Package leaflet: Information for the user
EMLA 5% w/w Cream
lidocaine/prilocaine

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness 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. See section 4.

What is in this leaflet

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

EMLA Cream contains two active substances 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, Adolescents and 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.

Adults and Adolescents

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.

Adults

It can also be used to numb the skin before:

- Cleansing or removal of damaged skin of leg ulcers.

2. What you need to know before you use EMLA Cream

Do not use EMLA Cream:

- if you are allergic to lidocaine or prilocaine, other similar local anaesthetics or any of the

other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using EMLA Cream:
- if you or your child have a rare inherited illness that affects the blood called 'glucose-6-phosphate dehydrogenase deficiency'.
- if you or your child have a problem with blood pigment levels called 'methaemoglobinaemia'.
- Do not use EMLA Cream on areas with skin rash, cuts, grazes or other open wounds, with the exception of a leg ulcer. If any of these problems are present, check with your doctor or pharmacist before using the cream.
- if you or your child have an itchy skin condition called 'atopic dermatitis', a shorter application time may be sufficient. Application times of longer than 30 minutes may result in an increased incidence of local skin reaction (see also section 4 "Possible side effects").
- if you take particular 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 the newly shaven skin, it is important to follow the recommended dosage, skin area and application time.

Avoid getting EMLA Cream in the eyes, as it may cause irritation. If you accidentally get EMLA Cream in your eye, you should immediately rinse it well with lukewarm water or salt (sodium chloride) solution. Be careful to avoid getting anything in your eye until feeling returns.

EMLA Cream should not be applied to an impaired eardrum.

When you use EMLA Cream before being vaccinated with live vaccines (e.g. tuberculosis vaccine), you should return to your doctor or nurse after the time period requested to follow-up the vaccination result.

Children and adolescents
In infants/newborn infants younger than 3 months a transient, clinically not relevant increase in blood pigment levels "methaemoglobinaemia" is commonly observed up to 12 hours after EMLA Cream is put on.

The effectiveness of EMLA Cream when drawing blood from the heel of newborn infants or to provide adequate analgesia for circumcision could not be confirmed in clinical studies.

EMLA Cream should not be applied to the genital mucosa (e.g. in the vagina) of children (below 12 years of age) owing to insufficient data on absorption of active substances.

EMLA Cream should not be used in children younger than 12 months of age who are being treated at the same time with other medicines that affect blood pigment levels "methaemoglobinaemia" (e.g. sulphonamides**,** see also section 2 Other medicines and EMLA Cream).

EMLA Cream should not be used in preterm newborn infants.

Other medicines and EMLA Cream

Tell your doctor or pharmacist if you are using / taking, have recently used / taken or might use / take 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 or pharmacist if you or your child have recently used or been given any of the following medicines:
- Medicines used to treat infections, called 'sulphonamides' and nitrofurantoin.
- Medicines used to treat epilepsy, called phenytoin and phenobarbital.
- Other local anaesthetics.
- Medicines to treat an 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 Cream in recommended doses.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Occasional use of EMLA Cream during pregnancy is unlikely to have any adverse effects on the foetus.

The active substances in EMLA Cream (lidocaine and prilocaine) are excreted 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 Cream has no or negligible influence on the ability to drive and use machines when used at the recommended doses.

EMLA Cream contains macrogolglycerol hydroxystearate
Macrogolglycerol hydroxystearate may cause skin reactions.

3. How to use EMLA Cream

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

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.
- When EMLA Cream is used on the genitals, a doctor or nurse should supervise its use.

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.

Persons frequently applying or removing cream should ensure that contact is avoided in order to prevent the development of hypersensitivity.

The protective membrane of the tube is perforated by applying the cap.

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 cream is then covered by a dressing [plastic wrap]. This is taken off just before the procedure starts. If you are applying the cream yourself, make sure that you have been given dressings by your doctor, pharmacist or nurse.
- The usual dose for adults and adolescents over 12 years is 2 g (grams).
- For adults and adolescents over 12 years put the cream on at least 60 minutes before the procedure (unless the cream is being used on the genitals). However, do not put it on more than 5 hours before.
- For children the amount of EMLA Cream used and how long depends on their age. Your doctor, nurse or pharmacist will tell you how much to use and when it should be applied.

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 from the 30 g tube is equal to 1 g of cream. Half a 5 g tube corresponds to about 2 g EMLA Cream. Do not rub the cream in.

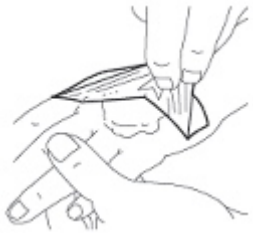
2. Peel the paper layer from the ‘centre cut-out’ of the non-adhesive side of the dressing (leaving a frame of paper).

3. Remove the cover of the adhesive side of the dressing.

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

5. Remove the paper backing. Smooth down the edges of the dressing carefully. Then leave it in place for at least 60 minutes if the skin has not been damaged. The cream should not be left in place for more than 60 minutes in children under 3 months or for more than 30 minutes in children with an itchy skin condition called ‘atopic dermatitis’. If the cream is used on the genitals or on ulcers, shorter applications times may be used as described below.

6. 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).



Use on larger areas of newly shaven skin before outpatient procedures (such as hair removal techniques):
The usual dose is 1 g of cream for each area of skin that is 10 cm² (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 cm² (600 square centimetres, e.g. 30 cm by 20 cm) in size. The maximum dose is 60 g.

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

- EMLA Cream can be used in this way on adults and adolescents over 12 years.
- The usual dose is 1.5 g to 2 g of cream for each of area of skin that is 10 cm^2 (10 square centimetres) in size.
- The cream is put on under a dressing for 2 to 5 hours.

Use on the skin prior to removal of wart-like spots called "mollusca"
- EMLA Cream can be used on children and adolescents with a skin condition called "atopic dermatitis".
- 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, nurse or pharmacist will tell you how much cream to use.

Use on genital skin before injections of local anaesthetics
- EMLA Cream can be used in this way on adults and adolescents over 12 years only.
- The usual dose is 1 g of cream (1 g to 2 g for female genital skin) for each area of skin that is 10 cm^2 (10 square centimetres) in size.
- The cream is put on under a dressing. This is done 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 Cream can be used in this way on adults and adolescents over 12 years only.
- The usual dose is 5 g to 10 g of cream for 10 minutes. A dressing is not used. The medical procedure should then start straight away.

Use on leg ulcers before cleaning or removal of damaged skin
- The usual dose is 1 g to 2 g of cream for each area of skin that is 10 cm^2 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.
- The EMLA Cream tube is intended for single use when used on leg ulcers: The tube with any remaining contents should be discarded after each occasion that a patient has been treated.

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 heartbeat. These effects may be life-threatening.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Contact your doctor or pharmacist if any of the following side effects bother you or do not seem to go away. Tell your doctor about anything else that makes you feel unwell while you are using EMLA Cream.

A mild reaction (paleness or redness of the skin, slight puffiness, initial burning or itching) may occur on the area on which EMLA is used. These are normal reactions to the cream and the anaesthetics and will disappear in a short while without any measures being needed.

If you experience any troublesome or unusual effects while you are using EMLA, stop using it and check with your doctor or pharmacist as soon as possible.

Common (may affect up to 1 in 10 people)
- 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 at the treated area during treatment of genital mucosa or leg ulcers.

Uncommon (may affect up to 1 in 100 people)
- An initially mild sensation of burning, itching or warmth at 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 (may affect up to 1 in 1,000 people)
- Allergic reactions, which in rare cases may develop into anaphylactic shock (skin rash, swelling, fever, respiratory difficulties and fainting) during treatment of skin, genital mucosa or leg ulcers.
- Methaemoglobinaemia (blood disorder) during treatment of the skin.
- Small dot-shaped bleeding on the treated area (particularly on children with eczema after longer application times) during treatment of the skin.
- Irritation of the eyes if EMLA Cream accidentally comes into contact with them during treatment of the skin.

Additional side effects in children
Methaemoglobinaemia, a blood disorder, which is more frequently observed, often in connection with overdose in newborn infants and infants aged 0 to 12 months.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta
ADR Reporting,
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store EMLA Cream

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package and tube after "EXP". The expiry date refers to the last day of that month.

Do not freeze.
Keep the tube tightly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What EMLA Cream contains

- The active substances are: lidocaine and prilocaine.
- 1 g cream contains: 25 mg lidocaine and 25 mg prilocaine.
- The other ingredients are carbomers, macrogolglycerol hydroxystearate, sodium hydroxide for pH adjustment, purified water.

What EMLA Cream looks like and contents of the pack

White, homogenous cream.
It is packed in an aluminium tube with a polypropylene cap with a piercing device.

EMLA is available in packs of:
1 tube containing 5 g cream
1 tube containing 5 g cream + 2 dressings

1 tube containing 5 g cream + 3 dressings
3 tubes containing 5 g cream + 8 dressings
5 tubes containing 5 g cream
5 tubes containing 5 g cream + 10 dressings
5 tubes containing 5 g cream + 12 dressings
1 tube containing 30 g cream

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation for EMLA 5% w/w Cream marketed in Ireland and Malta is held by Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

IE Tel: +353 (0)1 6308400

MT Tel: +356 21497982

EMLA 5% w/w Cream is manufactured by:

AstraZeneca AB, Astraallén, Gärtunaporten, (B674:5), S-151 85, Södertälje, Sweden

or

Recipharm Karlskoga AB, Björkbornsvägen 5, SE-691 33 Karlskoga, Sweden

or

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

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Emla 5% - Creme
Belgium	Emla 25mg/25mg crème
Cyprus	Emla Cream 5%
Finland	EMLA
France	EMLA 5 POUR CENT, crème
Greece	EMLA
Iceland	Emla
Ireland	EMLA 5% w/w Cream
Italy	EMLA
Luxembourg	Emla 25mg/25mg crème
Malta	EMLA 5% w/w Cream
Norway	Emla
Poland	EMLA
Spain	EMLA 25 mg/g + 25 mg/g crema
Sweden	EMLA
The Netherlands	Emla

This leaflet was last revised in January 2023.