New Zealand Data Sheet

1. PRODUCT NAME

Numit 5 % Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of Numit 5 % Cream contains 25 mg of lidocaine (lignocaine) and 25 mg of prilocaine.

Excipient(s) with known effect

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White soft cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Topical anaesthesia of the skin prior to insertion of i.v. catheters, blood sampling, vaccination; superficial surgical procedures, including split skin grafting.

Topical anaesthesia of leg ulcers to facilitate mechanical cleansing or debridement.

Topical anaesthesia of genital skin prior to superficial surgical procedures or infiltration anaesthesia.

Topical anaesthesia of the skin prior to minor superficial cosmetic procedures.

4.2. Dose and method of administration

In order to avoid cross-contamination, infection control procedures and principles should be strictly adhered to during application of Numit.

Dose

Pharmacokinetic data for application longer than 4 hours is not available in children. In adults, there is no benefit in application times longer than 5 hours, as the analgesic effectiveness of the cream dissipates over time.

Maximum Dose

Using too much Numit may cause unwanted side effects. Some of these can be serious, such as methaemoglobinaemia (a condition where the blood cannot take enough oxygen to your body) or cardiovascular effects (effects on your heart and lungs). Extra care should be taken where larger quantities of Numit are required such as for hair removal where adults must not use more than 60 g of Numit (two 30 g tubes) spread over an area not larger than 600 cm2 (the size of an A4 piece of paper).
Adults must not use more than 60 g (2 tubes).

Children

Refer to the dosage table for maximum children's doses.

Do not exceed the maximum recommended dose or length of administration. Children, particularly those aged below 3 months of age, are at an increased risk of serious adverse effects in overdose.

As an overall precaution if you or your child experience dizziness, difficulty breathing, numbness of the mouth, skin turning blue (a symptom of methaemoglobinaemia), blurred vision, shaky hands, or a rash where Numit has not been applied, or anything else making you or your child feel unwell, tell your doctor immediately, or go to your nearest hospital.

Surface/Age	Procedure	Application
Skin		A thick layer of cream to the skin, under an occlusive dressing. Following application for 1 – 2 hours, the minimum duration of anaesthesia is 2 hours after removal of the dressing.
Adults	Minor procedures: needle insertion, cosmetic procedures (on small areas) and surgical treatment of localised lesions.	Approx. 1.5 g/10 cm^2 Up to 2 g (approx. half a 5 g tube) for a minimum of 1 hour, maximum 5 hours (1)
	Procedures on larger areas of skin e.g. cosmetic procedures such as hair removal or other superficial surgical procedures (in an outpatient setting).	Maximum dose: 60g Maximum treatment area: 600 cm^2 for a minimum of 1 hour, maximum 5 hours (1,9)
	Dermal procedures on larger areas in a hospital setting (e.g. split-skin grafting).	Approx. 1.5-2 g/10 cm^2 for a minimum of 2 hours, maximum 5 hours (1)

Children		Approx. 1.0 g/10 cm^2 Application time: approx. 1 hour
Neonates and infants 0 up to 3 months [3]	Minor procedures, e.g. needle insertion and surgical treatment of localised lesions.	Up to 1.0 g and 10 cm^2 [2]
	Circumcision	1 g applied to the prepuce (for a maximum of 1 hour)
Infants 3 up to 12 months [3]	Minor procedures, e.g. needle insertion and surgical treatment of localised lesions.	Up to 2.0 g and 20 cm^2 [4]
Children 1 up to 6 years	Minor procedures, e.g. needle insertion and surgical treatment of localised lesions.	Up to 10.0 g and 100 cm^2 [8] for a minimum of 1 hour, maximum 4 hours
Children 6 up to 12 years	Minor procedures, e.g. needle insertion and surgical treatment of localised lesions.	Up to 20.0 g and 200 cm^2 [8] for a minimum of 1 hour, maximum 4 hours
Male genital skin Adults	Prior to injection of local anaesthetics.	Apply a thick layer of cream (1 g/10 cm^2) under an occlusive dressing for 15 minutes.
Female genital skin Adults	Prior to injection of local anaesthetics[7].	Apply a thick layer of cream (1-2 g/10 cm^2) under an occlusive dressing for 60 minutes.

Surface/Age	Procedure	Application
Leg ulcer		
Adults	Mechanical cleansing/ debridement of leg ulcer(s).	Apply a thick layer of the cream, approx. 1-2 g/10 cm^2 up to a total of 10 g to the leg ulcer(s)[5,6]. Cover with an occlusive dressing. Application time: at least 30 minutes. Up to 60 minutes may improve the anaesthesia further. Cleansing should start without delay after removal of the cream.

1) After a longer application time the anaesthesia decreases.
2) An application time longer than 1 hour has not been documented.
3) Until further clinical data is available, lidocaine/prilocaine cream should not be used in infants between 0-12 months of age receiving treatment with methaemoglobin-inducing agents.
4) No clinically significant increase in methaemoglobin levels has been observed after an application time of up to 4 hours on 16 cm^2.

5) Lidocaine/prilocaine cream has been used for the treatment of leg ulcers up to 15 times over a period of 1-2 months with no loss of efficacy or increase in local reactions.
6) The application of a larger dose than 10 g has not been studied with regard to plasma levels.
7) On female genital skin, lidocaine/prilocaine cream alone applied for 60 or 90 min does not provide sufficient anaesthesia for the thermocautery or diathermy of genital warts.
8) Doses significantly larger than 2 g are applicable to procedures on larger dermal areas.
9) Rates of absorption may be higher for shaved skin compared to unshaved skin due to possible removal of parts of the protective skin barrier during shaving.

Special populations

Elderly population

No dosage adjustments are required when lidocaine/prilocaine cream is applied to intact skin in the elderly.

Paediatric population

Use in premature infants with a gestational age of less than 37 weeks is not recommended (see section 4.4).

Method of Administration

The protective membrane of the tube is perforated by reversing the cap and piercing the membrane. When used on leg ulcers discard the tube with any remaining lidocaine/prilocaine cream after each occasion that a patient is treated.

A 1 g dose of lidocaine/prilocaine cream is achieved by squeezing the cream from the tube into a circular area with diameter of approximately 20 mm to a depth of approximately 4 mm. Keep the tube in close contact with the skin until the correct amount has been applied.

A 1 g dose of lidocaine/prilocaine cream can also be achieved by squeezing a length of lidocaine/prilocaine cream of approximately 3.5 cm from the tube.

4.3. Contraindications

- Hypersensitivity to prilocaine, lidocaine or any local anaesthetics of the amide type.
- Hypersensitivity to any of the excipients Numit (see section 6.1).
- Glucose-6-phospate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia.

4.4. Special warnings and precautions for use

Open wounds

Lidocaine/prilocaine cream should not be applied to open wounds other than leg ulcers, due to insufficient data on absorption from these sites.

Atopic dermatitis

Care should be taken when applying lidocaine/prilocaine cream to skin areas with atopic dermatitis. A shorter application time (15-30 minutes) may be sufficient.

Eyes

Lidocaine/prilocaine cream should not be applied to or near to the eyes since it causes corneal irritation. Damage to the eye may also occur from undetected foreign bodies. Special care should be employed to reduce the risk of rubbing the eyes with lidocaine/prilocaine cream. It is therefore important that the occlusive dressing should be secured against accidental dislocation, especially in young children.

Middle ear

Lidocaine/prilocaine cream is not recommended in any clinical situation in which its penetration into the middle ear is possible. In studied in rodents (guinea pigs) lidocaine/prilocaine cream was found to have an ototoxic effect when instilled directly into the middle ear, however no abnormalities were observed when lidocaine/prilocaine cream was applied to the animal's external auditory canal. Lidocaine/prilocaine cream caused minor structural damage to tympanic membrane in rats when applied directly to the membrane. The relevance of these findings to the clinical situation is unknown.

Genital mucosa

Lidocaine/prilocaine cream is presently not recommended for use on genital mucosa. Available data suggest that the anaesthetic efficacy of lidocaine/prilocaine cream on genital mucosa may be variable.

Paediatric use

Until further clinical data are available, lidocaine/prilocaine cream should not be used in infants between 0 and 12 months of age receiving treatment with methaemoglobin-inducing agents such as sulphonamides (see section 4.9) or in preterm infants with a gestational age less than 37 weeks. Studies have been unable to demonstrate the efficacy of lidocaine/prilocaine cream for heel lancing in neonates. Lidocaine/prilocaine cream should not be applied to the genital mucosa of children owing to insufficient data on absorption. However, when used in neonates for circumcision (genital skin), a dose of 1.0 g lidocaine/prilocaine cream on the prepuce has proven to be safe.

In children/neonates younger than 3 months of age, a transient increase in methaemoglobin is commonly observed up to 12 hours after an application of lidocaine/prilocaine cream. Caution is required in those at risk of tissue hypoxia, e.g. those with anaemia, respiratory and/or cardiac conditions. Prolonged exposure, e.g. greater than 60 minutes application, significantly increases the risk of methaemoglobinaemia. Repeated applications of lidocaine/prilocaine cream in neonates and infants have not been studied and should be avoided.

Vaccination

Lidocaine and prilocaine have bactericidal and antiviral properties in concentration above 0.52%. A clinical trial with MMR vaccine administered subcutaneously demonstrated that lidocaine/prilocaine cream does not adversely affect antibody response. There are no data on effects of lidocaine/prilocaine cream on other live viral vaccines administered subcutaneously. When lidocaine/prilocaine cream is used prior to intradermal BCG vaccination, the results of vaccination should be monitored.

Anti-arrhythmic drugs class III

Patient treated with anti-arrhythmic drugs class III (e.g. amiodarone) should be kept under close surveillance and ECG monitoring considered, since cardiac effects may be additive (refer to section 4.5).

Drugs reducing clearance of lidocaine

Drugs that reduce the clearance of lidocaine (e.g. cimetidine or betablockers) may cause potentially toxic plasma concentrations when lidocaine is given in repeated high does over a long time period. Such interactions should therefore be of no clinical importance following a short-term treatment with lidocaine at recommended doses (refer to section 4.5).

4.5. Interaction with other medicines and other forms of interaction

Methaemaglobinaemia-inducing agents

Lidocaine/prilocaine cream may accentuate the formation of methaemoglobin in patients treated with other drugs known to induce methaemaglobinaemia (e.g. sulphonamides).

Other local anaesthetic agents

With large doses of lidocaine/prilocaine cream, the risk of additional systemic toxicity should be considered in patients receiving other local anaesthetics or agents structurally related to local anaesthetics e.g. mexiletine.

Anti-arrhythmic drugs class III

Specific interaction studies with lidocaine and anti-arrhythmic drugs class III (e.g. amiodarone) have not been performed, but caution is advised (refer to section 4.4).

Drugs reducing clearance of lidocaine

Refer to section 4.4.

4.6. Fertility, pregnancy and lactation

Pregnancy

Category A.

Although the safety of lidocaine/prilocaine cream during pregnancy has not been established in animal reproductive toxicology studies, lidocaine and prilocaine have been used by large number of pregnant women and women of child-bearing age, without an increased incidence of malformations or other direct or indirect harmful effects on the foetus having been observed.

Breast-feeding

No information is available on the excretion of lidocaine, prilocaine or their metabolites into breast milk following the administration of lidocaine/prilocaine cream.

Following parenteral administration, lidocaine is excreted into breast milk. Because of low maternal systemic absorption following application of recommended doses of lidocaine/prilocaine cream, the amount of lidocaine and prilocaine that may be ingested by the breast-fed infant would be extremely small.

Fertility

Not applicable.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Frequency of adverse events

Intact skin	
Common events (≥1 % and < 10 %)	Skin: Transient local reactions at the application site such as, paleness, erythema (redness) and oedema.
Uncommon events (≥0.1 % and <1 %)	Skin: Skin sensations (an initial, usually mild burning sensation, itch or warmth at the application site).
Rare events (<0.1 %)	General: In rare cases, local anaesthetic preparations have been associated with allergic reactions (in the most severe instancesanaphylactic shock). Rare cases of discrete local lesions at the application site, described as purpuric or petechial, have been reported, especially after longer application times in children with atopic dermatitis or mollusca contagiosa. Increased methaemoglobin level. Methaemoglobinaemia and/or cyanosis. Corneal irritation after accidental eye exposure.

Leg ulcer	
Common events (≥1 % and <10 %)	Skin: Transient local reactions at the application site such as, paleness, erythema (redness), and oedema. Skin sensations (an initial, usually mild burning sensation, itch or warmth at the application site).
Uncommon events (≥0.1 % and <1 %)	Skin: skin irritation (at the application site).
Rare events (<0.1 %)	General: In rare cases, local anaesthetic preparations have been associated with allergic reactions (in the most severe instances anaphylactic shock).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected reactions https://pophealth.my.site.com/carmreportnz/s/

4.9. Overdose

Rare cases of methaemoglobinaemia have been reported.

Prilocaine in high doses may cause an increase in the methaemoglobin level particularly in conjunction with methaemoglobin-inducing agents (e.g. sulphonamdies). Clinically significant methaemoglobinaemia should be treated with a slow intravenous injection of methylene blue.

In the unlikely event of systemic toxicity following epidermal application of lidocaine/prilocaine cream, the signs and symptoms anticipated would be similar in nature to those observed following other routes of administration of local anaesthetics. Owing to slow absorption into the circulation from intact skin, a patient with signs of toxicity should be observed for several hours after treatment.

Systemic toxicity to amide type local anaesthetics is initially manifested as CNS excitation any may result in a slow onset of nervousness, dizziness, blurred vision and tremors followed by drowsiness, convulsions, unconsciousness and possibly respiratory arrest.

Toxic cardiovascular reactions to local anaesthetics are usually dependent in nature, may occur rapidly and with little warning and can lead to peripheral vasodilation, hypotension, myocardial depression, bradycardia, and possible cardia arrest. Severe neurological symptoms (convulsions, CNS depression) must be treated symptomatically by respiratory support and the administration of anticonvulsive drugs.

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

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: anaesthetics, local; amides ATC code: N01BB20

Numit is a 1:1 oil/water emulsion of a eutectic mixture of lidocaine and prilocaine. When lidocaine and prilocaine are mixed in equal amounts, the solid pure bases of lidocaine and prilocaine form an oil at temperatures above 16 °C (i.e. eutectic mixture). By avoiding the need for a non-aqueous solvent, higher concentrations of local anaesthetic in the cream can be achieved and maintained during application.

Lidocaine and prilocaine are both amide-type local anaesthetic agents. Both agents stabilise the neuronal membrane preventing the initiation and conduction of nerve impulses thereby effecting local anaesthetic action.

Numit provides dermal anaesthesia. The depth and quality of anaesthesia depends upon the application time and the applied dose.

Local anaesthesia with lidocaine/prilocaine cream is achieved after 60 minutes application. Lidocaine/prilocaine cream should be applied under an occlusive, impermeable dressing. Following the application of lidocaine/prilocaine cream for 1-2 hours, the duration of anaesthesia is at least 2 hours after removal of the occlusive dressing.

Reliable anaesthesia for the cleansing of leg ulcers is achieved after an application time of 30 minutes in most patients. An application time of 60 minutes may improve the anaesthesia. The cleansing procedure should start within 10 minutes of removal of the cream. There is no clinical data regarding cleaning started after 10 minutes of cream removal.

A reduced number of cleansing sessions are required to achieve a clean ulcer when lidocaine/prilocaine cream is used compared to a placebo.

No negative effects on ulcer healing or bacterial flora have been observed when lidocaine/prilocaine cream has been used.

Lidocaine/prilocaine cream may cause transient local peripheral vasoconstriction or vasodilation, observed as transient paleness or redness, at the treated area.

5.2. Pharmacokinetic properties

Systemic absorption and anaesthetic efficacy of lidocaine and prilocaine from the cream is dependent upon the characteristics of the leg ulcer, the applied dose, total application area,

application time, thickness of the skin (which varies between different area of the body), other conditions such as skin diseases, and shaving.

Intact skin

The extent of systemic absorption was approximately 10% following application to the face (10 g/100 cm^2 for 2 hours). Maximum plasma levels (mean 0.16 and 0.06 µg/mL of lidocaine and prilocaine respectively) were reached after approximately 2.5 hours.

After application to the thigh in adults (60 g cream/400 cm^2 for 3 hours) the extent of absorption was approximately 5 % of lidocaine and prilocaine. Maximum plasma concentrations (mean 0.12 and 0.07 µg/mL) were reached approximately 2-6 hours after the application.

In adults, a thick layer of lidocaine/prilocaine cream (corresponding to approximately 150 g), has been applied to intact skin area of up to 1,300 cm^2 for application times of up to 7 hours. The highest individual plasma levels observed to date were 1.1 µg/mL lidocaine and 0.2 µg/mL prilocaine. These levels were below those at which symptoms of toxicity would be expected to occur (5-10 µg/mL either agent) (see section 4.8).

Leg ulcers

Following a single application for 30 minutes of 5 to 10 g of lidocaine/prilocaine cream to leg ulcers, the maximum plasma levels of lidocaine (range 0.05- 0.25 µg/ml, one individual value of 0.84 µg/mL) and of prilocaine (0.02-0.08 µg/ml) were reached within 1-2.5 hours.

After an application time of 24 hours the maximum plasma levels of lidocaine (0.19-0.71 µg/mL) and of prilocaine (0.06-0.28 µg/mL) were usually reached within 2-4 hours.

Following repeated applications for 30-60 minutes of 2-10 g lidocaine/prilocaine cream 3-7 times a week, for up to 15 doses, during a period of one month, there was no apparent accumulation in plasma of lidocaine and its metabolites monoglycinexylidide and 2,6-xylidine or of prilocaine and its metabolites ortho-toluidine. The maximum observed plasma levels for lidocaine, monoglycinexylidide and 2,6-xylidine were 0.41, 0.03 and 0.01 µg/mL respectively. The maximum observed plasma levels for prilocaine and ortho-toluidine were 0.08 µg/mL and 0.01 µg/mL respectively.

Children

Following the application of 1.0 g of lidocaine/prilocaine cream in neonates below 3 months of age, to approximately 10 cm^2 for one hour, the maximum plasma concentrations of lidocaine and prilocaine were 0.135 µg/mL and 0.107 µg/mL respectively.

Following the application of 2.0 g of lidocaine/prilocaine cream in infants between 3 and 12 months of age, to approximately 16 cm^2 for four hours, the maximum plasma concentrations of lidocaine and prilocaine were 0.155 µg/mL and 0.131 µg/mL respectively.

Following the application of 10.0 g of lidocaine/prilocaine cream in children between 2 and 3 years of age, approximately 100 cm^2 for two hours, the maximum plasma concentrations of lidocaine and prilocaine were 0.315 µg/mL and 0.215 µg/mL respectively.

Following the application of 10.0-16.0 g of lidocaine/prilocaine cream in children between 6 and 8 years of age, to approximately 100-160 cm^2 for two hours, the maximum plasma concentrations of lidocaine and prilocaine were 0.299 µg/mL and 0.110 µg/mL respectively.

Clinical trials

In clinical trials, venepuncture or venous catheterisation was pain-free in 50-59 % patients, slightly painful in 35-40 % and painful in 3-6 %. Anaesthesia may be less for skin structures below the deep fascia.

In clinical trials in adults assessing pain associated with intramuscular influenza vaccination and intramuscular and subcutaneous injections of saline solution, lidocaine/prilocaine cream significantly reduced infection pain relative to placebo.

In clinical trials in infants and children assessing pain associated with subcutaneous and intramuscular vaccination, lidocaine/prilocaine cream significantly reduced injection pain behaviours and pain scores relative to placebo.

In clinical trials assessing the effects of lidocaine/ prilocaine cream on intramuscular and subcutaneous, live and non-live vaccines, it was demonstrated that lidocaine/prilocaine cream does not adversely affect antibody response. A clinical trial assessing the effect of lidocaine/prilocaine cream application prior to intracutaneous BCG injection demonstrated the lidocaine/prilocaine did not affect the immunisation response.

5.3. Preclinical safety data

Genotoxicity tests with lidocaine are inconclusive. In genotoxicity studies, a metabolite of lidocaine, 2,6-xylidine, showed evidence of activity on some tests but not in other tests. This metabolite has been shown to have carcinogenic potential (nasal and subcutaneous tumours) in preclinical toxicological studies evaluating chronic exposure. A metabolite of prilocaine, otoluidine, has also shown evidence of mutagenic activity in some genotoxicity tests but not others. O-toluidine has also shown evidence of mutagenic activity in some genotoxicity tests but not others. O-toluidine has also been shown to have carcinogenic potential (e.g. renal, bladder, spleen, subcutaneous tumours) in preclinical toxicological studies.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Numit cream contain the following excipients: water – purified, castor oil – ethoxylated hydrogenated, carbomer 934P, sodium hydroxide.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store at or below 30°C.

6.5. Nature and contents of container

5 g, 10 g, and 30 g laminated tubes and packed into a carton.
Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Pharmacy Only Medicine

8. SPONSOR

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9. DATE OF FIRST APPROVAL

09 December 2021

10. DATE OF REVISION OF THE TEXT

29 January 2026

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.8	Changed reporting link to ": https://pophealth.my.site.com/carmreportnz/s/ ".
8	Sponsor name updated to "Healthcare by Douglas Limited"