1.3.1.1 PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

EMLA 5 % cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of EMLA 5 % cream contains 25 mg of lidocaine (lignocaine) and 25 mg of prilocaine.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Creams

EMLA 5 % is a white, soft, homogenous cream.

EMLA 5 % cream is an oil-in-water emulsion system in which the oil phase consists of an eutectic mixture of the base forms of lidocaine (lignocaine) and prilocaine in the ratio 1:1.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

EMLA 5 % cream is indicated for:

- Topical anaesthesia of the skin in connection with needle insertion, e.g. IV catheters or prior to blood sampling, where application of EMLA 5 % cream 1 hour before the procedure is feasible.

- Topical anaesthesia of the genital mucosa prior to superficial surgical procedures lasting no longer than 10 minutes on small superficial localised lesions e.g. removal of condylomata by laser or cautery, and biopsies.

- Topical anaesthesia of leg ulcers to facilitate mechanical cleansing/debridement.

4.2. Posology and method of administration

Posology

Adults

Surface/ age	Procedure	Application
Skin (adults)	Minor procedures, e.g. needle insertion	A thick layer should be applied to the skin and covered with an occlusive dressing. A dose of approximately 1,5 g/10 cm^2 is recommended. The occlusive dressing may remain in place for up to 5 hours. After longer application time the anaesthesia will decrease. In order to provide reliable dermal anaesthesia, EMLA 5 % cream should be applied under an occlusive dressing for at least 1 hour. The duration of anaesthesia after an application time of 1 to 2 hours is at least 2 hours after removal of the dressing. Approximately half a tube (2 g) should be applied with a minimum application time of 1 hour.
	Newly shaven skin of large body areas (in an outpatient setting)	Maximum recommended dose: 60 g. Maximum recommended treated area: 600 cm^2 for a minimum of 1 hour and a maximum of 5 hours.
Adults and adolescents	Lesions, eg, removal of genital warts (condylomata acuminata) and prior to injection of local anaesthetics. Cervical curettage	No occlusive dressing is required. Commence procedure immediately thereafter. 10 g in the lateral vaginal fornices for 10 minutes.
Male genital skin (adults and adolescents)	Prior to injection of local anaesthetics	Apply a thick layer of EMLA 5 % cream (1 g/10 cm^2) under an occlusive dressing for 15 minutes.
Female genital skin (adults and adolescents)	Prior to injection of local anaesthetics[9]	Apply a thick layer of EMLA 5 % cream (1 to 2 g/10 cm^2) under an occlusive dressing for 60 minutes. On female genital skin, EMLA 5 % cream alone applied for 60 or 90 minutes does not provide sufficient anaesthesia for thermocautery or diathermy of genital warts.

Genital mucosa (adults and adolescents)	Surgical treatment of localised lesions e.g. removal of genital warts (condylomata acuminata)[7]	A dose of approximately 5 to 10 g is generally required. The entire treatment area, including mucosal folds, should be covered by the cream. The cream should be left in contact with the mucosa for 5 to 10 minutes. Occlusion is not necessary. The surgical treatment should commence immediately after removal of the cream. Analgesia duration is 15 to 20 minutes.
Leg ulcers (adults)	Facilitation of mechanical cleansing/ debridement[1]	A thick layer should be applied to the leg ulcer and covered with an occlusive dressing. A dose of approximately 1 to 2 g/10 cm^2 up to a total of 10 g is recommended. The occlusive dressing should remain in place for at least 30 minutes. Up to 60 minutes may improve the anaesthesia further. Cleansing should start immediately after removal of the cream. EMLA 5 % cream is intended for single use when used on leg ulcers. [10]

Paediatric population

Surface/age	Procedure	Application
Skin (children)	Minor procedures, e.g. needle insertion	Approximately 1,0 g/10 cm^2 should be applied with an application time of approximately 1 hour.
Infants 3 to11 months	Minor procedures, e.g. needle insertion	Up to 2,0 g of cream on an intact skin area not larger than 20 cm^2.
Children 1 to11 years	Minor procedures, e.g. needle insertion	Up to 10,0 g of cream on an intact skin area not larger than 100 cm^2 for a minimum of 1 hour, maximum 5 hours[2].
Children with atopic dermatitis	Prior to curettage of mollusc	Application time: 30 minutes.

[1] EMLA 5 % cream has been used for the treatment of leg ulcers up to 15 times over a period of 1 to 2 months with no loss of efficacy or increase in local reactions.

[2] After a longer application time the anaesthesia decreases.

[3] EMLA should not be used at less than 30 weeks gestational age, see section 4.4.

[4] Until further clinical data is available, EMLA should not be used in infants between 0 to 12 months of age receiving treatment with methaemoglobin-inducing medicines.

[5] A longer application time than 1 hour has not been documented.

[6] No clinically significant increase in methaemoglobin levels fraction has been observed

after an application time of up to 4 hours on 16 cm^2

(7) In adolescents weighing less than 20 kg the maximum dose of EMLA on genital mucosa should be proportionally reduced.

(8) The application of a larger dose than 10 g has not been studied with regard to plasma levels .

(9) On female genital skin, EMLA alone applied for 60 or 90 min does not provide sufficient anaesthesia for thermocautery or diathermy of genital warts.

(10) 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 further. The cleansing procedure should start within 10 minutes of removal of the cream. Clinical data from a longer waiting period are not available.

1 g of EMLA 5 % cream administered from the 30 g aluminium tube corresponds to a length of extruded cream of approximately 3,5 cm. If high levels of accuracy in dosing are required to prevent overdose (e.g., at doses approaching the maximum in newborn infants), a syringe can be used where 1 mL = 1 g.

Special populations

Elderly population

No dose reduction is necessary in elderly patients (see sections 5.1 and 5.2).

Renal impairment

A dose reduction is not necessary among patients with restricted renal function.

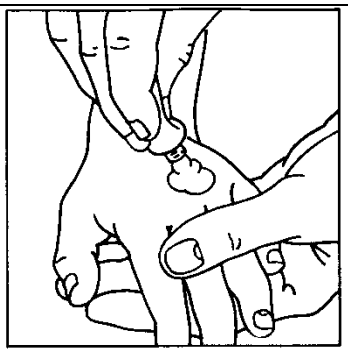
Hepatic impairment

A reduction of a single dose is not necessary in patients with impaired hepatic function.

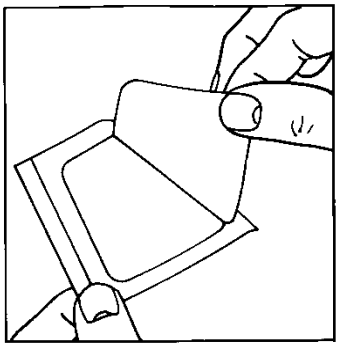
Paediatric population

EMLA should not be used at less than 30 weeks gestational age.

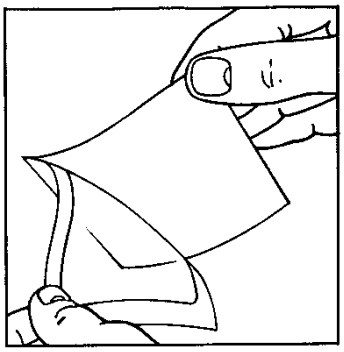
Method of administration



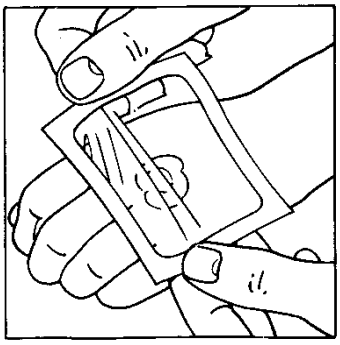
1. Press out a sufficient quantity of the cream covering at least one vein if used before blood draw. See dose recommendations in the leaflet or on the outer pack.



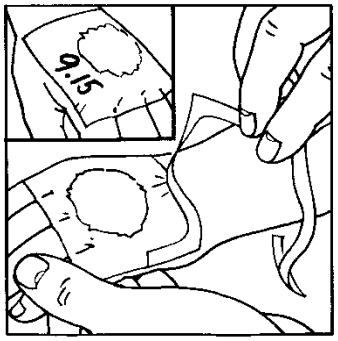
2. Take one of the enclosed occlusive dressings and remove the centre cut-out piece.



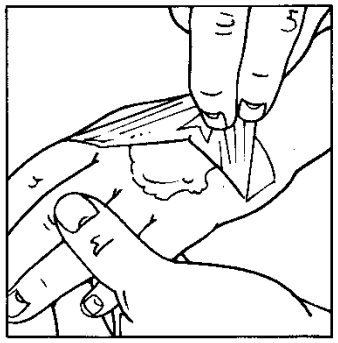
3. Peel the paper liner from the paper framed dressing.



4. Cover the EMLA 5 % cream so that you get a thick layer underneath. Do not spread out the cream. Smooth down the dressing edges carefully to avoid leakage.

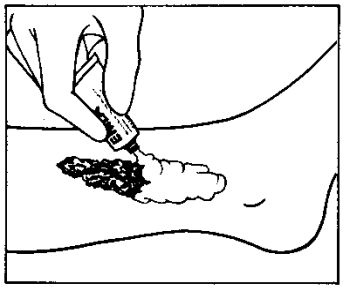


5. Remove the paper frame. The time of application can easily be marked directly on the occlusive dressing. EMLA 5 % cream must be applied at least 1 hour before the start of the procedure. See recommended application times.

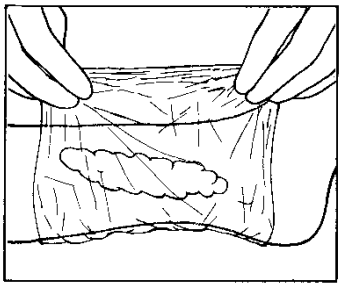


6. Remove the occlusive dressing, wipe off the cream. The skin may then be cleaned and prepared for the procedure.

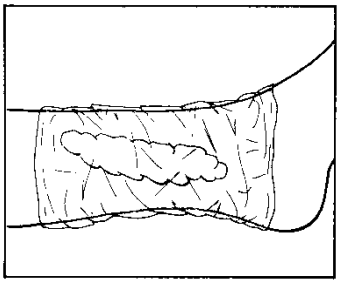
Leg Ulcer



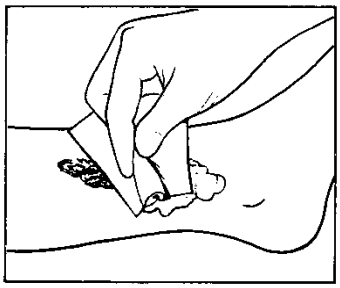
1. Cover the surface of the ulcer with a thick layer of cream, approximately 1 to 2 g per 10 cm^2. A maximum of 10 g per treatment is recommended. The tube is intended for single use on leg ulcers. Discard unused cream.



2. Cover the cream with an occlusive dressing (e.g. household plastic wrap).



3. Allow the cream to act for at least 30 minutes. For chronic ulcers which are very painful or resistant to absorption, the time can be extended up to 60 minutes.



4. Remove the occlusive dressing (plastic wrap), wipe off the cream and start debriding the wound within 10 minutes.

4.3. Contraindications

EMLA 5 % cream is contraindicated in:

- Patients with known hypersensitivity to local anaesthetics of the amide type or to any other component of the medicine.
- Infants between 0 and 12 months receiving treatment with methaemoglobin-inducing medicines e.g. dapsone, local anaesthetics such as prilocaine and benzocaine,

nitrites, nitrates, and sulphonamides.

- EMLA 5 % should not be used in any clinical situation where it can penetrate or migrate into the middle ear. Tests on laboratory animals (guinea pigs) have shown that EMLA 5 % has an ototoxic effect when instilled into the middle ear. there is insufficient data regarding the potential ototoxic effects in humans.
- EMLA 5% cream should not be used in preterm infants with a gestational age less than 30 weeks until further clinical data are available (see section 4.4).

4.4. Special warnings and precautions for use

EMLA 5 % cream contains macrogolglycerol hydroxystearate, which may cause skin reactions.

Patients with glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia are more susceptible to medicine-induced methaemoglobinaemia. In glucose-6-phosphate dehydrogenase deficient patients the antidote methylene blue is ineffective at methaemoglobin reduction, and is capable of oxidising haemoglobin itself, and therefore methylene blue therapy cannot be given.

Due to insufficient data on absorption and safety, EMLA 5 % cream should not be applied to open wounds other than leg ulcers, or to abraded skin in adults and children, or to the genital mucosa of children.

Studies have been unable to demonstrate the efficacy of EMLA 5 % cream for heel lancing in neonates.

Care should be taken when applying EMLA 5 % cream to skin areas of atopic dermatitis. A shorter application time of 15 to 30 minutes may be sufficient (see section 5.1). Application times of longer than 30 minutes in patients with atopic dermatitis may result in an increased

incidence of local vascular reactions, particularly application site redness and in some cases petechia and purpura (see section 4.8). Prior to curettage of mollusca in children with atopic dermatitis, 30 minutes application time is recommended.

Care should be taken not to allow EMLA 5 % cream to come in contact with the eyes as it causes eye irritation. Also the loss of protective reflexes may allow corneal irritation and potential abrasion. If eye contact occurs, immediately rinse the eye in water or saline solution and protect it until sensation returns.

Patients treated with anti-dysrhythmic medicines class III (e.g. amiodarone) should be under close surveillance and ECG monitoring considered, since cardiac effects may be additive.

Lidocaine (lignocaine) and prilocaine have bacteriocidal and antiviral properties in concentrations above 0,5 to 2 %. For this reason, the results of intracutaneous injections of live vaccines should be monitored.

Due to the potentially enhanced absorption on newly shaven skin, it is important to adhere to the recommended dosage, area and time of application (see section 4.2).

Paediatric population

Studies have been unable to demonstrate the efficacy of EMLA 5 % cream for heel lancing in newborn infants. In newborn infants/infants younger than 3 months a transient, clinically insignificant increase in methaemoglobin fractions is commonly observed up to 12 hours after an application of EMLA 5 % cream within the recommended dosing.

Safety and efficacy for the use of EMLA 5 % cream on genital skin and genital mucosa have not been established in children younger than 12 years.

Available paediatric data do not demonstrate adequate efficacy for circumcision.

4.5. Interaction with other medicines and other forms of interaction

- EMLA 5 % cream in high doses may cause an increase in the methaemoglobin level particularly in conjunction with methaemoglobin-inducing medicines (e.g. sulphonamides, nitrofurantoin, phenytoin, phenobarbital), (see section 4.3) and in children less than 3 months.
- EMLA 5 % should not be used in infants below 12 months of age receiving treatment with methaemoglobin inducing medicines.
- With large doses of EMLA 5 % cream, consideration should be given to the risk of additional systemic toxicity in patients receiving other local anaesthetics, or medicines structurally related to local anaesthetics, since the toxic effects are additive.
- Specific interaction studies with lidocaine (lignocaine)/prilocaine and anti-dysthymic medicines class III (e.g. amiodarone) have not been performed, but caution is advised (see also section 4.4).
- Medicines that reduce the clearance of lidocaine (lignocaine) (e.g. cimetidine or beta blockers) may cause potentially toxic plasma concentrations when lidocaine (lignocaine) is given in repeated high doses over a long time period.

4.6. Fertility, pregnancy and lactation

Pregnancy

The safety of EMLA 5 % cream in pregnancy and lactation has not been established. Lidocaine (lignocaine) and prilocaine cross the placental barrier and may be absorbed by the foetal tissues.

Although topical application is associated with only a low level of systemic absorption, the use of EMLA 5 % cream in pregnant women should be undertaken with care because insufficient data are available concerning the use of EMLA 5 % in pregnant women.

Animal studies do not indicate any direct or indirect negative effects on pregnancy, embryo-foetal development, parturition or postnatal development at clinically relevant doses. Reproduction toxicity has been shown with subcutaneous/intramuscular administration of high doses of lidocaine or prilocaine much exceeding the exposure from topical application.

Breastfeeding

Lidocaine (lignocaine) and prilocaine are also excreted in human breast milk, but in such small quantities that there is generally no risk of the child being affected at therapeutic dose levels. EMLA 5 % cream can be used during breastfeeding if clinically needed.

EMLA 5 % should not be applied directly to the breast where direct absorption by the infant may occur.

Fertility

Animal studies have shown no impairment of the fertility of male or female rats.

4.7. Effects on ability to drive and use machines

EMLA 5 % cream has no or negligible influence on the ability to drive and use machines when used at the recommended doses.

Patients should not drive, use machinery or perform any tasks that require concentration until they are certain that EMLA 5 % cream does not adversely affect their ability to do so safely (see section 4.4 and 4.8).

4.8. Undesirable effects

a) Summary of the safety profile

The most frequently observed adverse drug reactions (ADRs) are related to administration site conditions (transient local reactions at the application site), reported as common.

b) Tabulated list of adverse reactions

System organ class	Frequent	Less frequent
Blood and the lymphatic system disorders		Methaemoglobinaemia[1]
Immune system disorders		Allergic reactions (in the most severe instances anaphylactic shock).[1,2,3]
Eye disorders		Corneal irritation [1]
General disorders and administrative site conditions	Transient local reactions at the application site such as paleness, erythema (redness) and oedema[1,2,3.], local sensations (an initial, usually mild, burning sensation, itch or warmth at the application site)[1,2,3], skin sensations (an initial mild burning or itching sensation at the application site)[3].	Skin sensations (an initial mild burning or itching sensation at the application site)[1], local lesions at the application site, described as purpuric or petechial[1], local paraesthesia such as tingling[2]

[1] Skin

[2] Genital mucosa

[3] Leg ulcer

c) Description of selected adverse reactions

Immune system disorders

In rare cases, local anaesthetic preparations have been associated with allergic reactions (in the most severe instances anaphylactic shock).

General disorders and administrative site conditions

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 (see section 4.4).

Eye disorders

Corneal irritation after accidental eye exposure.

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 providers are asked to report any suspected adverse reactions to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9 Overdose

Symptoms

If the recommended dose is exceeded the patient should be monitored for system adverse reactions secondary to methaemoglobinaemia (see sections 4.2 and 4.8).

Cases of clinically significant methaemoglobinaemia have been reported. EMLA 5 % Cream in high doses may cause an increase in the methaemoglobin level particularly in susceptible individuals (see section 4.4), with too frequent dosing in newborn infants and infants below 12 months of age (see section 4.2) and in conjunction with methaemoglobin-inducing medicines (e.g. sulphonamides, nitrofurantoin, phenytoin and phenobarbital). Clinically significant methaemoglobinaemia should be treated with a slow intravenous injection of methylene blue (see section 4.4).

Should other symptoms of systemic toxicity occur, the signs are anticipated to be similar in nature to those following the administration of local anaesthetics by other routes of administration. Local anaesthetic toxicity is manifested by symptoms of nervous system excitation and, in severe cases, central nervous and cardiovascular depression.

Severe neurological symptoms (convulsions, CNS depression) must be treated symptomatically by respiratory support and the administration of anticonvulsive medicines.

Since the rate of absorption from intact skin is slow, a patient showing signs of toxicity should be kept under observation for several hours following emergency treatment.

Treatment

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and Class: A 4 Local anaesthetics

ATC Code: N01BB52, Anaesthetics, local, lidocaine combinations

Mechanism of action

EMLA 5 % cream provides dermal anaesthesia through the release of lidocaine (lignocaine) and prilocaine from the cream into the epidermal and dermal layers of the skin and the vicinity of dermal pain receptors and nerve endings. Lidocaine (lignocaine) and prilocaine are amide-type local anaesthetic medicines. They both stabilise neuronal membranes by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby producing local anaesthesia. The quality of anaesthesia depends upon the application time and the dose.

Skin

EMLA 5 % cream is applied to intact skin under an occlusive dressing. The time needed to achieve reliable anaesthesia of intact skin is 1 to 2 hours, depending on the type of procedure.

The duration of anaesthesia following the application of EMLA 5 % cream for 1 to 2 hours is at least 2 hours after removal of the dressing, except in the face where the duration is shorter. EMLA 5 % cream is equally effective and has the same anaesthetic onset time across the range of light to dark pigmented skin (skin types I to VI).

The depth of cutaneous anaesthesia increases with application time. In 90% of patients the anaesthesia is sufficient for the insertion of a biopsy punch (4 mm diameter) to a depth of 2 mm after 60 minutes and 3 mm after 120 minutes of lidocaine (lignocaine) and prilocaine treatment. Topical anaesthesia is recommended on intact, limited skin areas (needle insertions, skin. Lidocaine (lignocaine) and prilocaine has the same anaesthetic onset time across the range of light to dark pigmented skin (skin types I to VI).

Lidocaine (lignocaine) and prilocaine produces a biphasic vascular response involving initial vasoconstriction followed by vasodilatation at the application site (see section 4.8). The vascular response to lidocaine (lignocaine) and prilocaine does not influence the local anaesthetic action. In patients with atopic dermatitis, a similar but shorter vascular reaction is seen, with erythema occurring after 30 to 60 minutes, indicating more rapid absorption through the skin (see section 4.4).

Genital mucosa

Absorption from the genital mucosa is more rapid and onset time is shorter than after application to the skin.

Leg ulcers

EMLA 5 % cream reduces the postoperative pain for up to 4 hours after debridement. EMLA 5 % cream reduces the number of cleansing sessions required to achieve a clean ulcer compared to debridement with placebo cream. No negative effects on ulcer healing or bacterial flora have been observed.

5.2. Pharmacokinetic properties

Absorption

The systemic absorption of lidocaine (lignocaine) and prilocaine from EMLA 5 % cream is dependent upon the dose, area of application and application time. Other factors include

thickness of the skin, which varies in different areas of the body, and other conditions such as skin diseases, and shaving of the skin on the day of application. Following application to leg ulcers, the characteristics of the ulcers may also affect the absorption.

Intact skin.

Following 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 to 6 hours after application.

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) were reached after approximately 1,5 to 3 hours.

Plasma levels of lidocaine and prilocaine in both geriatric and non-geriatric patients following application of EMLA to intact skin are very low and well below potentially toxic levels.

Distribution

Plasma levels of lidocaine (lignocaine) and prilocaine in both geriatric and non-geriatric patients following application of lidocaine (lignocaine) and prilocaine to intact skin are very low and well below potentially toxic levels.

Absorption from the genital mucosa is more rapid and onset time is shorter than after application to the skin.

Paediatric population

The maximum plasma concentrations of lidocaine and prilocaine after application of EMLA in paediatric patients of different ages were also below potentially toxic levels.

Maximum plasma concentrations of lidocaine and prilocaine in paediatric age groups from 0 months to 8 years of age				
Age	Applied amount of cream	Application time of the cream on the skin	Plasma concentration ug/mL	
			Lidocaine	Prilocaine

Preterm newborn infants 30 to 36 weeks gestational age	0,5 g	1 hour	<0,0301)	<0,6401)
0 to 3 months	1 g/10 cm^2	1 hour	0,135	0,107
3 to 12 months	2 g/16 cm^2	4 hours	0,155	0,131
2 to 3 years	10 g/100 cm^2	2 hours	0,315	0,215
6 to 8 years	10 to 16 g/100 to160 cm^2 (1 g/ 10 cm^2)	2 hours	0,299	0,110

In preterm newborn infants exposed to 0,5 g EMLA cream for 1 hour, plasma concentrations of lidocaine and prilocaine were below the limit of determination (0,030 to 640 µg/mL), which varied according to the amount of blood retrieved from each newborn. Symptoms of local anaesthetic toxicity become increasingly apparent at increasing plasma concentration from 5 to 10 µg/mL of either active substance. It should be assumed that the toxicity of lidocaine and prilocaine are additive.

Leg ulcer:

Following a single application of 5 to10 g of lidocaine (lignocaine) and prilocaine cream to leg ulcers with an area of up to 64 cm^2 for 30 minutes, the maximum plasma levels of lidocaine (lignocaine) (range 0,05 to 0,25 µg/mL, one individual value of 0,84 µg/mL) and of prilocaine (0,02 to 0,08 µg/mL) were reached within 1 to 2,5 hours. After an application time of 24 hours to leg ulcers with an area of up to 50 to 100 cm^2, the maximum plasma levels of lidocaine (lignocaine) (0,19 to 0,71 µg/mL) and of prilocaine (0,06 to 0,28 µg/mL) were usually reached within 2 to 4 hours.

Following repeated application of 2 to 10 g of lidocaine (lignocaine) and prilocaine cream to leg ulcers with an area of up to 62 cm^2 for 30 to 60 minutes 3 to 7 times a week for up to 15 doses during a period of 1 month, there was no apparent accumulation in plasma of lidocaine (lignocaine) and its metabolites monoglycinexylidide and 2,6-xylidine or of prilocaine and its metabolite ortho-toluidine. The maximum observed plasma levels for lidocaine (lignocaine), 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.

Preclinical safety data

In animal studies the toxicity noted after high doses of either lidocaine or prilocaine, alone or in combination, consisted of effects on the central nervous and cardiovascular systems. When lidocaine and prilocaine were combined, only additive effects were seen, with no indication of synergism or unexpected toxicity. Both compounds were shown to have a low oral acute toxicity, providing a good safety margin in the event that EMLA 5 % is inadvertently swallowed. No drug-related adverse effects were seen in the reproduction toxicity studies, using either compound separately or together at clinically relevant doses.

In studies on reproduction toxicity, embryotoxic or foetotoxic effects of lidocaine were detected at doses of 25 mg/kg s.c. in the rabbit and foetal hydronephrosis for prilocaine starting at doses of 100 mg/kg i.m. in the rat. At doses below the maternal toxic range in the rat, lidocaine or prilocaine has no effect on the postnatal development of the offspring. An impairment of the fertility of male or female rats by lidocaine or prilocaine was not observed. Lidocaine crosses the placental barrier by means of simple diffusion. The ratio of the embryofoetal dose to the maternal serum concentration is 0,4 to 1,3 .

Neither local anaesthetic showed a mutagenic potential in either *in vitro* or *in vivo* mutagenicity tests. Cancer studies have not been performed with either lidocaine or prilocaine alone or in combination, due to the indication and duration of therapeutic use of these medicines.

A metabolite of lidocaine, 2,6-dimethylaniline, and a metabolite of prilocaine, o-toluidine, showed evidence of mutagenic activity. These metabolites have been shown to have carcinogenicity potential in preclinical toxicological studies evaluating chronic exposure. Risk

assessments comparing the calculated maximum human exposure from intermittent use of lidocaine and prilocaine, with the exposure used in preclinical studies, indicate a wide margin of safety for clinical use.

Local tolerance studies using a 1:1 *(w/w)* mixture of lidocaine and prilocaine as an emulsion, cream or gel indicated that these formulations are well tolerated by intact and damaged skin and mucosal membranes.

A marked irritative reaction was seen after single ocular administration of a 50 mg/g lidocaine + prilocaine 1:1 *(w/w)* emulsion, in an animal study. This is the same concentration of local anaesthetics and a similar formulation as for EMLA cream and patch. This ocular reaction may have been influenced by the high pH of the formulation of the emulsion (approximately 9), but is probably also partly a result of the irritative potential of the local anaesthetics themselves.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Carboxypolymethylene, macrogolglycerol hydroxystearate, purified water, sodium hydroxide (for pH adjustment)

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store at or below 25 °C.

Do not freeze.

6.5. Nature and contents of container

5 g cream in an aluminium tube, closed with a membrane and sealed with a polypropylene cap with a spike for perforation of the membrane. Pack size of 5 tubes in a unit cardboard carton together with 12 Tegaderm plasters.

30 g cream in an aluminium tube, closed with a membrane and sealed with a polypropylene cap with a spike for perforation of the membrane. Pack size of 1 tube in a unit cardboard carton.

Not all packs or pack sizes may be marketed.

6.6. Special precautions for disposal

The protective membrane of the tube is perforated by applying the cap. The EMLA tube is intended for single use when used on leg ulcers: discard the tube with any remaining contents after each occasion that a patient has been treated.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMCARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead, 2191

8. REGISTRATION NUMBER

Z/4/51

9. DATE OF FIRST AUTHORISATION

20 April 2012

10. DATE OF REVISION OF TEXT

03 August 2021

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

ZA_EMLACRM_2108_00