

6. Contents of the pack and other information

What Emla Cream contains

- The active substances are lidocaine and prilocaine. Each gram of cream contains 25 mg of lidocaine and 25 mg of prilocaine.
- The other ingredients are macrogolglycerol hydroxystearate, Carbomer 974P, sodium hydroxide and purified water.

What Emla Cream like and contents of the pack

Emla Cream is a white soft cream available in aluminum tube with a plastic screw cap, without any dressing.

It is available in pack size of 30 g.

Product License holder

Procured from within the EU and repackaged for the PL Holder: Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom.

Manufacturer

Aspen Bad Oldesloe GmbH, 32-36 Industriestrasse, 23843 Bad Oldesloe, Germany.

PL: 45763/1554

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Package leaflet: Information for the patient

Emla® 5% Cream

(lidocaine/prilocaine)

Your medicine is known as Emla® 5% Cream but will be referred to as Emla Cream throughout the following patient information leaflet.

Read all of this leaflet carefully before you or your child start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor, pharmacist or nurse if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Emla Cream is and what it is used for

Emla Cream contains two active substances called lidocaine and prilocaine. These belong to a group of medicines called local anaesthetics.

Emla Cream works by numbing the surface of the skin for a short time. It is put on the skin before certain medical procedures. This helps to stop pain on the skin, however you may still have the feelings of pressure and touch.

Adults, Adolescents and Children

It can be used to numb the skin before:

- Having a needle put in (for example, if you are having an injection or a blood test).
- Minor skin operations.

Adults and Adolescents

It can also be used:

- To numb the genitals before:
 - Having an injection.
 - Medical procedures such as removal of warts.

A doctor or nurse should apply Emla Cream on the genitals.

Adults

It can also be used to numb the skin before:

- Cleansing or removal of damaged skin of leg ulcers.

For other purposes than application to intact skin, the product should be used only upon recommendation of a doctor, nurse or pharmacist.

2. What you need to know before you use Emla Cream

Do not use Emla Cream:

- if you are allergic to lidocaine or prilocaine, other similar local anaesthetics or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Emla Cream:

- if you or your child have a rare inherited illness that affects the blood called 'glucose-6-phosphate dehydrogenase deficiency'.
- if you or your child have a problem with blood pigment levels called "methaemoglobinaemia".
- Do not use Emla Cream on areas with skin rash, cuts, grazes or other open wounds, with the exception of a leg ulcer. If any of these problems are present, check with your doctor, pharmacist or nurse before using the Cream.

- if you or your child have an itchy skin condition called 'atopic dermatitis', a shorter application time may be sufficient. Application times of longer than 30 minutes may result in an increased incidence of local skin reaction (see also section 4 "Possible side effects").
- if you take particular products for heart rhythm disorders (class III antiarrhythmics, such as amiodarone). In that case the doctor will monitor your heart function.

Due to the potentially enhanced absorption on the newly shaven skin, it is important to follow the recommended dosage, skin area and application time.

Avoid getting Emla Cream in the eyes, as it may cause irritation. If you accidentally get Emla Cream in your eye, you should immediately rinse it well with lukewarm water or salt (sodium chloride) solution. Be careful to avoid getting anything in your eye until feeling returns.

Emla Cream should not be applied to an impaired eardrum.

When you use Emla Cream before being vaccinated with live vaccines (e.g. tuberculosis vaccine), you should return to your doctor or nurse after the time period requested to follow-up the vaccination result.

Children and adolescents

In infants/newborn infants younger than 3 months a transient, clinically not relevant increase in blood pigment levels "methaemoglobinaemia" is commonly observed up to 12 hours after Emla Cream is put on.

The effectiveness of Emla Cream when drawing blood from the heel of newborn infants or to provide adequate analgesia for circumcision could not be confirmed in clinical studies.

Emla Cream should not be applied to the genital skin (e.g. penis) and genital mucosa (e.g. in the vagina) of children (below 12 years of age) owing to insufficient data on absorption of active substances.

Emla Cream should not be used in children younger than 12 months of age who are being treated at the same time with other medicines that affect blood pigment levels "methaemoglobinaemia". (e.g. sulphonamides, see also Section 2 Other medicines and Emla Cream).

Emla Cream should not be used in preterm newborn infants.

Other medicines and Emla Cream

Tell your doctor, pharmacist or nurse if you are using/ taking, have recently used / taken or might use /take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Emla Cream can affect the way some medicines work and some medicines can have an effect on Emla Cream.

In particular, tell your doctor, pharmacist or nurse if you or your child have recently used or been given any of the following medicines:

- Medicines used to treat infections, called 'sulphonamides' and nitrofurantoin.
- Medicines used to treat epilepsy, called phenytoin and phenobarbital.
- Other local anaesthetics.
- Medicines to treat an uneven heartbeat, such as amiodarone.
- Cimetidine or beta-blockers, which may cause an increase in the blood levels of lidocaine. This interaction is of no clinical relevance in short-term treatment with Emla Cream in recommended doses.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Occasional use of Emla Cream during pregnancy is unlikely to have any adverse effects on the foetus.

The active substances in Emla Cream (lidocaine and prilocaine) are passed into breast milk. However, the amount is so small that there is generally no risk to the child.

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

Driving and using machines

Emla Cream has no or negligible influence on the ability to drive and use machines when used at the recommended doses.

Emla Cream contains macrogolglycerol hydroxystearate
Macrogolglycerol hydroxystearate may cause skin reactions.

3. How to use Emla Cream

Always use Emla 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 not sure.

This product is available in different pack sizes. You will have been provided with a suitable pack size for your intended use.

Using Emla Cream

- Where to put the Cream, how much to use and how long to leave it on will depend on what it is used for. Half a 5 g tube corresponds to about 2 g Emla Cream. One gram of Emla Cream pressed out of a tube of 30g is approximately 3.5 cm.
- Emla Cream should be used on the genitals only by a doctor or nurse.
- When Emla Cream is used on leg ulcers, a doctor or nurse should supervise its use.

Do not use Emla Cream on the following areas:

- Cuts, grazes or wounds, excluding leg ulcers.
- Where there is a skin rash or eczema.
- In or near the eyes.
- Inside the nose, ear or mouth.
- In the back passage (anus).
- On the genitals of children.

Persons frequently applying or removing Cream should ensure that contact is avoided in order to prevent the development of hypersensitivity.

The protective membrane of the tube is perforated by applying the cap.

Use on the skin before small procedures (such as having a needle put in or minor skin operations):

- The cream is put on to the skin in a thick layer. Follow the instructions on the leaflet or those from your health care professional. In certain cases your healthcare professional has to apply the cream.
- The cream is then covered by a dressing [plastic wrap]. This is taken off just before the procedure starts. If you are applying the cream yourself, make sure that you have been given dressings by your doctor, pharmacist or nurse.
- The usual dose for adults and adolescents over 12 years is 2 g (grams).
- For adults and adolescents over 12 years put the cream on at least 60 minutes before the procedure (unless the cream is being used on the genitals). However, do not put it on more than 5 hours before.

Children

Use on the skin before small procedures (such as having a needle put in or minor skin operations) Application time: approx. **1 hour**.

Newborn infants and infants 0-2 months: Up to 1 g of cream on a skin area not larger than 10 cm² (10 square centimetres) in size. Application time: **1 hour, not more. Only one single dose should be given in any 24 hour period.**

Infants aged 3-11 months: Up to 2 g of cream on a total skin area not larger than 20 cm² (20 square centimetres) in size. Application time: approx **1 hour**.

Children aged 1-5 years: Up to 10 g of cream on a total skin area not larger than 100 cm² (100 square centimetres) in size. Application time: approx **1 hour**, maximum 5 hours.

Children aged 6-11 years: Up to 20 g of cream on a total skin area not larger than 200 cm² (200 square centimetres) in size. Application time: approx **1 hour**, maximum 5 hours.

A maximum of 2 doses at least 12 hours apart may be given to children over 3 months of age in any 24 hour period.

Emla Cream can be used on children with a skin condition called “atopic dermatitis” but the application time is then 30 minutes, no longer.

When you apply the cream, it is very important to exactly follow the instructions below:

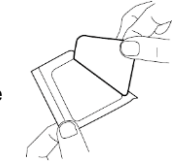
- Squeeze the cream into a mound where it is needed on your skin (for example where the needle is going to be put in). Half a 5 g tube corresponds to about 2 g Emla Cream. One gram of Emla Cream pressed out of a tube of 30g is approximately 3.5 cm. Do not rub the cream in.



- Peel the paper layer from the ‘centre cut-out’ of the non-adhesive side of the dressing (leaving a frame of paper).



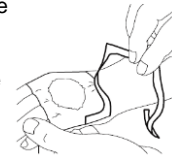
- Remove the cover of the adhesive side of the dressing.



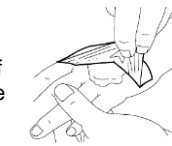
- Place the dressing carefully over the mound of cream. Do not spread the cream under the dressing.



- Remove the paper backing. Smooth down the edges of the dressing carefully. Then leave it in place for at least 60 minutes if the skin has not been damaged. The cream should not be left in place for more than 60 minutes in children under 3 months or for more than 30 minutes in children with an itchy skin condition called ‘atopic dermatitis’. If the cream is used on the genitals or on ulcers, shorter applications times may be used as described below.



- Your doctor or nurse will take the dressing off and remove the cream just before they do the medical procedure (for example just before the needle is put in).



Use on larger areas of newly shaven skin before outpatient procedures (such as hair removal techniques):

Follow the instructions from your healthcare professional.

The usual dose is 1 g of cream for each area of skin that is 10 cm² (10 square centimetres) in size, applied for 1 to 5 hours under a dressing. Emla Cream should not be used on an area of newly shaven skin larger than 600 cm² (600 square centimetres, e.g. 30 cm by 20 cm) in size. The maximum dose is 60 g.

Use on the skin before hospital procedures (such as split-skin grafting) that require deeper skin anaesthesia:

- Emla Cream can be used in this way on adults and adolescents over 12 years, but only under the supervision of a doctor or nurse.
- The usual dose is 1.5 g to 2 g of cream for each area of skin that is 10 cm² (10 square centimetres) in size.
- The cream is put on under a dressing for 2 to 5 hours.

Use on the skin prior to removal of wart-like spots called “mollusca”

- Emla Cream can be used on children and adolescents with a skin condition called “atopic dermatitis”.
- The usual dose depends on the child’s age and is used for 30 to 60 minutes (30 minutes if the patient has atopic dermatitis). Your doctor, nurse or pharmacist will tell you how much Cream to use.

Use on genital skin before injections of local anaesthetics

- Emla Cream can be used in this way only by healthcare professionals on adults and adolescents over 12 years.
- The usual dose is 1 g of Cream (1 g to 2 g for female genital skin) for each area of skin that is 10 cm² (10 square centimetres) in size.
- The cream is put on under a dressing. This is done for 15 minutes on male genital skin and for 60 minutes on female genital skin.

Use on the genitals before minor skin surgery (such as removal of warts)

- Emla Cream can be used in this way only by healthcare professionals on adults and adolescents over 12 years.
- The usual dose is 5 g to 10 g of cream for 10 minutes. A dressing is not used. The medical procedure should then start straight away.

Use on leg ulcers before cleaning or removal of damaged skin

Emla Cream can be used in this way in adults, but only under the supervision of a doctor or nurse.

- The usual dose is 1 g to 2 g of cream for each area of skin that is 10 cm² up to a total of 10 g.
- The cream is put on under an airtight dressing such as plastic wrap. This is done for 30 to 60 minutes before the ulcer is to be cleansed. Remove the cream with cotton gauze and start cleansing without delay.
- Emla Cream can be used before cleansing of leg ulcers for up to 15 times over a period of 1-2 months.
- The Emla Cream tube is intended for single use when used on leg ulcers: The tube with any remaining contents should be discarded after each occasion that a patient has been treated.

If you use more Emla Cream than you should

If you use more Emla Cream than is described in this leaflet or more than your doctor, pharmacist or nurse has told you to, talk to one of them straight away, even if you do not feel any symptoms.

Symptoms of using too much Emla Cream are listed below. These symptoms are unlikely to happen if Emla Cream is used as recommended.

- Feeling light-headed or dizzy.
- Tingling of the skin around the mouth and numbness of the tongue.
- Abnormal taste.
- Blurred vision.
- ringing in the ears.
- There is also a risk of ‘acute methaemoglobinaemia’ (a problem with blood pigment levels). This is more likely when certain medicines have been taken at the same time. If this happens, the skin becomes bluish-grey due to a lack of oxygen.

In serious cases of overdose, symptoms may include fits, low blood pressure, slowed breathing, stopped breathing and altered heartbeat. These effects may be life-threatening.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor or pharmacist if any of the following side effects bother you or do not seem to go away. Tell your doctor about anything else that makes you feel unwell while you are using Emla Cream.

If you experience any of the following effects while you are using Emla Cream, stop using it and check with your doctor or pharmacist as soon as possible: Allergic reactions, which in rare cases may develop into anaphylactic shock (skin rash, swelling, fever, respiratory difficulties and fainting) during treatment of skin, genital mucosa or leg ulcers.

Methaemoglobinaemia (blood disorder), which in rare cases may develop during treatment of the skin, and may cause signs and symptoms of hypoxaemia (abnormally low level of oxygen in the blood). Methaemoglobinaemia is more frequently observed, often in connection with overdose, in newborn infants and infants aged 0 to 12 months.

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

If you experience any troublesome or unusual effects while you are using EMLA, stop using it and check with your doctor or pharmacist as soon as possible.

Common (may affect up to 1 in 10 people)

- Transient local skin reactions (paleness, redness, swelling) in the treated area during treatment of skin, genital mucosa or leg ulcers.
- An initially mild sensation of burning, itching or warmth at the treated area during treatment of genital mucosa or leg ulcers.

Uncommon (may affect up to 1 in 100 people)

- An initially mild sensation of burning, itching or warmth at the treated area during treatment of the skin.
- Numbness (tingling) in the treated area during treatment of genital mucosa.
- Irritation of the treated skin during treatment of leg ulcers.

Rare (may affect up to 1 in 1,000 people)

- Small dot-shaped bleeding on the treated area (particularly on children with eczema after longer application times) during treatment of the skin.
- Irritation of the eyes if Emla Cream accidentally comes into contact with them during treatment of the skin.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

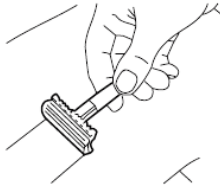
5. How to store Emla Cream

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C and do not freeze. Keep the tube tightly closed.
- Do not use this medicine after the expiry date which is stated on the package and tube after “EXP:”. The expiry date refers to the last day of that month.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

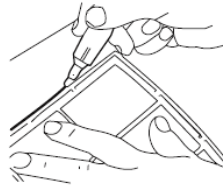
Emla® 5% Cream

Application instructions for surgical use only (split skin grafting).

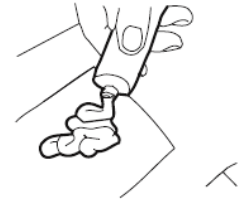
Apply approximately 1.5–2 g/10 cm² Emla 5% Cream, at least 2 hours and not more than 5 hours before split skin graft procedure.



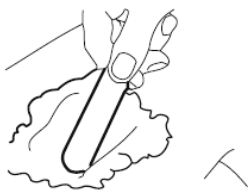
1. Shave the skin of the selected donor site area. Clean the area of skin with alcohol.



2. Select the exact area of the donor site by using the graduated ruled edge of this leaflet, e.g., 10 cm x 10 cm or 10 cm x 20 cm – and mark this area using an indelible thick marker pen to delineate the margins of the site.



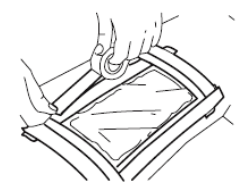
3. Squeeze out between ½–1 (30 g) tube of Emla 5% Cream per 100 cm² on the area of the donor site to be anaesthetised.



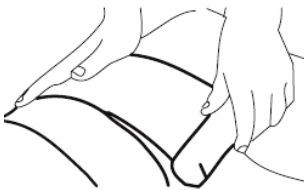
4. Spread the Emla 5% Cream to form an even, thick layer. It is important to cover completely the entire donor area including over the marked margins of the site.



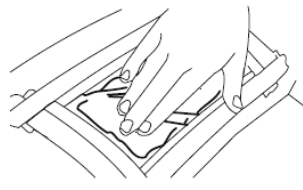
5. Take a strip of transparent occlusive plastic film wrapping cut to the appropriate size (slightly larger than the area of the donor site). Carefully apply the wrapping to cover completely the layer of Emla 5% Cream.



6. Smooth down and tape the edges of the occlusive film wrapping to the skin using a surgical synthetic adhesive tape.



7. Wrap the entire site using an elastic crepe bandage to protect the site and avoid leakage of the Emla 5% Cream – but avoid undue compression and do not wrap too tight. Leave the Emla 5% Cream and occlusive wrapping in place for at least 2 hours. As a reminder, the time can be written on the wrapping or bandage.



8. After 1 hour and hourly thereafter – remove only the crepe bandage (not the adhesive tape or film wrapping) and massage the Emla 5% Cream through the film wrapping to ensure a thick, even layer of Emla is maintained over the entire donor site. Replace the bandage.



9. After a minimum of 2 hours – just prior to surgery – remove the bandage and occlusive wrapping. Wipe off the Emla 5% Cream. Analgesic efficacy may decline if application time is >5 hours. The anaesthetised donor site may appear either pale or red. These reactions are normal and are associated with the skin anaesthesia. Disinfect and prepare the anaesthetised donor site prior to cutting the split skin graft.