

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
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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.

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.

It can also be used on adults 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.

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).

Do not use EMLA Cream on premature babies (gestational age less than 37 weeks).

Do not use EMLA Cream on babies aged 0 to 12 months who are being treated with medicines called 'sulphonamides' such as sulfamethoxazole.

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 'methaemoglobinemia'.
- 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.

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.

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.
- 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 usual dose is 2 g applied for 1 to 5 hours under a dressing.

Use on the skin before procedures on larger areas

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, 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 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 cm² (10 square centimetres) in size, applied for 15 minutes under a dressing.

Use on genital skin before minor skin surgery (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.

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 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 3-12 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**, maximum 4 hours.

Children aged 1-6 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 7-11 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.

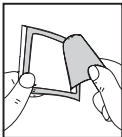
A maximum of 2 doses at least 12 hours apart may be given to children over 3 months of age in any 24 hour period.

Applying the correct dose

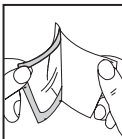
Cream applied to a circular area with a diameter of about 18 mm (a 1 pence coin) and depth of about 5 mm is equal to 1 g of EMLA cream. Alternatively, a line of cream of about 3.5 cm squeezed from the 30 g tube is equal to 1 g of cream.

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

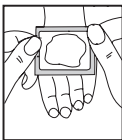
1. Squeeze the cream into a mound where it is needed on your skin (for example where the needle is going to be put in). A line of cream of about 3.5 cm is equal to 1 g of cream.
2. **Do not rub the cream in.**
3. Peel the 'centre cut-out' from the dressing.



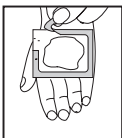
4. Peel the paper layer from the dressing.



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 'methaemoglobinaemia' (a problem with blood pigment levels). This is more likely in children and 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 in children (rare, affects less than 1 in 1,000 children) In children, the skin may become bluish-grey due to a lack of oxygen. If this happens to your child, **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.

Leaflet prepared: October 2008

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PAI 08 0067

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