider use of the medicine in question (eg, greater herd immunity as a result of improved access to a communicable disease vaccine)?

Not applicable

9. Integrated benefit-risk statement

A summary of the reclassification benefits. Podiatric Surgeons will have access to Marcain when performing foot surgery. This will assist in patient having longer surgical anaesthetic and analgesia and reducing post-operative pain medication.

A summary of the reclassification risk of harm. The risk of overdose by inadvertent intravascular injection or incorrect calculation of maximum safe dose could result in systemic toxicity resulting in respiratory depression and cardiac collapse which would result in death.

A summary of the need for the medicine at the classification proposed. Podiatric Surgeons have been using long acting anaesthetics as noted by Street (2009), most likely under- standing orders. Reclassification for use only by Podiatrists with the added scope of practice that being Podiatric Surgeons would ensure restricted authorisation.

Precedent – how are other medicines in the same class classified? Podiatrist registered with the Podiatry Board are permitted to use Lignocaine for minor surgical procedures. Podiatrists have demonstrated competence to safely and effectively administer Lignocaine (a restricted medicine classification).

10. Risk mitigating strategies

Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required eg, healthcare professional education; integration of care; consumer information to be provided etc?

Podiatric Surgeons will attend an education course on the indications of Marcain, contraindications, precautions, review calculation of MSD and advanced anaesthetic foot blocks, and the further Annual Practising Certificate requirements in submitting documentation with the use of Marcain.

What is the evidence that these proposed risk mitigation strategies would be effective?

To date podiatrists have used Lidocaine safely since 2002, without any ADRs, this has been due to the rigorous undergraduate training in the safe use of Lidocaine. The strict adherence to preoperative history and physicals (vascular etc) and justification for the type of surgical procedure. The identification of patients that are at risk, checking for drug interactions with Lidocaine based on medication history the calculation of maximum safe dose of Lignocaine (3mg/kg). The safety whilst injecting with patients' vitals being monitored, aspirating during the injection to avoid intravascular injection and systemic toxicity. To date these procedures have effectively mitigated the risk.

What post-market surveillance activities would be carried out?

Post-market surveillance (PMS) will be carried out systematically and proactively by the Podiatrists Board of New Zealand to collect and review experience gained from the use of Marcain in clinical practice. The purpose is to identify any need for corrective action. A PMS plan will be developed and gathering non-serious and serious clinical incidents including Adverse Drug Reactions (ADRs). The podiatric surgeon will be required to detail the use of Marcain that is the procedure, drug (Marcain +/- adrenaline), calculated maximum safe dose (mg), volume of drug administered (mL), type of block performed and any documented ADRs.

The podiatric surgeon is required to report suspected adverse reactions after authorisation/administration of a medicine. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions. New Zealand Pharmacovigilance Centre.

The podiatric surgeon will be required to submit an anaesthetic log book each year when lodging their Annual Practising Certificate, to the Podiatrists Board New Zealand. This is achievable as the information of the type of local anaesthesia used concentration, total dose (mg) and/or volume is recorded in the surgical report. The Podiatrists Board will also collect information regarding any feedback and complaints from patients that relate to the practitioners use of Marcain +/- adrenaline.

Is the proposed reclassification supported by professional bodies? Yes,

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References

Balakrishnan, K., Ebenezer, V., Dakir, A., Kumar, S., & Prakash, D. (2015). Bupivacaine versus lignocaine as the choice of local anesthetic agent for impacted third molar surgery a review. *Journal of pharmacy & bioallied sciences*, 7(Suppl 1), S230-3.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4439680/>

Medsafe Data sheet for Bupivacaine

<https://medsafe.govt.nz/Profs/Datasheet/m/MarcainAndadrenalineinj.pdf>

FDA access data sheet

https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/018692s015lbl.pdf

New Zealand Pharmacovigilance Centre. <https://nzphvc.otago.ac.nz/reporting>