482280050

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EMLA cream 5%

lidocaine, prilocaine

Composition
Lidocaine 25 mg/g
Prilocaine 25 mg/g
Excipient with known effect:
EMLA Cream contains macrogol glycerol hydroxystearate which can cause skin reactions.

For excipients see chapter ***List of excipients***

Pharmaceutical form
Cream
Properties of the pharmaceutical form
EMLA 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 indication
Surface anaesthesia of the skin in connection with needle insertion and for superficial surgical procedures.
Surface anaesthesia of leg ulcers prior to cleaning and superficial surgical procedures, for example removal of fibrin, pus and necroses.
Surface anaesthesia of the genital mucosa.

Posology and method of administration
Adults
Intact skin:

	Dose and administration	Application time
for needle insertion e.g. insertion of intravenous lines, taking blood samples	½ tube (approx. 2 g) per 10 cm^2. A thick layer of cream is applied to the skin and covered with an occlusive dressing	1 hour; maximum 5 hours
for minor superficial surgical procedures, e.g. curettage of the lesions caused by mollusca contagiosa	1.5-2 g per 10 cm^2. A thick layer of cream is applied to the skin and covered with an occlusive dressing.	1 hour; maximum 5 hours
for more extensive superficial surgical procedures e.g. split skin grafting	1.5-2 g per 10 cm^2. A thick layer of cream is applied to the skin and covered with an occlusive dressing	2 hours; maximum 5 hours

Leg ulcers:
For cleaning of leg ulcers: approx. 1-2 g per 10 cm^2. The cream is applied in a thick layer to the surface of the ulcer, but not more than 10 g per treatment procedure. Cover the surface of the ulcer with an occlusive dressing. An opened tube is intended for a single use, and any remaining cream must therefore be discarded after each treatment procedure.
Application time: at least 30 minutes.
For leg ulcers with tissue that is particularly difficult to penetrate the application time may be extended to 60 minutes. Cleaning of the ulcer should begin within 10 minutes after the cream has been removed.
EMLA has been used for up to 15 treatment procedures over a period of 1-2 months without a decline in effect or an increase in the number of local reactions.
Genital use
Skin:
Use prior to injection of local anaesthetics:
Men: 1 g per 10 cm^2. A thick layer of cream is applied to the skin.
Application time: 15 minutes.
Women: 1-2 g per 10 cm^2. A thick layer of cream is applied to the skin.
Application time: 60 minutes.
Genital mucosa:
For removal of condyloma or prior to injection of local anaesthetics: approx. 5-10 g, depending on the area to be treated. The whole surface, including the mucosal folds, must be covered. Occlusion is not necessary.
Application time: 5-10 minutes. The surgery must be begun immediately after removal of the cream.
Children
For needle insertion, curettage of the lesions caused by mollusca contagiosa and other minor surgical procedures:
1 g per 10 cm^2.
A thick layer of cream is applied to the skin and covered with an occlusive dressing. The dose should not exceed 1 gram per 10 cm^2 and must be adjusted according to the application area:

Age	Application area	Application time
0-3 months	maximum 10 cm^2 (total of 1 g) *(maximum daily dose)*	1 hour *(note: not longer)*
3-12 months	maximum 20 cm^2 (total of 2 g)	1 hour
1-6 years	maximum 100 cm^2 (total of 10 g)	1 hour; maximum 5 hours
6-12 years	maximum 200 cm^2 (total of 20 g)	1 hour; maximum 5 hours

After a longer application time, the anaesthesia decreases.
Children with atopic dermatitis: reduce application time to 30 minutes.

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

Special warnings and precautions for use
Patients with glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia are more susceptible to drug induced methaemoglobinaemia.
Studies have been unable to demonstrate the efficacy of EMLA for heel lancing in neonates.

Caution when using near the eyes, as EMLA 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.

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.

Caution when using on areas on skin with atopic dermatitis; the application time should be reduced (15-30 minutes). 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 Undesirable effects).

Prior to removal of mollusca contagiosa in children with atopic dermatitis it is recommended to apply the cream for 30 minutes.

EMLA cream contains macrogol glycerol hydroxystearate which can cause skin reactions.

In children under 3 months, safety and efficacy have only been studied with application of a single dose. In these children, a transient increase in methaemoglobin levels is often seen for up to 13 hours after EMLA has been applied. However, the increases that have been observed are probably of no clinical significance.
EMLA should not be used on damaged tympanic membrane or in other situations where penetration into the middle ear may occur. EMLA should not be applied to open wounds.
EMLA should not be used on the genital mucosa in children on account of incomplete data of absorption.
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 for children aged 0-12 months during concomitant treatment with methaemoglobin-inducing drugs (see also chapter ***Overdose***).

Interaction
EMLA can potentiate the formation of methaemoglobin in patients who are being treated with certain methaemoglobin- inducing preparations (e.g. sulpha preparations).

With high doses of EMLA, the risk of additive systemic effects should be taken into account in patients who are given local anaesthetics or preparations that are structurally similar to local anaesthetics, e.g. tocainide.
Specific interaction studies with lidocaine/prilocaine and anti-arrhythmic drugs class III (e.g. amiodarone) have not been performed, but caution is advised (see also ***Special warnings and precautions for use***).

Medicinal products that reduce the clearance of lidocaine (e.g. cimetidine or beta-blockers) may cause potentially toxic plasma levels when lidocaine is given in repeated high doses for prolonged periods of time. Such interactions are not clinically significant in short-term treatment with lidocaine at recommended doses.

Pregnancy and lactation
Pregnancy: There is insufficient data concerning treatment of pregnant women with EMLA. Animal studies are incomplete with regards to

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Text area for artwork

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AW Version: 01	**Page:** 1 of 2
New Item Code: 482280050	
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effects on pregnancy, embryonal/foetal development, parturition and development after birth. Lidocaine and prilocaine cross the placental barrier and cab be absorbed in foetal tissue.
It is reasonable to assume that both lidocaine and prilocaine have been used by a large number of pregnant women and women of childbearing age. No particular disturbances in the reproductive process such as an increased frequency of malformations or other direct or indirect effects on the foetuses have been reported. However, caution should be exercised when treating pregnant women.
Lactation: Lidocaine and prilocaine pass into the breast milk, but the risk of an effect on the child appears unlikely with therapeutic doses.

Effects on ability to drive and use machines
Reaction capacity is not affected by treatment with EMLA.

Undesirable effects
Adverse events with local anaesthetics in the actual sense of the term occur in fewer than 1/1000 patients treated.

Common (>1/100)	Skin: transient local reactions at the application site, such as local paleness, redness, oedema. [1) 2) 3)] An initial and usually mild sensation of burning, itching or warmth at the application site. [2) 3)]
Less common (1/1000 to 1/100)	Skin: Initially a slight burning sensation, itching (at the application site) [1)] Local paresthesia on the application site, e.g. a tingling sensation.[2)] Skin irritation on the application site.[3)]
Rare (<1/1000)	General: Allergic reactions, in the most severe cases anaphylactic shock. [1) 2) 3)] Methaemoglobinaemia [1)] (See Interaction and Overdose). Skin reactions at the application site, such as purpura or petechiae, especially following longer application times in children with atopic dermatitis or mollusca_ contagiosa. [1)] In cases of accidental contact with the eye, corneal irritation may occur.[1)]

1) Intact skin
2) Genital mucosa
3) Leg Ulcers

Overdose
Systemic toxicity is very unlikely with normal use of EMLA. In the event of toxicity, the symptoms are expected to be similar to those seen after local anaesthesia treatment, i.e. excitatory CNS symptoms and in severe cases CNS depression and myocardial depression.
Rare cases of clinically significant methaemoglobinaemia have been reported (See Undesirable effects). Prilocaine in high doses can increase the methaemoglobin level.
Topical administration of 125 mg *prilocaine* for 5 hours caused moderate methaemoglobinaemia in a 3-months-old child. Topical administration of 8.6-17.2 mg/kg lidocaine caused very serious intoxication in infants.
Severe neurological symptoms (convulsions, CNS depression) require symptomatic treatment such as assisted ventilation and anticonvulsant therapy.
In the event of methaemoglobinaemia methylthionium is the antidote.
On account of a slow systemic absorption, a patient with symptoms of toxicity should be kept under observation for several hours following any treatment of these symptoms.

Pharmacodynamic properties
Pharmacotherapeutic group: Local anaesthetics of the amide type.
ATC code: N01B B20
EMLA cream contains *lidocaine* and *prilocaine*, which are local anaesthetics of the amide type. On penetration into the epidermis and dermis, these substances produce dermal anaesthesia.
The degree of anaesthesia depends on application time and dose.
Intact skin
With an application time of 1-2 hours the effect lasts for approximately two hours after the occlusive dressing has been removed.
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. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
The superficial vascular bed is affected by EMLA, and this can cause transient paleness or redness. These reactions appear to occur more rapidly in atopic dermatitis, after only 30-60 minutes, indicating more rapid absorption through the skin (see also ***Special warnings and precautions for use***).
A study in healthy volunteers with intact skin shows that in 90% the anaesthesia is sufficient for use of biopsy punch (4 mm in diameter) to an insertion depth of 2 mm, following 60 minutes application time and to a depth of 3 mm following 120 minutes application time. The effectiveness of EMLA is independent of the colour of the skin/ pigmentation of the skin (skin types I-IV).
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.
Genital mucosa
The time to onset of the necessary anaesthesia is shorter, as absorption is more rapid than with application to intact skin.
Following 5-10 minutes application of EMLA to the genital mucosa in women, the anaesthetic effect against argon laser induced pain lasted for 15-20 minutes (with an interindividual variation from 5-45 minutes).
Leg ulcers
No negative effect on ulcer healing or bacterial flora has been observed. When cleaning leg ulcers EMLA has analgesic effect for up to 4 hours after application.

Pharmacokinetic properties
The systemic absorption of EMLA depends on the amount of cream, the application time, the thickness of the skin (which varies on different surfaces of the body) and the condition of the skin in other respects such as skin diseases (e.g. absorption increases in atopic dermatitis, see Special warnings and precautions for use) and shaving. When used on leg ulcers, the characteristics of the leg ulcer can affect absorption, e.g. absorption increases with increased size of the leg ulcer.
Intact skin
After application of 60 g EMLA cream per 400 cm^2 (1.5 g per 10 cm^2) for three hours to intact skin (the thigh) in adults, systemic absorption was measured as 3 % for *lidocaine* and 5 % for *prilocaine*. Absorption takes place slowly. With the above mentioned dose, peak plasma concentrations for *lidocaine* (mean 0.12 µg/ml) and *prilocaine* (mean 0.07 µg/ml) were reached within approximately 4 hours after application. Only at levels of 5-10 µg/ml are there risks of toxic symptoms. In this case, shaving of the skin took place 8-12 hours before application of the cream.
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. However, there are no sufficient data to evaluate quantitative differences in systemic plasma levels of lidocaine and prilocaine between geriatric and non-geriatric patients following application of EMLA. Consideration should be given for those elderly patients who have enhanced sensitivity to systemic absorption.
Leg ulcers
After application to leg ulcers of 5-10g EMLA for 30 minutes peak plasma levels of *lidocaine* and *prilocaine* were reached after approximately 1-2.5 hours (for *lidocaine* within the range 0.05-0.84 µg/ml and for *prilocaine* 0.02-0.08 µg/ml).
Following repeated application of EMLA to leg ulcers there was no apparent accumulation in plasma of *lidocaine*, *prilocaine* or their metabolites.
2-10 g EMLA was applied for 30-60 minutes to a maximal surface of 62 cm^2, in total 15 times during a period of one month, 3-7 sessions a week.
Genital mucosa
After application of 10 g EMLA cream to vaginal mucosa for 10 minutes, peak plasma concentrations were measured after approximately 35 minutes (mean values: lidocaine 0.18 µg/ml, prilocaine 0.15 µg/ml).

List of excipients
Carbomer, macrogol glycerol hydroxystearate. Sodium hydroxide to pH 8.7-9.7, water.

Incompatibilities
Not relevant

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
Please refer to outer carton for pack size

Instructions for use and handling
Information for the user and instructions for use are contained in every pack.
Use the tube cap in order to perforate the membrane covering the tip of the tube.

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Name and address of manufacturer
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