

Patient Information Leaflet
EMLA Cream 5%
(for 5 g and pre-medication packs)
 lidocaine 2.5% and prilocaine 2.5%

Read all of this leaflet carefully before you start taking this medicine.

This medicine is available without prescription. However, you still need to use EMLA Cream 5% 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 or pharmacist.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What EMLA Cream 5% is and what it is used for
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1. What EMLA Cream 5% is and what it is used for

EMLA Cream 5% contains lidocaine and prilocaine, which belong to a group of medicines called local anaesthetics. These are medicines that can numb an area of the body.

EMLA Cream 5% is used to temporarily numb the surface of the skin. It is used for pain relief on the skin prior to procedures such as needle insertion and minor skin surgery in adults and children older than 1 year. Under the supervision of a medical professional, it may also be used to temporarily numb the genitals in adults prior to an injection or surgical treatment like removal of warts.

2. Before you use EMLA Cream 5%

Make sure you have told your doctor, pharmacist or nurse about any other medicines that you are taking, including those you have bought without prescription.

Do not use EMLA Cream 5% if you are allergic (hypersensitive) to lidocaine, prilocaine or any of the other ingredients of EMLA Cream 5%. Do not use EMLA Cream 5% for infants.

Please read the following questions carefully.

The questions below are to check that it is suitable for you to use this medicine. If you can answer **yes** to any of these, talk to your doctor, pharmacist or nurse **before** using this medicine.

- Are you or your child anaemic (a blood disorder which means you have too few red blood cells)?
- Do you or your child suffer from the rare metabolic conditions glucose-6-phosphate dehydrogenase deficiency (an inherited disorder affecting your blood) or congenital or idiopathic methaemoglobinemia (an abnormal blood pigment level that affects the movement of oxygen around your body)?
- Are you or your child taking any medication containing sulphonamides, e.g. sulfamethoxazole?
- Have you or your child recently used or been given any other local anaesthetics or medicines used to treat or prevent an irregular heartbeat, such as mexiletine or amiodorone?

Important: You should not use EMLA Cream 5% if you have had problems in the past when taking medicines containing lidocaine or prilocaine.

When using EMLA Cream 5%, it should **not** be applied to the following areas:

- cuts, grazes or wounds
- where there is a skin rash or eczema
- in or near the eyes
- inside the nose
- in the ear
- in the mouth
- in the anus (back passage)
- the genitals of children.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

The active ingredients of EMLA cream are passed into breast milk, but in such small quantities that there is generally no risk for the child.

3. How to use EMLA Cream 5%

Always use EMLA Cream 5% exactly as your doctor, pharmacist or nurse has told you to.

You should check with your doctor, pharmacist or nurse if you are not sure.

Use on the skin prior to procedures such as needle insertion and minor skin surgery

(adults and children older than 1 year):

Your doctor, pharmacist or nurse will either apply the cream or show you how much to use. The usual dose is 2 g. The cream will be applied for 1–5 hours in a thick layer under a dressing, which is removed just before the medical procedure starts.

Diagrams showing how to apply EMLA Cream 5% prior to procedures like needle insertion are in the section below. If applying the cream yourself, before you do you must get dressings from your doctor, nurse or pharmacist to use with EMLA Cream 5%. Where you apply the cream depends on the procedure that will be performed. Your doctor or nurse will tell you where you should apply the cream.

Use on the skin prior to surgical procedures on larger areas (adults and children older than 1 year):

The usual dose is 1.5–2 g/10 cm² applied for 2–5 hours under a dressing.

Use on genital skin prior to injections of local anaesthetics (adult men only):

The usual dose is 1g/10 cm² applied for 15 minutes under a dressing.

Use on genital skin prior to minor skin surgery (adults only):

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

If you feel that the effect of EMLA Cream 5% is too strong or too weak, tell your doctor, pharmacist or nurse.

You should avoid getting EMLA Cream 5% in your eyes as it may cause irritation. If you accidentally get EMLA in your eye, you should immediately rinse it well with lukewarm water or sodium chloride solution and protect it until sensation returns.


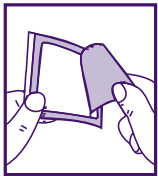

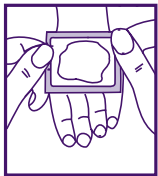
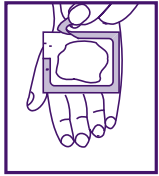
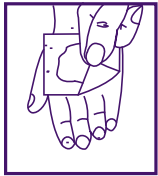
Talk to your doctor, pharmacist or nurse straight away if EMLA Cream 5% is accidentally swallowed.

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

How to apply EMLA Cream 5%

For minor procedures it is very important to follow exactly the instructions given below.

Apply EMLA Cream 5% at least 60 minutes, unless being used on the genitals, before insertion of the needle (but not more than 5 hours before).

<p>1. Squeeze the cream into a mound on the site where the needle is going to be inserted. Do not rub the cream in. A cream string of approximately 3.5 cm corresponds to 1 g of cream.</p>			<p>2. Peel the 'centre cut-out' from the occlusive dressing.</p>
<p>3. Peel the paper layer from the dressing.</p>			<p>4. Remove the covers of the dressing and place the dressing over the mound of cream. Do not spread the cream under the dressing.</p>
<p>5. Remove the plastic backing. Smooth down the edges of the dressing carefully and leave in place for at least 60 mins.</p>			<p>6. The nurse or doctor will remove the dressing just before the medical procedure starts.</p>

If you use more EMLA Cream 5% than you should

If you have used more than the recommended dose of EMLA Cream 5%, talk to your doctor, pharmacist or nurse straight away, even if you do not feel any symptoms.

Overdose with EMLA Cream 5% is unlikely to occur if it is used as recommended. Symptoms of overdose include light-headedness, dizziness, tingling of the skin around the mouth, numbness of the tongue, abnormal taste, blurred vision and ringing in the ears. In serious cases of overdose, symptoms may include fits, low blood pressure, slowed (rarely stopped) breathing and altered heart beat, which may be life-threatening.

There is also a risk of acute methaemoglobinemia, especially in children and when certain medicines have been taken at the same time. Methaemoglobinemia is characterised by a bluish-grey discolouration of the skin due to a reduced capacity of the blood to carry oxygen.

4. Possible side effects

Like all medicines, EMLA Cream 5% can cause side effects, although not everybody gets them. Common side effects (that affect less than 1 in 10 people) are redness, slight swelling, or temporary paleness of the place where the cream was used.

Uncommon side effects (that affect less than 1 in 100 people) are an initial mild burning or itching sensation (although this can become a common side effect when used on the genitals) or a tingling feeling that may occur where the cream is used.

Rare side effects (that affect less than 1 in 1000 people) include allergic reactions, which may cause rashes and swelling. In severe cases, a combination of rash, breathlessness, low blood pressure and swelling may occur, in which case you should see a doctor immediately. Bluish-grey discolouration of the skin in children may occur rarely due to a reduced capacity of the blood to carry oxygen. If this happens to your child, go and see your doctor immediately.

Other rare side effects are small red dots (petechiae) at the application site, especially in children with skin problems such as atopic dermatitis (an allergic reaction on your skin that can cause redness and swelling) or mollusca (a disease causing lumps to appear on the skin) and eye irritation after accidental eye exposure.

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

5. How to store EMLA Cream 5%

- 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 5% after the expiry date which is shown on the tube.
- Remember to return any unused medicine to your pharmacist (chemist).

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 pre-medication pack containing 5 tubes of cream and 12 dressings or in a tube containing 5 g of cream without any dressings.

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% pre-medication pack is manufactured by AstraZeneca AB, S-151 85, Södertälje, Sweden and EMLA Cream 5% 5 g pack is manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

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