483820052

EMLA

lidocaine prilocaine
cream 5%

Qualitative and quantitative composition
Active constituents: 1 g of EMLA Cream contains lidocaine 25 mg, prilocaine 25 mg.

For excipients, see *List of excipients*.

Pharmaceutical form
EMLA Cream is an oil/water emulsion in which the oil phase consists of a eutectic mixture of lidocaine and prilocaine in the ratio 1:1.

Therapeutic indications
Topical anaesthesia of:
The skin in connection with
- needle insertion, e.g. IV catheters or blood sampling
- superficial surgical procedures

Posology and method of administration

Surface/Age	Procedure	Application
Skin		A thick layer of cream to the skin, under an occlusive dressing
Adults		Approx.1.5 g/10 cm^2
	Minor procedures, e.g. needle insertion and surgical treatment of localised lesions.	2 g (approx. half a 5 g tube) for a minimum of 1 hour.
	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
Children 3-12 months	Minor procedures, e.g. needle insertion and surgical treatment of localised lesions.	The total amount should not exceed 2 g and the skin area treated should not exceed 16 cm^2 Application time: at least 1 hour and more than 3 hours.
Children 1-5 years		Up to 10.0 g and 100 cm^2
Children 6-11 years		Up to 20.0 g and 200 cm^2

Contraindications
Known hypersensitivity to local anaesthetics of the amide type or to any of the excipient. Congenital or idiopathic methaemoglobinemia. EMLA must not be used in premature infants (born before week 37 of pregnancy).

Special warnings and special precautions for use
Patients with glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia are more susceptible to drug induced methaemoglobinaemia.

Due to insufficient data on absorption, EMLA should not be applied to open wound.

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

Care should be taken when applying EMLA to patients with atopic dermatitis. A shorter application time, 15 – 30 minutes, may be sufficient. Prior to curettage of mollusca in children with atopic dermatitis, an application time of 30 minutes is recommended.

EMLA should not be applied to the genital mucosa of children owing to insufficient data on absorption.

Care should be taken not to allow EMLA to come in contact with the eyes as it may cause 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 sodium chloride solution and protect until sensation returns.

EMLA should not be applied to an impaired tymphanic membrane or in other situations where penetration into the middle ear may occur.

In children/neonates younger than 3 months, clinically insignificant increase in methaemoglobin levels is commonly observed up to 12 hours after an application of EMLA.

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

Lidocaine and prilocaine have bacteriocidal and antiviral properties in concentrations above 0.5 – 2%. For this reason, the results of intracutaneous injections of live vaccines (e.g. BCG) should be monitored.

Until further clinical experience is available, EMLA should not be used in following cases:
a) in infants between 0 and 12 months of age receiving treatment with methaemoglobin – inducing agents.
b) in preterm infants with a gestational age less than 37 weeks.

Interactions with other medicinal products and other forms of interaction
Prilocaine in high doses may cause an increase in the methaemoglobin level particularly in conjuction with methaemoglobin – inducing agents (e.g. sulphonamides).

With large doses of EMLA, consideration should be given to the risk of additional systemic toxicity in patients receiving other local anaesthetics or agents structurally related to local anaesthetics, since the toxic effects are addictive.

Specific interaction studies with lidocaine/prilocaine and anti-arrhythmic drugs class III (e.g. amiodarone) have not been performed, but caution is advised (see *Special warnings and special precautions for use*)

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 doses over a long time period. Such interactions should therefore be of no clinical importance following short term treatment with lidocaine (e.g. EMLA Cream) at recommended doses.

Pregnancy and lactation
Pregnancy
Lidocaine and prilocaine cross the placental barrier and may be absorbed by the foetal tissues. It is reasonable to assume that lidocaine and prilocaine have been used in 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 directly or indirectly harmful effects on the foetal. However, caution should be exercised when used in pregnant women.

Lactation
Lidocaine and, in all probability, prilocaine are excreted in breast milk, but in such small quantities that there is generally no risk of the child being affected at therapeutic dose levels. Caution should be exercised when EMLA cream is administered to a nursing mother.

Effects on ability to drive and use machines
Not applicable at the recommended dosage.

PHARMA CODE N° 4337

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AW Version: 4	**Page:** 1 of 2
New Item Code: 483820052	
Previous Item Code: 483820052	
Market Indonesia	
Number of Colours: 1	
BLACK	
Manufacturing Site: Recipharm Karlskoga	
Drawing Reference: RKAL009A	
Drawing Version: 01	
Originated by: Sami Hajredin	
Originated at: ASPEN Dandenong	
Originated on: 16-FEB-2022	
Amended on: 07-JUN-2022	

150 mm Measuring Bar

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DISETUJUI OLEH BPOM : 28/02/2024

ID REG : EREG10002812300100

Undesirable effects

FREQUENCY OF ADVERSE EVENTS

Common events (>1%)	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 initially mild burning (or itching sensation at the application site)
Rare events (<0.1%)	General: Methaemoglobinaemia (see *Interactions with other medicinal products and other forms of interaction* and *Overdose*). 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. Corneal irritation after accidental eye exposure. In rare cases, local anaesthetic preparations have been associated with allergic reactions (in the most severe instances anaphylactic shock)

Overdose

Rare cases of clinically significant methaemoglobinaemia have been reported. Prilocaine in high doses may cause an increase the methaemoglobin level particularly in conjunction with methaemoglobin-inducing agents (e.g., sulphonamides). Clinically significant methaemoglobinaemia should be treated with a slow intravenous injection of methylene blue.
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. 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 drugs.

Pharmacological properties

Pharmacodynamic properties

Pharmacotherapeutic group : Local anaesthetics of the amide – type, ATC code: N01B B20

EMLA Cream 5 % provides dermal anaesthesia through the release of lidocaine and prilocaine from the cream into the epidermal and dermal layers of the skin and the accumulation of lidocaine and prilocaine in the vicinity of dermal pain receptors and nerve endings. Lidocaine and prilocaine are amide-type local anaesthetics agents. They both stabilize neuronal membranes by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby producing local anaesthesia.

The quality of anaesthesia depens upon the application time and the dose.

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

In clinical studies of EMLA on intact skin, no differences in safety or efficacy (including anaesthetic onset time) were observed between geriatric patients (aged 65-96 years) and younger patients.

The duration of anaesthesia following the application of EMLA Cream for 1 – 2 hours is at least 2 hours after removal of the dressing.

The depth of cutaneous anaesthesia increases with application time. In 90 % of patients the anaesthesia is sufficient for the insertion of biopsy punch (4 mm diameter) to a depth of 2 mm after 60 min and 3 mm after 120 min EMLA treatment. EMLA is equally effective and has the same anaesthetics onset time across the range of light to dark pigmented skin (skin types I to VI)

The use of EMLA prior to measles-mumps-rubella or intramuscular diphtheria-pertussis-tetanus-inactivated poliovirus-*Haemophilus influenzae b* or Hepatitis B vaccines does not affect mean antibody titres, rate of seroconversion, or the proportion of patients achieving protective or positive antibody titres post immunization, as compared to placebo treated patients.

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

Pharmacokinetic properties

The systemic absorption of lidocaine and prilocaine from EMLA is dependent upon the dose, area of application and application time. Additional factors include thickness of the skin (which varies in different areas body), other conditions such as skin diseases and shaving.

Intact skin

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

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

Preclinical safety data

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 drugs.

A metabolite of lidocaine, 2,6-dimethylaniline, and a metabolite of prilocaine, σ-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.

List of excipients

Carboxypolymethylene
Macrogol glycerol hydroxystearate
Sodium hydroxide to pH 8.7 – 9.7
Purified water

Incompatibilities

Not applicable.

Shelf life

Please refer to expiry date on the outer carton.

Special precautions for storage

Do not store above 30°C. Do not freeze.

Pack size

Box, 1 tube @ 5 gram (Reg. No.: DKI1909500229A1)

HARUS DENGAN RESEP DOKTER

Manufactured by:
Recipharm Karlskoga AB, Karlskoga,
Sweden for Aspen Global Incorporated

Imported by:
PT Mitsubishi Tanabe Pharma Indonesia
Bandung, Indonesia

Date of revision of the text
March 2022

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PHARMA CODE N° 4337

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