

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

The medicine is dispensed without a doctor's prescription

# Emla® 5% Cream

## The inactive ingredients and their concentrations:

Composition:  
Lidocaine 2.5% w/w  
Prilocaine 2.5% w/w

Inactive and allergenic ingredients in the preparation – see in section 2 "Important information about some of the ingredients in the medicine" and section 6 "Further information".

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Use the medicine in accordance with the instructions in the Dosage section of this leaflet. Consult a pharmacist if you need further information.

### 1. WHAT IS THIS MEDICINE INTENDED FOR?

Emla 5% cream is used for:

- Topical anesthesia of the skin in adults and children, in connection with:
  - Needle insertion, e.g., intravenous catheters or blood sampling;
  - Superficial surgical procedures;
- Topical anesthesia of the genital mucosa, e.g., prior to superficial surgical procedures or infiltration anaesthesia;
- Topical anesthesia of leg ulcers to facilitate cleansing or debridement, in adults only.

**Therapeutic group:** Local anesthetic of the amide group. Emla 5% cream works by numbing the surface of the skin for a short time. It is applied to the skin before certain medical procedures. This helps relieve the pain on the skin; however, you may still feel pressure and touch.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine:

If you are sensitive (allergic) to the active ingredients, or to any of the additional ingredients contained in the medicine, or to another similar local anesthetic (see section 6 "Further information").

#### Special warnings regarding use of the medicine

##### Before treatment with Emla 5% cream, tell the doctor if:

- You or your child has a rare inherited illness that affects the blood, called "glucose-6-phosphate dehydrogenase (G6PD enzyme) deficiency" (hypersensitivity to fava beans).
- You or your child has a problem with blood pigment levels called "methemoglobinemia".
- Do not use Emla 5% cream on areas with a skin rash, cuts, grazes or other open wounds, with the exception of a leg ulcer. If any of these problems are present, check with the doctor or pharmacist before using the medicine.
- You or your child has 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 this 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 areas 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 thoroughly 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 results.

Repeated use of Emla 5% may increase the blood levels of the active ingredients lidocaine and prilocaine. Use Emla 5% with caution in patients who may be more sensitive to the systemic effects of these substances in their blood, including acutely ill, debilitated, or elderly patients, and patients with severe hepatic impairment.

#### Children and adolescents

In newborns/babies under 3 months of age, a transient, clinically not relevant increase in blood pigment levels "methemoglobinemia" is commonly observed up to 12 hours after applying Emla 5% cream.

The effectiveness of Emla 5% cream when drawing blood from the heel of newborn infants has not been approved in clinical trials.

Do not use Emla 5% cream in infants under 12 months of age who are being treated at the same time with other medicines that affect levels of the blood pigment "methemoglobinemia" (e.g., sulfonamides, also see section "Drug interactions"). Do not use Emla 5% cream in preterm newborns.

#### Drug interactions

**If you are taking, or have recently taken other medicines, including non-prescription medicines, nutritional supplements and herbal medicines, tell the doctor or pharmacist.** This is because Emla 5% cream can affect the way certain medicines work and some medicines can affect how Emla 5% cream works.

**In particular, tell the doctor or pharmacist if you or your child is taking or has recently taken:**

- Medicines used for the 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 heart rhythm, such as amiodarone.
- Cimetidine or beta blockers, which may cause an increase in the blood levels of lidocaine. This drug interaction is of no clinical relevance in short-term treatment with Emla 5% cream at the recommended dosages.

#### Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

Occasional use of Emla 5% cream during pregnancy is unlikely to have 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 operating machinery

Emla 5% cream has no effect at all or has a negligible effect on ability to drive and operate machinery when used at the recommended dosages.

#### Important information about some of the ingredients in the medicine

Emla 5% cream contains macroglyglycerol hydroxystearate, which may cause skin reactions.

### 3. HOW SHOULD THE MEDICINE BE USED?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

#### Use of Emla 5% cream

- Where to apply the cream, how much to use and how long to leave it on the skin depends on the purpose of its use.
- One gram of Emla 5% cream that comes out of a 30 gram tube is approximately 3.5 cm.
- **Application of Emla 5% cream on genital mucosa, genital skin or leg ulcers must only be done by or under the supervision of a healthcare professional, with the exception of application in infants undergoing a circumcision.**

#### Do not use Emla 5% cream in the following areas:

- cuts, grazes or wounds, with the exception of leg ulcers.
- in areas in which there is a skin rash or eczema.
- in or near the eyes.
- in the nose, ear or mouth.
- in the anus.

People who frequently apply or remove the cream must be sure to avoid contact to prevent development of hypersensitivity.

The cap can be used to pierce the membrane protecting the tube.

#### The recommended dosage unless instructed otherwise by the doctor

##### Dosage for adults and adolescents (over 12 years of age):

##### Use on the skin before minor procedures (such as needle insertion or minor skin operations):

- Apply a thick layer of the cream on the skin. Follow the instructions in the leaflet or your doctor's instructions. In certain cases, the doctor or nurse will apply the cream.
- Cover the applied cream with an occlusive dressing (plastic wrap) that is removed immediately before starting the procedure. If you apply the cream on your own, make sure that you receive an occlusive dressing from your doctor, pharmacist or nurse.
- The recommended dosage for adults and adolescents over 12 years of age is 2 grams.
- For adults and adolescents over 12 years of age, apply the cream at least 60 minutes before the procedure (unless the cream is being used on the genitals). However, do not apply it more than 5 hours before.

##### Dosage in children:

##### For use on the skin before minor medical procedures (such as needle insertion or minor skin operations).

**Application time of the cream on the skin:** Apply approximately **one hour** before the procedure.

##### Newborns and infants aged 0-2 months:

Up to 1 gram of cream on a skin area no larger than 10 cm<sup>2</sup> (10 square centimeters). Application time on the skin: **no more than one hour. Only one dose should be given per 24 hours.**

For use for **circumcision** in infants, a **single** dose of 1.0 gram Emla 5% cream applied on the foreskin has been proven safe. In term newborns and in infants under 3 months of age, apply only one dose, every 24 hours.

##### Infants aged 3-11 months:

Up to 2 grams of cream on overall skin surface that does not exceed 20 cm<sup>2</sup> (20 square centimeters). Application time on the skin: approximately **one hour.**

##### Children aged 1-5 years:

Up to 10 grams of cream on overall skin surface that does not exceed 100 cm<sup>2</sup> (100 square centimeters). Application time on the skin: approximately **one hour**, maximum 5 hours.

##### Children aged 6-11 years:

Up to 20 grams of cream on overall skin surface that does not exceed 200 cm<sup>2</sup> (200 square centimeters). Application time on the skin: approximately **one hour**, maximum 5 hours.

A maximum of 2 doses at an interval of at least 12 hours may be given to children over 3 months of age, over a 24-hour period.

Emla 5% cream can be used in children with "atopic dermatitis", but the application time on the skin with this condition is, no longer than 30 minutes.

#### Instructions for use:

When applying the cream, it is very important that you carefully adhere to the following instructions:

1. Squeeze the Emla 5% tube to extract a layer of the cream on the required area on the skin (e.g., where the needle will be inserted). One gram of Emla 5% cream extracted from a 30 gram tube is approximately 3.5 cm. Do not rub the cream into the skin.



2. Carefully cover the skin to which Emla 5% cream was applied with an occlusive dressing, such as plastic wrap. Do not spread the cream under the dressing.



3. If the skin is not damaged, leave the dressing in place for at least 60 minutes. Do not leave the applied cream for more than 60 minutes in children under 3 months of age or for more than 30 minutes in children with an itchy skin condition called "atopic dermatitis". If the cream is being applied on the genitals or on ulcers, leave it for shorter periods of time, as detailed below.



4. The doctor or nurse will remove the dressing, and immediately wipe off Emla 5% cream before starting the medical procedure (e.g., before insertion of a needle).



#### Use on large areas of newly shaven skin before procedures that do not require hospitalization (e.g., hair removal techniques):

Follow the doctor's and healthcare professionals' instructions. The usual dosage is 1 gram of cream for each 10 cm<sup>2</sup> (10 square centimeters) skin area, to be left on the skin for 1 to 5 hours under a dressing. Do not use Emla 5% cream on a newly shaven skin area that is larger than 600 cm<sup>2</sup> (600 square centimeters, e.g., 30 cm by 20 cm). The maximum dosage is 60 grams.

#### Use on skin before procedures performed in a hospital (e.g., split-skin grafting) requiring deep skin anesthesia:

- Emla 5% can be used for this purpose in adults and adolescents over 12 years of age, but only under the supervision of a doctor or nurse.
- The usual dosage is 1.5 g to 2 g of cream for each area of skin that is 10 cm<sup>2</sup> (10 square centimeters) in size.
- The cream is left under a dressing for 2 to 5 hours.

#### Use on the skin prior to removal of wart-like spots called "mollusca":

- Emla 5% can be used on children and adolescents with a skin condition called "atopic dermatitis".
- The usual dosage depends on the child's age and is applied for 30 to 60 minutes (30 minutes if the patient has atopic dermatitis). The doctor will tell you how much cream to use.

#### Use on genital skin before injections of local anesthetics:

- Emla 5% can only be used for this purpose by healthcare professionals, in adults and adolescents over 12 years of age.

- The usual dosage is 1 g of cream (1 g to 2 g for female genital skin) for each area of skin that is 10 cm<sup>2</sup> (10 square centimeters) in size.

- The cream is applied and covered with a dressing 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 5% can only be used for this purpose by healthcare professionals, in adults and adolescents over 12 years of age.
- The usual dosage is 5 g to 10 g of cream for 10 minutes. Do not use a dressing. The medical procedure should start immediately thereafter.

#### Use on leg ulcers before cleansing or removal of damaged skin:

##### Emla 5% can be used for this purpose in adults, but only under the supervision of a doctor or nurse.

- The usual dosage is 1 g to 2 g of cream for each area of skin that is 10 cm<sup>2</sup>, up to a total of 10 g.
- The cream is applied under an airtight dressing such as plastic wrap and left for 30 to 60 minutes before the ulcer is cleansed. Remove the cream with a cotton gauze pad and start cleansing without delay.
- Emla 5% can be used before cleansing leg ulcers for up to 15 times over a period of 1-2 months.
- The Emla 5% tube is intended for single use when used on leg ulcers: the tube with any remaining contents should be discarded after each treatment.

#### Elderly

There is no need to reduce the dosage for elderly patients.

#### Patients with impaired liver function

There is no need to reduce a single dose for patients with impaired liver function (see in section 2 "Special warnings regarding use of the medicine").

#### Patients with impaired kidney function

There is no need to reduce the dosage for patients with impaired kidney function (see in section 2 "Special warnings regarding use of the medicine").

#### Do not exceed the recommended dose.

Do not swallow! This medicine is intended for external use only.

**If you applied a larger amount than recommended** in this leaflet or more than the doctor or pharmacist told you to, talk to them immediately, even if you do not feel any symptoms.

Symptoms of applying too much Emla 5% cream are listed below. These symptoms are unlikely to happen if Emla 5% cream is used at the recommended dosage.

- 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 methemoglobinemia" (a problem with blood pigment levels). This is more likely to occur 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, breathing cessation and variable heart rate. These effects may be life-threatening.

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

If you applied more Emla 5% cream than recommended or if a child or anyone else accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

#### Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

### 4. SIDE EFFECTS

As with any medicine, use of Emla 5% cream may cause side effects in some users. Do not be alarmed when 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 do not seem like they are going away. Tell the doctor about anything else that makes you feel unwell while you are using Emla 5% cream.

If you experience any of the following effects while using Emla 5% cream, **stop using it and refer to a doctor immediately:**

- Allergic reactions, which in rare cases may develop into anaphylactic shock (skin rash, swelling, fever, breathing difficulties and fainting) during treatment of skin, genital mucosa or leg ulcers.
- Methemoglobinemia (a blood problem), 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 was 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 irritation) may occur on the area on which Emla 5% cream is applied. These are normal reactions to the cream and anesthetic substances, and will disappear in a short while without need for any additional measures.

If you experience any troublesome or unusual effects while using Emla 5% cream, stop using it and check with your doctor or pharmacist as soon as possible.

#### Common side effects (occur in 1-10 in 100 users):

- 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, irritation or warmth in the treated area during treatment of genital mucosa or leg ulcers.

#### Uncommon side effects (occur in 1-10 in 1,000 users):

- An initially mild sensation of burning, irritation or warmth in 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 side effects (occur in 1-10 in 10,000 users):

- Small dot-shaped bleeding on 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 into contact with them during treatment of the skin.

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

#### 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](http://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>

In addition, they can be reported to Padagis via the following address: [Padagis.co.il](mailto:Padagis.co.il)

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants 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 for up to 4 weeks after first opening the tube, but no later than the expiry date.
- Do not dispose of the medicine in wastewater or the household waste. Consult the pharmacist about how to dispose of medicines you no longer use. These measures will help protect the environment.

### 6. FURTHER INFORMATION

**In addition to the active ingredients, the medicine also contains:**

Macroglyglycerol hydroxystearate, Carbomer 974P, sodium hydroxide, purified water.

#### What does the medicine look like and what are the contents of the package?

Emla 5% cream is a white, soft cream packaged in a package that contains a single aluminum tube of 30 grams cream.

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

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**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 04325.25706