

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **EMLA Cream 5%** **(for 30 g surgical packs)** lidocaine 2.5%, prilocaine 2.5%

**Read all of this leaflet carefully before you or your child start using this medicine.**

This medicine is available without prescription. However, you still need to use EMLA Cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse.

#### **In this leaflet:**

1. What EMLA Cream is and what it is used for
2. Before you use EMLA Cream
3. How to use EMLA Cream
4. Possible side effects
5. How to store EMLA Cream
6. Further information

## **1. What EMLA Cream is and what it is used for**

EMLA Cream contains two medicines 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*

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.
- Some types of skin graft.
- Cleansing and debridement of leg ulcers.

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 supervise the use of EMLA Cream on the genitals.

#### *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.

## **2. Before you use EMLA Cream**

#### **Do not use EMLA Cream if:**

- You are allergic (hypersensitive) to lidocaine, prilocaine or any of the other ingredients of EMLA Cream (listed in Section 6: Further information).

### **Take special care with EMLA Cream**

Check with your doctor, pharmacist or nurse before using EMLA Cream if:

- You or your child are anaemic (a blood problem which means you have too few red blood cells).
- You or your child have a rare inherited illness that affects the blood called 'glucose-6-phosphate dehydrogenase deficiency'.
- You or your child have a problem with blood pigment levels called 'methaemoglobinaemia'.
- You or your child have a skin condition called 'atopic dermatitis'. This is because the cream may need to be put on the skin for a shorter time.
- Your child is a pre-term newborn infant.
- Your child is younger than 12 months and is being treated at the same time with other medicines that affect blood pigment levels 'methaemoglobinaemia'.

### **Taking other medicines**

Please tell your doctor, pharmacist or nurse if you are taking, or have recently taken, 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 called 'sulphonamides' such as sulfamethoxazole.
- Other local anaesthetics.
- Medicines to treat an uneven heart beat, such as mexiletine or amiodarone.

### **Pregnancy and breast-feeding**

- Talk to your doctor, pharmacist or nurse before using EMLA Cream if you are pregnant, may become pregnant or are breast-feeding.
- The medicines 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.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

### **Important information about some of the ingredients of EMLA Cream**

EMLA cream contains polyoxyethylene hydrogenated castor oil. This may cause skin reactions.

## **3. How to use EMLA Cream**

Always use EMLA Cream exactly as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are not sure.

### **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.

## **Using EMLA Cream**

- Where to put the cream, how much to use and how long to leave it on for will depend on what it is needed for.
- Your doctor, pharmacist or nurse will put the cream on or show you how to do it yourself.
- If applying the cream yourself, before you do you must get dressings from your doctor, nurse or pharmacist to use with EMLA.
- When EMLA Cream is used on the genitals, a doctor or nurse should supervise its use.

## **Adults and adolescents aged 12 years and over**

### **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. Your doctor, pharmacist or nurse will tell you where to put it. The usual dose is 2 g applied for 1 to 5 hours under a dressing.

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

The usual dose is 1.5 g to 2 g of cream for each area of skin that is 10 cm<sup>2</sup> (10 square centimetres) in size, applied for 2 to 5 hours under a dressing. The attached 'User Leaflet for the Healthcare Professional' contains further information for your doctor or nurse.

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

The usual dose is 1.5 g of cream for each area of skin that is 10 cm<sup>2</sup> (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 cm<sup>2</sup> (600 square centimetres, e.g. 30 cm by 20 cm) in size. The maximum dose is 60 g.

### **Use on genital skin before injections of local anaesthetics (adult men only):**

The usual dose is 1 g of cream for each area of skin that is 10 cm<sup>2</sup> (10 square centimetres) in size, applied for 15 minutes under a dressing.

### **Use on genital skin before minor skin surgery (such as removal of warts for adults only):**

The usual dose is 5 g to 10 g of cream applied for 10 minutes with no dressing. The medical procedure should then start immediately.

### **Use on leg ulcers before cleaning or debridement:**

The usual dose is 1-2g of cream for each area of skin that is 10 cm<sup>2</sup> 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.

## **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 under the age of 3 months:*** Up to 1 g of cream on a skin area not larger than 10 cm<sup>2</sup> (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 3-12 months:** Up to 2 g of cream on a total skin area not larger than 20 cm<sup>2</sup> (20 square centimetres) in size. Application time: approx **1 hour**, maximum 4 hours.

**Children aged 1-6 years:** Up to 10 g of cream on a total skin area not larger than 100 cm<sup>2</sup> (100 square centimetres) in size. Application time: approx **1 hour**, maximum 5 hours.

**Children aged 7-11 years:** Up to 20 g of cream on a total skin area not larger than 200 cm<sup>2</sup> (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”. The application time is 30 minutes.

### **Applying the correct dose**

Cream applied to a circular area with a diameter of about 18 mm (a 1 pence coin) and depth of about 5 mm is equal to 1 g of EMLA cream.

Alternatively, a line of cream of about 3.5 cm squeezed from the 30 g tube is equal to 1 g of cream.

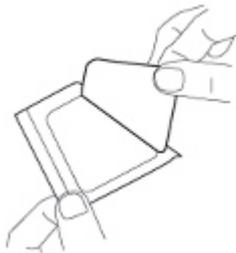
When you apply the cream, it is very important to exactly follow the instructions below:

1. Squeeze the cream into a mound where it is needed on your skin (for example where the needle is going to be put in). A line of cream of about 3.5 cm is equal to 1 g of cream.



2. **Do not rub the cream in.**

3. Peel the ‘centre cut-out’ from the dressing.



4. Peel the paper layer from the dressing.



5. Remove the covers of the dressing. Then place the dressing carefully over the mound of cream. Do not spread the cream under the dressing.



6. Remove the plastic backing. Smooth down the **edges** of the dressing carefully. Then leave it in place for at least 60 minutes.



7. 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).



#### **What to do if you get EMLA Cream in your eye**

- Do not get EMLA Cream in your eyes. This is because it may irritate your eyes.
- If you get EMLA Cream in your eye by mistake, rinse your eye well with lukewarm water or salt (sodium chloride) solution. Be careful to avoid getting anything in your eye until feeling returns.

**If EMLA Cream is accidentally swallowed**, talk to your doctor, pharmacist or nurse straight away.

#### **If you use more EMLA Cream than you should**

- If you use more EMLA Cream 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 heart beat. These effects may be life-threatening.

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

#### **4. Possible side effects**

Like all medicines, EMLA Cream can cause side effects, although not everybody gets them.

**Severe allergic reactions** (rare, affect less than 1 in 1,000 people)

If you have a severe allergic reaction, **stop using EMLA Cream and see a doctor straight away**. The signs may include sudden onset of:

- Rash.
- Feeling short of breath.
- Low blood pressure, which may make you feel faint or dizzy.
- Swelling of the face, lips, tongue or other parts of the body.

**Bluish-grey skin** (rare, affects less than 1 in 1,000 people)

The skin may become bluish-grey due to a lack of oxygen. If this happens to you, **see a doctor straight away**.

#### **Other possible side effects:**

**Common** (affect less than 1 in 10 people)

- Redness, slight swelling, or pale skin where the cream was used. This usually goes away after a short time.

**Uncommon** (affect less than 1 in 100 people)

- A mild burning or itching sensation when the cream is put on the skin. (When EMLA Cream is used on the genitals, this is a common side effect, affecting less than 1 in 10 people.)
- A tingling feeling where the cream was put on the skin.

**Rare** (affect less than 1 in 1,000 people)

- Mild allergic reactions (which may cause rash or swelling).
- Small red dots on the skin where the cream was applied. This is more likely in children with skin problems such as ‘atopic dermatitis’ or ‘mollusca’.
- Eye irritation after getting cream into your eyes by mistake.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse.

## **5. How to store EMLA Cream**

- Keep out of the reach and sight of children.
- Do not store above 30°C and do not freeze.
- Do not use the EMLA Cream after the expiry date which is shown on the tube.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

## **6. Further information**

### **What EMLA Cream 5% 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 polyoxyethylene hydrogenated castor oil, Carbomer 974P, sodium hydroxide and purified water.

### **What EMLA Cream 5% looks like and contents of the pack**

EMLA Cream 5% is a white soft cream. Your cream will come in a tube containing 30 g of cream without any dressings. A wooden spatula is enclosed for applying your cream.

### **Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation for EMLA Cream 5% is held by AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, UK.

EMLA Cream 5% 30 g pack is manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

**Product name**            **EMLA Cream 5%**

**Reference number**      **17901/0120**

This is a service provided by the Royal National Institute of Blind People.

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## User Leaflet for Healthcare Professionals

### EMLA Cream 5%

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

Apply approximately 1.5–2 g/10 cm<sup>2</sup> EMLA Cream 5%, 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 Cream 5% per 100 cm<sup>2</sup> on the area of the donor site to be anaesthetised.



4. Spread the EMLA Cream 5% using the enclosed spatula 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 Cream 5%.



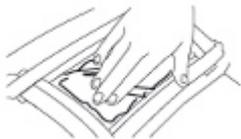
6. Smooth down and tape the edges of the occlusive film wrapping to the skin using a surgical synthetic adhesive tape.



7. Wrap the entire site using an elastic crepe bandage to protect the site and avoid leakage of the EMLA Cream 5% – but avoid undue compression and do not wrap too tight. Leave the EMLA Cream 5% 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 Cream 5% 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 Cream 5%. 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.

