PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine can be sold without a doctor's prescription

Emla 5%

Cream

The active ingredients and their concentration:
Composition:
Lidocaine 2.5%
Prilocaine 2.5%
Inactive ingredients and allergens in the preparation – see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.
Use the medicine correctly. Consult a pharmacist if you need additional information.

1. WHAT IS THE MEDICINE INTENDED FOR?

Emla 5% is used for dermal local anasthesia, for pain relief before procedures involving the insertion of a needle (e.g., an infusion, blood tests) and minor skin operations.
Emla 5% cream works by temporarily numbing the skin surface so that it helps relieve the pain. However, you may still feel touch and pressure in the area.

Therapeutic group: Local anesthetic of the amide group.

2. BEFORE USING THE MEDICINE

Do not use the medicine:
If you are hypersensitive (allergic) to the active ingredients, or to any of the other ingredients contained in the medicine, or to another similar local anesthetic (see section 6).

Special warnings regarding the use of the medicine
Before treatment with Emla 5% cream tell the doctor if:
- You or your child have a rare inherited illness that affects the blood, called "glucose-6-phosphate dehydrogenase (G6PD enzyme) deficiency" (hypersensitivity to fava beans).
- You or your child have a problem with blood pigment levels called "methemoglobinemia".
- Do not use Emla 5% cream on areas with skin rash, cuts, grazes, scratches or other open wounds, with the exception of a leg ulcer. If any of these problems is present, check with the doctor or pharmacist before using the medicine.
- You or your child have an itchy skin condition called "atopic dermatitis". A shorter application time on the skin may suffice. Application times of the cream on the skin for more than 30 minutes can cause an increase in the incidence of local skin reactions (see also section 4 "Side effects").
- You are taking certain medicines 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 newly shaven skin, it is important to follow the recommended dosage, skin area and application time of the cream on the skin.
Avoid getting Emla 5% cream in the eyes, as it may cause irritation. If Emla 5% cream accidentally gets in the eyes, immediately rinse the eyes well with lukewarm water or a salt (sodium chloride) solution. Be careful to avoid getting anything in the eye until feeling returns.
Do not apply Emla 5% cream to an impaired eardrum.
When you use Emla 5% cream before being vaccinated with live vaccines (e.g., tuberculosis vaccine), you should return to the doctor or nurse after the requested time in order to monitor the vaccination result.
In children – do not use on the genital mucosa (see also in section 3).

In the following cases consult the doctor before starting the treatment:
- In infants under one year of age that are being concomitantly treated with methemoglobinemia inducing medicines such as sulfonamides ("sulfa drugs").
- In premature infants until they have reached the chronological age of 37 weeks of pregnancy.

Drug interactions
If you are taking, or have recently taken other medicines, including non-prescription medicines, nutrition supplements and herbal remedies, tell the doctor or pharmacist. This is because Emla 5% cream can affect the way certain medicines work and some medicines can have an effect on Emla 5% cream.
In particular, tell the doctor or pharmacist if you are taking:
- Medicines used for treatment of infections, called "sulfonamides" and nitrofurantoin.
- Medicines used for the treatment of epilepsy, called phenytoin and phenobarbital.
- Other local anesthetics.
- Medicines for the treatment of 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 5% cream at the recommended doses.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult the doctor or pharmacist before using this medicine.
Occasional use of Emla 5% cream during pregnancy is unlikely to cause any adverse effects on the fetus.
The active ingredients in Emla 5% 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 5% cream has no or negligible influence on the ability to drive and use machines when used at the recommended doses.

Important information about some of the ingredients of the medicine
Emla 5% cream contains macrogolglycerol hydroxystearate which may cause skin reactions.

3. HOW TO USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the preparation dosage and treatment regimen.
See further below: "Measuring the correct amount of cream"
Do not use Emla 5% cream on mucous membranes or on damaged skin without consulting the doctor. In such cases reduce the application time of the cream.

Recommended dosage unless otherwise instructed by the doctor
Dosage in adults (over 12 years of age):
For minor surgical procedures (such as needle insertion for an intravenous infusion or when undergoing blood tests, or curettage of viral skin lesions (mollusca contagiosum):
Approximately 1.5-2 grams for every 10 cm^2 area of skin. Apply a thick layer of the cream, cover it with an occlusive dressing, such as a plastic wrap, and leave for 1-5 hours.
For surgical procedures requiring deeper local anesthesia:
Approximately 1.5-2 grams for every 10 cm^2 area of skin. Apply a thick layer of the cream, cover it with an occlusive dressing, such as a plastic wrap, and leave for 2-5 hours.
Maximum dosage: Up to 60 grams (2 tubes of 30 grams) per 24 hours may be applied. Do not leave the cream on the treated area for longer than 5 hours.
For recently shaven skin areas, do not apply Emla 5% cream on an area larger than 600 cm^2 (20 x 30 cm).
For removal of leg ulcers – apply 1-2 grams for every 10 cm^2 area of skin. Apply a thick layer of cream on the area of the ulcer, but not more than 10 grams per treatment. Cover with an occlusive dressing and dispose of any remaining cream left in the tube. Application time: at least 30 minutes.
In cases of tissues with particularly difficult permeability, the application time can be extended to a maximum of 60 minutes.
Ulcer removal should begin within 10 minutes after cream removal. Emla 5% can be used for up to 15 treatments over a period of 1-2 months without a decrease in effectiveness or an increase in the number of local reactions.
On genitalia (men only) – before injection of local anesthetics – apply approximately 1 gram for every 10 cm^2 area of skin. Cover with an occlusive dressing for 15 minutes.
On genitalia (women) – before injection of local anesthetics – apply approximately 1-2 grams for every 10 cm^2 area of skin. Cover with an occlusive dressing for 60 minutes.
On genital mucosa (adults only) – prior to minor skin operations such as surgery for removing condylomas: apply 5-10 grams, depending on the size of the treated area. Cover the whole area, including the mucosal folds. Occlusion is not necessary. Application time: 5-10 minutes.
Start the surgery immediately after removal of the cream.

Dosage in children:
For use on the skin before medical procedures such as needle insertion or minor skin operations. Apply about an hour before the procedure.
Do not exceed the recommended dose (see dosage table).
When used in infants up to 3 months of age, methemoglobin should be checked before and after use.
In children, do not use Emla 5% on the genital mucosa.

Dosage table in infants and children:

Age / body weight	Maximal amount of Emla 5% cream	Maximal application area	Maximal application time on the skin
Up to 3 months / up to 5 kg	1 gram	10 cm^2	1 hour
3-12 months / 5-10 kg	2 grams	20 cm^2	4 hours
1-6 years / 10-20 kg	10 grams	100 cm^2	4 hours
7-12 years / over 20 kg	20 grams	200 cm^2	4 hours

In children with atopic dermatitis, remove the cream 15-30 minutes after application.

Applying additional doses:
In infants up to 3 months of age – do not apply another dose for 24 hours.
In infants and children over 3 months of age – wait at least 12 hours until reapplying Emla 5%. Do not apply more than 2 doses within 24 hours.

Measuring the correct amount of the cream (for use in children and adults):
To measure 1 gram of Emla 5% cream, gently squeeze out of the tube a narrow strip of cream that is 3.8 cm long and 5 mm wide. The strip of cream should be contained within the lines of the diagram below:

Strip ≈ 1 gram

3.8 cm X 5 mm

Do not exceed the recommended dose. See detailed instructions for use at the end of this leaflet.
Do not swallow! This medicine is intended for external use only.
Avoid contact of the medicine with the eyes, mucous membranes and ears. In case of contact, wash thoroughly with water. Protect the eye until sensation is restored to the eye.
If you have applied more than recommended you may experience: bluish-grey colored skin, drowsiness or dizziness, blurred vision or ringing in the ears, changes in the sense of taste, confusion, hot/cold or paresthesia sensation, tingling of the skin around the mouth and numbness of the tongue. In severe cases of overdose the following may occur: fits, decrease in blood pressure, slowed breathing, stopped breathing and altered heart rate – evacuate the patient to an emergency room immediately!
If you have applied more Emla 5% cream than recommended or if a child or someone else has accidentally swallowed the medicine, proceed immediately to a doctor or hospital emergency room and bring the package of the medicine with you.
Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Emla 5% cream may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.
Refer to your doctor or pharmacist if any of the following side effects bother you or does not seem to be passing. Tell the doctor about anything else that is causing you to feel unwell while you are using Emla 5% cream.
If you experience one of the following effects while you are using Emla 5% 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 difficulty and fainting) during treatment of skin, genital mucosa or leg ulcers.
- Methemoglobinemia (a blood disorder), which in rare cases may develop during treatment of the skin, and may cause signs and symptoms of hypoxemia (abnormally low levels of oxygen in the blood). Methemoglobinemia has been observed more frequently, often in association with an overdose, in newborn infants and infants aged 0 to 12 months.

A mild reaction (paleness or redness of the skin, slight puffiness, an initial burning sensation or itching) may occur in the area on which Emla 5% cream is applied. These are normal reactions to the cream and the anesthetic ingredients and they will disappear within a short time without any additional measures being needed.
If you experience worrisome or unusual effects when you use Emla 5% cream, stop using the cream and check with your doctor or the pharmacist as soon as possible.

Common side effects (appear in 1-10 users out of 100):
- 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 in the treated area during treatment of the genital mucosa or leg ulcers.

Uncommon side effects (appear in 1-10 users out of 1,000):
- An initially mild sensation of burning, itching or warmth in the treated area during treatment of the skin.
- Numbness (tingling) in the treated area during treatment of the genital mucosa.
- Irritation of the treated skin during treatment of leg ulcers.

Rare side effects (appear in 1-10 users out of 10,000):
- Small dot-shaped bleeding in the treated area (particularly in children with eczema after longer application times of the cream) during treatment of the skin.
- Irritation of the eyes if Emla 5% cream accidentally comes in contact with them during treatment of the skin.

If a side effect occurs, if one of the side effects worsens, or when you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Side effects and drug interactions in children and infants:
Parents must inform the attending doctor about any side effect, as well as any additional medicine being given to the child. See above detailed side effects and particular drug interactions.

Reporting side effects:
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il
Additionally, you can report to Padagis via the following address: Padagis.co.il

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store the medicine below 30°C. Do not freeze.
- Emla 5% cream can be used up to 4 weeks after first opening the tube, but not later than the expiry date.
- The medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, this medicine also contains:
Macrogolglycerol hydroxystearate, Carbomer 974P, sodium hydroxide, purified water.

What the medicine looks like and contents of the package?
Emla 5% cream is a white soft cream packed in a package containing a single 30 g aluminum tube of cream.

Registration holder and address: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.

Manufacturer and address: Recipharm, Karlskoga AB, Sweden, for Aspen.

Revised in June 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 4325.25706

Instructions for use:

1. Squeeze the Emla 5% tube to extract a sufficient amount (see dosage instructions) and apply a thick layer of the cream to the skin. Do not rub the area.

1

2. Cover the skin to which Emla 5% was applied with an occlusive dressing, such as a plastic wrap. Secure it firmly, and make sure that all of the cream is covered.

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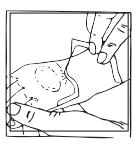
3. Wait the necessary period of time (see information regarding the application time in section 3) before performing the required treatment.



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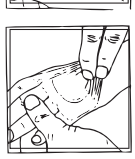
4. Remove the dressing, wipe off Emla 5% cream and prepare for the required treatment. The area treated with Emla 5% will remain anesthetized for at least 30 minutes and up to several hours.



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