1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

EMLA 5 % Cream

Lidocaine, Prilocaine

Read all of this leaflet carefully because it contains important information for you

EMLA 5 % cream is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use EMLA 5 % cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share EMLA 5 % cream with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after several days.

What is in this leaflet

1. What EMLA 5 % cream is and what it is used for
2. What you need to know before you use EMLA 5 % cream
3. How to use EMLA 5 % cream
4. Possible side effects
5. How to store EMLA 5 % cream
6. Contents of the pack and other information

1. What EMLA 5 % cream is and what it is used for

EMLA 5 % cream is a local anaesthetic which is used on the skin, the genital mucosa and leg ulcers. It is used to cause temporary numbness or loss of sensation at the area where it is applied.

EMLA 5 % cream is available in tubes of 5 g and 30 g.

- EMLA 5 % cream is used for pain relief on the skin prior to procedures such as needle insertion and minor skin surgery.
- EMLA 5 % cream may also be used on the genital mucosa prior to superficial surgical procedures or before injections of other local anaesthetics.
- EMLA 5 % cream is also used for pain relief on leg ulcers to facilitate cleansing.

2. What you need to know before you use EMLA 5 % cream

Do not use EMLA 5 % cream

- if you are hypersensitive (allergic) to lidocaine or prilocaine or any of the other ingredients of EMLA 5 % cream.
- EMLA 5 % cream should not be used in infants between the age of 0 to 12 months with other medicines that affect methaemoglobin levels in the blood. Ask your doctor, pharmacist or other health care professional.
- EMLA 5 % cream should not be applied to a damaged eardrum.
- on areas with skin rash, cuts, grazes or other open wounds, with the exception of a leg ulcer.
- EMLA 5% cream should not be used in preterm infants with a gestational age less than 30 weeks.

Warnings and precautions

Take special care with EMLA 5 % cream:

- if you have had an allergic, unpleasant or unusual reaction to EMLA 5 % cream or the other ingredients in EMLA 5% cream or to any other medicine.
- avoid getting EMLA 5 % cream in the eyes, as it may cause irritation. If you accidentally get EMLA 5 % cream in your eye, you should immediately rinse it well with lukewarm water or saline solution and protect it until sensation returns (see section 4).

- when you use EMLA 5 % cream before live vaccines (e.g. tuberculosis vaccines) are injected superficially into the skin (intracutaneously), you should return to your doctor or nurse after the time period requested to follow-up the vaccination result.
- if you have one of the rare metabolic conditions, glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia, as this increases the risk of drug-induced methaemoglobinaemia (see section 4)

Methaemoglobinaemia is a condition where an excess of haemoglobin has changed into methaemoglobin. A small amount of haemoglobin is normally present in the blood in a modified form called methaemoglobin. If too much methaemoglobin is formed, it becomes more difficult for the blood to provide the body with oxygen.

Children and adolescents

In children/neonates younger than 3 months, a temporary increase in methaemoglobin levels is commonly observed up to 12 hours after an application of EMLA cream, this is where it becomes more difficult for the blood to provide the body with oxygen.

Other medicines and EMLA 5 % cream

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following:

Do not use EMLA 5 % cream in infants less than 3 months of age, if they are using medicines that contain sulphonamides (antibiotics) as this may cause an increase in methaemoglobin levels.

Pregnancy, breastfeeding and fertility

- You should not use EMLA 5 % cream if you are pregnant or breastfeeding your baby.

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

Driving and using machines

EMLA 5 % cream has no effect on the ability to drive and use machines.

3. How to use EMLA 5 % cream

Do not share medicines prescribed for you with any other person.

Always use EMLA 5 % cream exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are unsure. The protective membrane of the tube is perforated by applying the cap.

Use of EMLA 5 % cream on the skin:

Apply a thick layer of cream to the skin. Cover with an airtight dressing such as Tegaderm or plastic wrap.

Half a 5 g tube corresponds to about 2 g EMLA 5 % cream

1 g of EMLA 5 % cream administered from the 30 g aluminium tube corresponds to a length of extruded cream of about 3,5 cm.

Adults:

Skin procedures on small areas of the skin, e.g. needle insertion and surgical treatment of localised lesions: approximately 2 g for a minimum of 1 hour, maximum 5 hours.

Newly shaven skin of larger body areas (maximum recommended treated area, 600 cm^2 – this is an area of 30 x 20 cm, approximately the size of an A4 sheet of paper): Approximately 1 g/10 cm2 for a minimum of 1 hour, maximum 5 hours. The maximum recommended dose is 60 g.

Children:

Skin procedures on small areas, e.g. needle insertion and surgical treatment of localised lesions.

Application time: approximately 1 hour.

Infants aged 3 to 11 months:

Up to 2 g of cream on a total skin area not larger than 20 cm^2.

Children aged 1 to 11 years:

Up to 10 g of cream on a total skin area not larger than 100 cm^2.

Application time: approximately 1 hour, maximum 5 hours.

Special skin problems:

If you have skin problems such as atopic dermatitis (skin rash) or mollusca (a type of scaly eczema), a shorter application time, 15 to 30 minutes, may be sufficient. When mollusca are removed from the skin in children with atopic dermatitis, a 30 minutes application time of EMLA 5 % cream is recommended.

Use of EMLA 5 % cream on genital mucous membrane or genital skin:

Adults:

Genital mucous membrane: Surgical treatment of localised lesions, e.g., removal of genital warts (condylomata acuminata): EMLA cream will be applied by your doctor or nurse 5 to 10 minutes prior to the procedure.

Normal dosage: 5 to 10 g EMLA 5 % cream for 5 to 10 minutes.

No occlusive dressing is required. The procedures should be commenced immediately thereafter.

Male genital skin: Prior to injection of local anaesthetics: Use according to your doctor's instructions. Normal dosage: 1 g/10 cm^2 for 15 minutes.

Female genital skin: Prior to injection of local anaesthetics: Use according to your doctor's instructions. Normal dosage: 1 to 2 g/10 cm^2 for 60 minutes.

Children:

EMLA 5 % cream should not be applied to the genital mucous membrane in children.

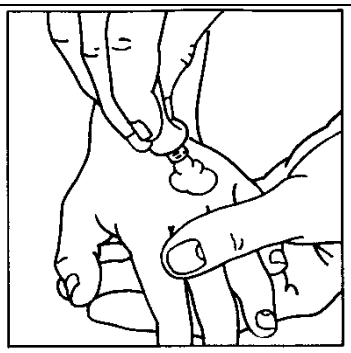
Use of EMLA 5 % cream on leg ulcer(s): The cream must be applied to the leg ulcer(s) and covered with an airtight dressing such as plastic wrap. The application time should be at least 30 minutes.

An application time of 60 minutes may improve the anaesthesia further. Remove the cream with cotton gauze. Cleansing should start without delay after removal of the cream.

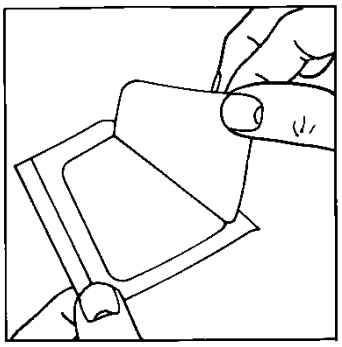
Adults:

A thick layer of EMLA 5 % cream, approximately 1 to 2 g/10 cm^2 up to a total of 10 g is applied to the leg ulcer(s). EMLA 5 % cream can be used prior to the cleansing of leg ulcers for up to 15 times over a period of 1 to 2 months.

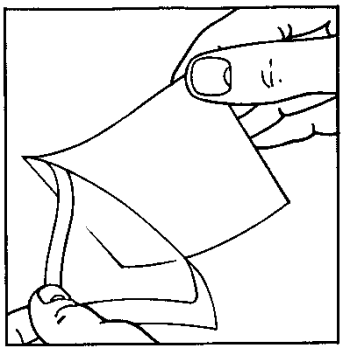
Instructions for use



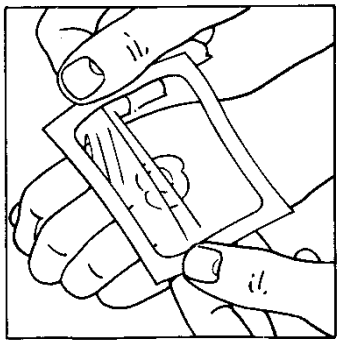
1. Press out a sufficient quantity of the cream covering at least one vein if used before blood draw. See dose recommendations in the leaflet or on the outer pack.



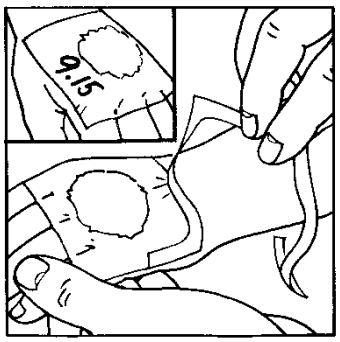
2. Take one of the enclosed occlusive dressings and remove the centre cut-out piece.



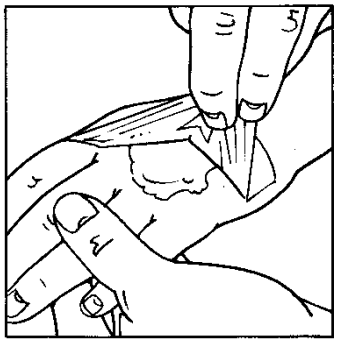
3. Peel the paper liner from the paper framed dressing.



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.



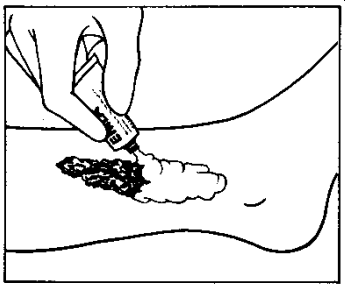
5. Remove the paper frame. The time of application can easily be marked directly on the occlusive dressing. EMLA 5 % must be applied at least 1 hour before the start of the procedure. See recommended application times.



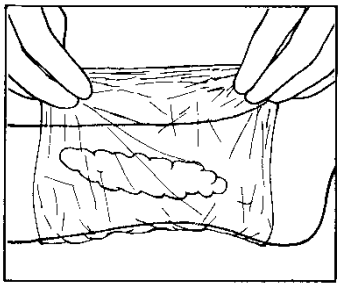
6. Remove the occlusive dressing, wipe off the cream. The skin may then be cleaned and prepared for the procedure.

EMLA 5 % cream

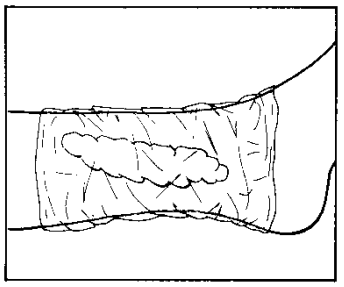
Instructions for use – Leg Ulcer



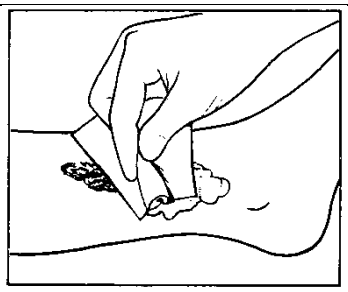
1. Cover the surface of the ulcer with a thick layer of cream, approximately 1 to 2 g per 10 cm^2. A maximum of 10 g per treatment is recommended. The tube is intended for single use on leg ulcers. Discard unused cream.



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.

If you use more EMLA 5 % cream than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Always contact a doctor, pharmacist, other health care professional emergency centre or hospital if too much EMLA 5 % cream has been used, even if you do not feel any symptoms.

With the recommended dose of EMLA 5 % cream, no toxic effects have been reported.

When too much EMLA 5 % cream has been used, and when certain medicines have been taken at the same time, there is a risk of acute methaemoglobinaemia.

Methaemoglobinaemia is characterised by a slate-grey cyanosis (a bluish-grey discoloration of the skin).

If you forget to use EMLA 5 % CREAM

Do not use a double dose to make up for forgotten individual doses

4. Possible side effects

EMLA 5 % cream can have side effects.

Not all side effects reported for EMLA 5 % cream are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using EMLA 5 % cream, please consult your healthcare provider for advice.

If any of the following happens, stop using EMLA 5 % cream and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EMLA 5 % cream. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- methaemoglobinaemia (bluish-grey discoloration of the skin).

This is a serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following

Frequent side effects:

- a mild reaction (paleness or redness of the skin, slight puffiness, initial burning or itching) may occur on the area on which EMLA 5 % cream is used. These are normal reactions to the cream and the anaesthetics and will disappear in a short while without any measures being needed

Less frequent side effects:

- an initial mild burning, itching sensation, tingling or skin irritation at the application site.
- eye irritation when EMLA 5 % cream accidentally has been exposed to the eyes.
- rare cases of small red dots (petechiae) at the application site have been reported especially after longer application times in children with skin problems (atopic dermatitis or mollusca) (see section 3).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

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

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of EMLA 5 % cream.

5. How to store EMLA 5 % cream

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not freeze.

- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EMLA 5 % cream contains

The active substances are 25 mg of lidocaine and 25 mg of prilocaine.

The other ingredients are carboxypolymethylene, macrogolglycerol hydroxystearate, purified water and sodium hydroxide (for pH adjustment).

What EMLA 5 % cream looks like and contents of the pack

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

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.

Holder of Certificate of Registration

Pharmacare Limited

Healthcare Park

Woodlands Drive

Woodmead, 2191

Hotline: 0800 122 912

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03 August 2021

Registration number

Z/4/51

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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