

EMLA

Prilocaine 2.5%, Lidocaine 2.5%

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **EMLA**. It does not contain all the information that is known about **EMLA**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist will have weighed the risks of you using **EMLA** against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What EMLA is used for

EMLA is used as a local anaesthetic (i.e. for pain relief) on the skin prior to procedures. These procedures can include taking blood samples, vaccination, skin grafting, cleaning leg ulcers, inserting an intravenous catheter, minor superficial cosmetic procedures and procedures on genital skin.

EMLA is available as a cream (**EMLA Cream**) which is applied then covered with a dressing, or as a patch (**EMLA Patch**), which has the cream and dressing all ready to use.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

EMLA is a mixture of two local anaesthetics, lidocaine and prilocaine.

These local anaesthetics are combined with special agents which allow the products to pass through the skin. Once through the skin the numbing effect they produce allows minor surgical procedures to be done without you feeling any pain. However you may still experience sensations such as pressure and touch in this area.

EMLA is not addictive.

EMLA is available from your pharmacy.

Before you use EMLA

When you must not use it

EMLA should only be used on unbroken skin. Do not use **EMLA** on areas with an infection, skin rash, cuts, grazes or other open wounds, with the exception of leg ulcers. If any of these problems are present, check with your doctor or pharmacist before using **EMLA**.

If you are going to have a vaccine, tell the doctor or nurse that you have used **EMLA**. They can ensure that the specific vaccine you are to receive can be used together with **EMLA**.

Do not use **EMLA** on pre-term newborn babies.

Do not use EMLA near the eyes, as it may cause some irritation. If **EMLA** does accidentally get into your eyes, immediately rinse them with large amounts of lukewarm water and contact your doctor or pharmacist.

EMLA should not be applied inside the ear to the eardrum.

If you are pregnant or breast-feeding you should always be very careful with the use of medicines. **EMLA** has not been shown to have any harmful effects in these situations. Even so, you should always check with your doctor before using any medicine during pregnancy or breast-feeding.

Do not use after the use by (expiry) date printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you use it after the expiry date. Do not use **EMLA** if the packaging is torn or shows signs of tampering. Do not use it to treat any other complaints unless your doctor says it is safe.

Before you start to use it

You must tell your doctor or pharmacist about any of these:

1. Allergies you have to any

- Ingredients listed at the end of this leaflet
- Local anaesthetic, for example those used at the dentist
- Adhesives or sticking plasters.

If you have an allergic reaction, you may get a skin rash, hay fever or an asthma attack.

2. Any of these medical conditions

- dermatitis
- methaemoglobinaemia
- glucose-6-phosphate dehydrogenase deficiency

It may not be safe for you to use **EMLA** if you have any of these conditions.

Care should be taken when applying **EMLA** to patients with atopic dermatitis. A shorter application time, 15-30 minutes, may be sufficient. When mollusca are removed from the skin in children with atopic dermatitis, a 30 minutes application time is recommended.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- a sulphonamide antibiotic e.g. cotrimoxazole
- medicines used to treat irregular heartbeat such as amiodarone
- other local anaesthetics
- medicines that you buy at your pharmacy, supermarket or health food shop.

These medicines may affect the way **EMLA** works.

Using EMLA

How to use it

Instructions on how to use EMLA are included in the box. Please read them carefully. The instructions also give maximum doses for adults and children. Do not exceed the maximum doses.

Using EMLA Cream

Be sure to follow the instructions in the pack on how to apply the cream carefully.

Apply a thick layer of **EMLA Cream** to the skin under an **airtight dressing** such as Tegaderm® or plastic food wrap.

On skin:

Adults: For minor skin procedures on small areas of the skin (e.g. needle insertion, surgical treatment and cosmetic procedures) apply approximately ½ tube (2 g) for a minimum of 1 hour, maximum 5 hours. For procedures requiring deeper skin anaesthesia (e.g. skin biopsy) or when prescribed by your doctor prior to another procedure apply 1.5-2 g/10 cm² for a minimum of 2 hours, maximum 5 hours.

Newly shaven skin of larger body areas (maximum treated area, 600 cm² – this is an area of 30 x 20 cm, approximately the size of an A4 sheet of paper) apply approximately 1 g/10 cm² for a minimum of 1 hour, maximum 5 hours. The maximum recommended dose is 60 g of **EMLA Cream**.

Children: Minor skin procedures (e.g. needle insertion and surgical treatment), apply approximately 1 g/10cm², application time approximately 1 hour.

Neonates under the age of 3 months: Apply up to 1 g of **EMLA Cream** on a skin area no larger than 10 cm².

Infants between 3 and 11 months of age: Apply up to 2 g of **EMLA Cream** on a total skin area of no larger than 20 cm².

Children between 1-5 years: Apply up to 10 g of **EMLA Cream** on a skin area no larger than 100 cm².

Children between 6-11 years: Apply up to 20 g of **EMLA Cream** on a total skin area no larger than 200 cm².

Things you must do

Remember to apply **EMLA** to intact skin at least one hour before your procedure is due. If you do not, the procedure may hurt more than it would otherwise.

Make sure the dressing covering the **EMLA Cream** is firmly fixed, especially on young children. If **EMLA Cream** is not covered carefully it may not work effectively.

Leg ulcers in adults:

Apply a thick layer of **EMLA Cream** approximately 1-2 g/10 cm² up to a total of 10 g to the leg ulcer. Cover with an air-tight dressing. The application time should be at least 30 minutes, but up to 60 minutes may improve the anaesthesia further. Cleansing should start without delay after the removal of the **EMLA Cream**. Remove the cream with cotton gauze.

Things you must do

For leg ulcers remember to apply **EMLA Cream** 30 minutes before your ulcer is due to be cleaned. Tell your doctor exactly when you put **EMLA Cream** on. If you do not, the procedure may hurt more than it would otherwise.

If you are using **EMLA Cream** on leg ulcers, only use the tube once. Throw out any cream left in the tube after use.

Things to be careful of

Do not use **EMLA Cream** on leg ulcers for longer than 2 months without checking with your doctor or pharmacist.

Be careful not to let **EMLA Cream** get into the eyes. It may cause eye irritation. If **EMLA Cream** does get into your eyes, immediately rinse them with large amounts of water and contact your doctor or pharmacist for advice.

If you forget to use it

Apply **EMLA Cream** as soon as you realise it if it is less than one hour until you are supposed to have the procedure. Tell your doctor exactly when you put **EMLA Cream** on and they will decide when the procedure can take place.

Using EMLA Patch

Be sure to follow the instructions in the pack on how to apply **EMLA Patch** carefully.

Adults and children over 1 yr of age: one or more patches can be applied. Application time between 1 and 5 hours.

In infants under the age of 3 months: not more than one patch should be applied at the same time. Approximate application time: 1 hour (maximum).

Infants between 3 and 12 months of age, not more than 2 patches should be applied at the same time. Application time at least 1 hour and not more than 4 hours.

The size of the patch makes it less suitable for use on certain parts of the body in neonates and infants.

Things you must do

Remember to apply **EMLA Patch** to intact skin at least one hour before your procedure is due. If you do not, the procedure may hurt more than it would otherwise.

Things to be careful of

Make sure the **EMLA Patch** is firmly fixed, especially on young children.

If you forget to use it

Apply **EMLA Patch** as soon as you realise it if it is less than one hour until you are supposed to have the procedure. Tell your doctor exactly when you put **EMLA Patch** on and they will decide when the procedure can take place.

Overdose

With the recommended doses of **EMLA**, no toxic effects have been reported. However, if you use too much **EMLA** you will probably feel nervous, dizzy, have blurred vision and shaky hands.

Telephone your doctor or the National Poisons Centre on 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have used too much **EMLA**, even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using **EMLA**.

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 anaesthetics and will disappear in a short while without any measures being needed.

If any of the following happen, remove the **EMLA** and tell your doctor immediately or go to casualty at your nearest hospital:

- a rash at a spot where **EMLA** is not being used
- difficulty with breathing
- dizziness

- shaky hands
- blurred vision
- areas of the skin becoming blue.

These are very serious side effects. If you or your child have them, you may have a serious reaction to **EMLA**. You may need urgent medical attention or hospitalisation. These side effects are very rare. Some people may get other side effects while taking **EMLA**.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **EMLA**.

After using it

Storage

Keep your **EMLA** in the pack until it is time to use it. If you squeeze **EMLA Cream** out of the tube it will not keep well. Keep it in a cool dry place where the temperature stays below 30°C. Do not let it freeze. Do not store it or any other medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines. Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines. Do not leave it in the car on hot days.

Disposal

Ask your pharmacist what to do with any **EMLA** you have left over if your doctor tells you to stop using it, or you find that it has expired.

Product description

EMLA Cream contains the active ingredients:

- lidocaine 25 mg/g and prilocaine 25 mg/g

Plus

- Carboxypolymethylene
- Polyoxyl hydrogenated castor oil
- sodium hydroxide
- purified water

EMLA Cream is available in packs of 1 x 5 tubes (2 dressings), 5 x 5 g tubes (with 10 dressings) or 30 g tube.

EMLA Patch consists of two main parts: a user part and a protective liner. The user part is composed of a skin-coloured dressing with a round, white pad and a frame of adhesive tape. The white pad contains **EMLA**.

EMLA Patch contains the active ingredients: lidocaine 25 mg and prilocaine 25 mg, plus

- carboxypolymethylene,
- polyoxyl hydrogenated castor oil,
- sodium hydroxide
- purified water
- acrylate (adhesive)

EMLA Patch is available in packs of 2 and 20 patches.

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