LEAFLET: INFORMATION FOR THE USER

Emla, hydrophilic cream 5%
lidocaine and prilocaine

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.Keep this leaflet. You may need to read it again.
Do you have any questions? Contact your doctor or pharmacist.
Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
Contents of this leaflet

1. Emla contains two active substances called lidocaine and prilocaine.

These belong to a group of medicines called local anesthetics. These belong to the group of medicines called local anesthetics.

Emla works by numbing the surface of the skin for a short time. It is applied to the skin before certain medical procedures take place. It helps to not feel pain on the skin; however, you may still feel pressure and touch.

Adults, teenagers, and children
This medicine can be used to numb the skin for:
- the insertion of a needle (for example, during an injection or a blood test).
- minor skin surgeries.

Adults and teenagers
This medicine can also be used:
- to numb the genital area for:
  - receiving an injection.
  - medical procedures, such as the removal of warts.

A doctor or nurse should supervise when Emla is used on the genital area.

Adults
This medicine can also be used to numb the skin for:
- cleaning or removing damaged skin from a leg ulcer.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra cautious with this medicine?
Contact your doctor or pharmacist before using this medicine

- if you or your child has a rare hereditary disease called 'glucose-6-phosphate dehydrogenase deficiency', which affects the blood.
- if you or your child has 'methemoglobinemia', which is an excess of blood pigment.
- do not use Emla on areas with a rash, cut, abrasions, or other open wounds, except for a leg ulcer. If any of these problems occur, contact your doctor or pharmacist before using the cream.
- if you or your child has an itchy skin condition called 'atopic dermatitis', a shorter application time may be sufficient. An application time of more than 30 minutes may lead to more frequent occurrence of a local skin reaction (see also section 4 'Possible side effects').
- if you are taking specific medicines for heart rhythm disorders (class III antiarrhythmic drugs, such as amiodarone). Your doctor will then monitor your heart function.

Due to the risk of increased absorption through freshly shaved skin, it is important to adhere to the recommendations for amount, area of skin, and application time.

Avoid contact of Emla with the eyes, as it can cause irritation and chemical burns to the eyes. If it accidentally gets into your eye, rinse your eye immediately with lukewarm water or a saline solution (sodium chloride). Be careful not to get anything in your eye until the feeling in your eyes returns.

When children use Emla on a certain body part, they should be closely monitored to prevent Emla from getting into the eyes.

Emla should not be applied to a damaged eardrum.

When you use Emla before being vaccinated with a live vaccine (e.g., tuberculosis vaccine), you should return to your doctor or nurse after the required period to check the vaccination result.

Children and adolescents up to 18 years
In infants/newborns younger than 3 months, a transient, clinically non-relevant increase in the amount of blood pigment, 'methemoglobinemia', is often observed up to a maximum of 12 hours after Emla is applied.

The efficacy of Emla for heel pricks in newborns or for obtaining adequate anesthesia for circumcision could not be confirmed during clinical studies.

Emla should not be applied to the mucous membranes of the genitals (e.g., in the vagina) of children (under 12 years) due to insufficient data on the absorption of the active substances.

Emla should not be used in children under 12 months if they are simultaneously being treated with other medicines that affect the amount of blood pigment, 'methemoglobinemia' (e.g., sulfonamides, see also section 2 'Are you taking any other medicines?').

Emla should not be used in premature infants.

Are you taking any other medicines?
Are you taking any other medicines besides Emla, or have you done so recently, or is there a possibility that you will take other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription and herbal medicines. The reason for this is that Emla can affect the action of some medicines and some medicines can affect the action of Emla. Tell your doctor or pharmacist especially if you or your child has recently used the following medicines:

- medicines against infections, such as sulfonamides and nitrofurantoin.
- medications for epilepsy, such as phenytoin and phenobarbital.
- other local anesthetics.
- medications for heart rhythm disorders, such as amiodarone.
- cimetidine or beta-blockers, these can cause an increase in the blood level of lidocaine. This interaction is not clinically relevant for short-term treatment with Emla in the recommended dosages.

Pregnancy, breastfeeding, and fertility
Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

With occasional use of Emla during pregnancy, it is unlikely to have an adverse effect on the fetus.

The active substances in Emla (lidocaine and prilocaine) are excreted in breast milk, but the level is so low 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 has no or negligible influence on the ability to drive vehicles or use machines at the recommended dosages.

Emla contains macrogolglycerol hydroxystearate (polyoxyl hydrogenated castor oil)
Macrogolglycerol hydroxystearate can cause skin reactions.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor, pharmacist, or nurse has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

All dosages are possible with the product from this leaflet. However, there are also products on the market with more grams of cream per tube, requiring fewer tubes.

Use of Emla

- Where to apply the cream, how much to use, and how long to leave it on depends on the reason you are using Emla.
- Your doctor, pharmacist, or nurse will apply the cream or show you how to apply the cream yourself.
- If Emla is used on the genitals, a doctor or nurse must supervise the use.

Do not use Emla on the following areas:
- cuts, abrasions, or wounds, except on a leg ulcer.
- where there is a rash or eczema.
- in or near the eyes.
- in the nose, ear, or mouth.
- in the opening of the rectum (anus).
- on the genitals of children.

Persons who frequently apply or remove cream should be careful to avoid contact, to prevent the development of hypersensitivity.

The tube's sealing foil can be pierced using the cap.

Use on the skin prior to minor procedures (such as needle insertion or minor skin surgeries):
- The cream is applied in a thick layer on the skin. Your doctor, pharmacist, or nurse will indicate where the cream should be applied.
- The cream is then covered with a dressing. This is removed immediately before the procedure. If you apply the cream yourself, make sure you have already received the dressing from your doctor, pharmacist, or nurse. - In adults and adolescents over 12 years, the usual dosage is 2 g (grams).
- In adults and adolescents over 12 years, the cream should be applied at least 60 minutes before the procedure, (unless the cream is used on the genitals). However, the cream should not be applied more than 5 hours in advance.
- In children, the amount of Emla to be used and the duration of use depend on the age. Your doctor, pharmacist, or nurse will indicate how much to use and when the cream should be applied.

When applying the cream, you must follow the instructions below carefully:
1. Squeeze the cream into a mound on the area of your skin where the cream is needed (for example, where the needle will be inserted). A strip of cream about 3.5 cm from the 30 g tube corresponds to 1 g of cream. Half a 5 g tube corresponds to about 2 g Emla. Do not rub the cream in.

2. Remove the paper layer from the pre-cut central part of the non-sticky part of the dressing (leaving a paper frame).

3. Remove the protective layer from the sticky side of the dressing.

4. Then carefully apply the dressing over the mound of cream. Do not spread the cream under the dressing.

5. Remove the paper backing. Smooth the edges of the dressing carefully. Leave the dressing in place for at least 60 minutes if the skin is not damaged. The cream should not remain for more than 60 minutes in children younger than 3 months or longer than 30 minutes in children with an itchy skin condition called 'atopic dermatitis'. If the cream is used on the genitals or on sores, shorter application times can be used as indicated below.

6. Your doctor or nurse will remove the dressing and cream just before the medical procedure (for example, just before the needle is inserted).

Use on large areas of freshly shaved skin for outpatient procedures (e.g., for hair removal): The usual dosage is 1 g of cream per 10 cm^2 (10 square centimeters) of skin surface, acting for 1 to 5 hours under a dressing. Emla should not be used on a freshly shaved skin surface larger than 600 cm^2 (600 square centimeters, e.g., 30 cm x 20 cm). The maximum dose is 60 g.

Use on the skin prior to hospital procedures (such as skin grafting) requiring anesthesia of the deeper skin:
- Emla can be used in this way in adults and adolescents over 12 years old.
- The usual dosage is 1.5 g to 2 g of cream for each skin surface of 10 cm^2 (10 square centimeters).
- The cream is applied under a dressing for 2 to 5 hours.

Use on the skin prior to removal of a “molluscum”, also known as water warts:
- Emla can be used in children and adolescents with a skin condition called 'atopicdermatitis'.
- 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, pharmacist, or nurse will indicate how much cream you should use.

Use on the skin of the genitals prior to injections for local anesthesia:
- Emla can only be used in adults and adolescents over 12 years of age in this way.
- The usual dosage is 1 g of cream (1 g to 2 g for female genital skin) for each skin surface of 10 cm^2 (10 square centimeters).
- The cream is applied under a dressing. On the male genital skin, the cream should act for 15 minutes; on the female genital skin, the cream should act for 60 minutes.

Use on the genitals prior to a minor surgical procedure on the skin (such as wart removal):
- Emla can only be used in adults and adolescents over 12 years of age in this way.
- The usual dosage is 5 g to 10 g of cream for 10 minutes. No dressing is used. The medical procedure should then be performed immediately.

Use on leg ulcers prior to cleaning or removal of damaged skin:
- The usual dosage is 1 g to 2 g of cream for each skin surface of 10 cm^2 up to a total of 10 g.
- The cream is applied under an airtight dressing, such as plastic wrap. The cream is applied 30 to 60 minutes prior to cleaning the ulcer. Remove the cream with cotton gauze and clean the ulcer immediately.
- Emla can be used up to 15 times within a period of 1-2 months for cleaning leg ulcers.
- When used for leg ulcers, the tube of Emla should only be used once. The tube with any remaining contents must be discarded once a patient has been treated.

Have you used too much of this medicine?
Immediately inform your doctor, pharmacist, or nurse if you have used more of this medicine than indicated, even if you do not experience any symptoms.

The symptoms that may occur if you use too much Emla are indicated below. These symptoms are unlikely to occur if you use Emla as recommended.
- Lightheadedness or dizziness.
- Tingling of the skin around the mouth and numbness of the tongue.

- Abnormal taste sensation.
- Blurred vision.
- Ringing in the ears.
- You may also develop acute methemoglobinemia (a problem with the amount of blood pigment). This risk is higher when certain medications are used simultaneously with this medicine. You can recognize methemoglobinemia by a blue-gray discoloration of the skin due to lack of oxygen.

In case of a severe overdose, symptoms such as seizures, low blood pressure, slower breathing, respiratory arrest, and abnormal heart rhythm may occur. These symptoms can be life-threatening.

Do you have any other questions about the use of this medicine? Then contact your doctor, pharmacist, or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone will experience them.
Contact your doctor or pharmacist if you experience the following side effects or if they persist. Let your doctor know if there are other things that make you feel unwell while using Emla.

A mild reaction may occur (paleness or redness of the skin, slight swelling, initial burning sensation, or itching) in the area where Emla is used. These are normal reactions to the cream and the anesthesia that will disappear within a short time without any measures needed.

If you experience unpleasant or unusual side effects while using Emla, you should stop using it and contact your doctor or pharmacist as soon as possible.

Common (may affect up to 1 in 10 people)
- Transient local skin reactions (pallor, redness, swelling) at the application site during treatment of the skin, genital mucosa, or leg ulcers.
- An initial mild burning sensation, itching, or warmth at the application site during treatment of genital mucosa or leg ulcers.

Uncommon (may affect up to 1 in 100 people)
- An initial mild burning sensation, itching, or warmth at the application site during treatment of the skin.
- Numbness (tingling) at the application site during treatment of the genital mucosa.
- Irritation at the application site during treatment of leg ulcers.

Rare (may affect up to 1 in 1,000 people)
- Allergic reactions that in rare cases can lead to anaphylactic shock (rash, swelling, fever, breathing difficulties, and fainting) during treatment of the skin, genital mucosa, or leg ulcers.
- Methemoglobinemia (blood disorder) during treatment of the skin.
- Small pinpoint bleedings at the application site (especially in children with eczema where this product has been left on for a long time) during treatment of the skin.

- Eye irritation when Emla accidentally comes into contact with the eyes during treatment of the skin.

Frequency not known (cannot be estimated from the available data)
Chemical burns to the eyes if Emla accidentally comes into contact with the eyes during treatment.

Additional side effects that may occur in children
Methemoglobinemia, a blood disorder, more frequently observed, often associated with overdose in newborns and infants aged 0 to 12 months.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.
Do not use this medicine after the expiry date. It can be found on the label on the packaging after "EXP:". It includes a month and a year. The last day of that month is the expiry date. Do not store in the freezer. Keep the tube tightly closed.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?
- The active substances in this medicine are lidocaine and prilocaine. 1 gram of cream contains 25 mg of lidocaine and 25 mg of prilocaine.
- The other substances in this medicine are carbomers, macrogolglycerol hydroxystearate (polyoxyl hydrogenated castor oil), sodium hydroxide for pH adjustment, purified water.

What does Emla look like and what is in a package?
White, uniform (homogeneous) cream. It is packaged in an aluminum tube with a plastic cap. Emla is available in packages of 5 tubes with 5 grams of cream + 10 dressings and 1 tube with 30 grams.

Marketing authorization holder and manufacturer Marketing authorization holder:
Euro Registratie Collectief b.v.
Kempkens 2200
5465 PR Veghel
Repacker (see

label on the outer packaging): Brocacef B.V., Ma
Brocacef B.V., Maroastraat 43, 1060 LG Amsterdam
or
Stephar B.V., Kempkens 2200, 5465 PR Veghel

Manufacturer:
AstraZeneca AB
Astraalén, Gärtunaporten (B 674:5)
SE-151 85 Södertälje
Sweden

AstraZeneca UK Limited
Silk Road Business Park
Macclesfield
Cheshire SK10 2NA
United Kingdom

Recipharm Karlskoga AB
Björkbornsvägen 5
SE-691 33 Karlskoga
Sweden

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

Registered under:
RVG 100630//11015 Emla, hydrophilic cream 5% (Greece)
RVG 133425//11015 Emla, hydrophilic cream 5% (Spain)

This medicine is marketed in the country of origin under the name: Greece: Emla (2.5 + 2.5) %
Spain: EMLA 25 mg/g + 25 mg/g cream

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