

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**EMLA® Patch****Lidocaine and Prilocaine Transdermal Patch**

Read this carefully before you start taking **EMLA Patch** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **EMLA Patch**.

What is EMLA Patch used for?

EMLA Patch is used to temporarily numb small areas of skin that are slightly larger than a two dollar coin or “toonie”. It can only be used on healthy, unbroken skin:

- before getting a needle or having blood taken;
- before being vaccinated with only the following vaccines:
 - MMR (Measles-Mumps-Rubella)
 - DPTP (Diphtheria-Pertussis-Tetanus-Poliovirus)
 - *Haemophilus influenzae b*
 - Hepatitis B.

How does EMLA Patch work?

EMLA Patch contains the drugs lidocaine and prilocaine. These drugs are anesthetics and they cause a temporary numbness of the skin where the patch is applied.

What are the ingredients in EMLA Patch?

Medicinal ingredients: lidocaine 2.5% and prilocaine 2.5%

Non-medicinal ingredients: carboxypolymethylene, polyoxyethylene hydrogenated castor oil, purified water, sodium hydroxide.

The transdermal patch is made from: cellulose and cotton disc, polyethylene foam with acrylate adhesive, polyamide/aluminium/plastic and polypropylene/aluminium/plastic laminates. The patch is made with natural rubber latex.

EMLA Patch comes in the following dosage forms:

1 g transdermal patches

Each transdermal patch has a tan-coloured adhesive tape with a round white pad in the centre.

Do not use EMLA Patch if:

- you are allergic to lidocaine, prilocaine, any other “-caine” type anesthetics, or any of the non-medicinal ingredients in the product
- you have a blood disorder called methaemoglobinaemia
- it is for infants who are 12 months of age or younger and are taking drugs that may cause the blood disorder called methaemoglobinaemia (e.g. sulphonamides, used to treat infections)
- it is for infants who were born after less than 37 weeks of pregnancy
- it is for medical procedures that aren’t done in a hospital and that require many EMLA patches over a large body area

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take EMLA Patch. Talk about any health conditions or problems you may have, including if you:

- have glucose- 6-phosphate dehydrogenase deficiency
- have ever had a bad, unusual or allergic reaction to lidocaine or prilocaine, also available under brand names such as Xylocaine® (lidocaine) and Citanest® (prilocaine)
- might be sensitive or allergic to other ingredients of the patch
- have an infection, skin rash or cut at, or near, the area where you want to apply EMLA Patch
- have atopic dermatitis, eczema or any other skin problems or diseases
- have severe kidney or liver disease
- are pregnant or trying to become pregnant
- are breastfeeding. If you are breastfeeding EMLA Patch should not be applied on or near the breasts.
- are 65 years of age or older.

Other warnings you should know about:**• Risk of serious side effects**

Be careful to apply no more than the maximum recommended dose of EMLA Patch.

Serious and life threatening side effects have occurred when EMLA Patch was not used properly. This includes a serious blood disorder called methaemoglobinaemia, where the blood brings less oxygen to your body. If you develop this condition, you may have brownish or greyish skin especially around lips and nails. If your condition worsens, you can have:

- Heart problems leading to a heart attack, difficulty breathing or not breathing
- Problems with your central nervous system such as:
 - seizures
 - dizziness
 - fainting
 - feeling drowsy

Other symptoms you may have include:

- numbness of the tongue
- light-headedness
- confusion
- headache
- sight or hearing problems
- vomiting
- dizziness
- weakness
- nervousness
- unusual sweating
- trembling

If you get any of these side effects, stop taking EMLA Patch and get medical help right away.

- Children are at greater risk for serious side effects. Always follow your healthcare professional's instructions for using EMLA Patch, especially in young children and infants under 3 months old. Make sure young children don't accidentally swallow used EMLA patches. EMLA Patch should not be used on the genitals of children or infants.
- EMLA Patch should not be used close to the ear or eyes because it can cause damage.

Driving and using machines:

- Know how you feel after using EMLA Patch before you drive or use heavy machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with EMLA Patch:

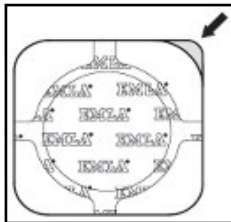
- medicines for heart rhythm problems (e.g. mexilitine, amiodarone)
- other anesthetics used to numb the skin
- other medicines which may cause methaemoglobinaemia, including: sulfonamides, acetanilide, aniline dyes, benzocaine (or other "-caine" type anesthetics), chloroquine, dapson, naphthalene, nitrates or nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenytoin, primaquine, quinine and high doses of acetaminophen

How to take EMLA Patch:

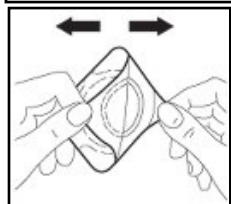
- Be careful not to apply more EMLA Patch or replace it more frequently than your healthcare professional recommended. Serious and life-threatening side effects have occurred when EMLA Patch was not used properly and more than the recommended amounts were used

- Be sure to only put EMLA Patch on unbroken skin
- Do not put EMLA Patch in your mouth or swallow it. Take special care to ensure that infants and young children do not put the patch in their mouth. If EMLA Patch is accidentally swallowed, call your healthcare professional
- Do not re-use EMLA Patch
- The numbing effect of EMLA Patch starts working about 1 hour after it is applied. You may still feel pressure and touch in the area where you applied EMLA Patch. The numbness of the skin may continue to increase after the patch is removed, and will last for at least 2 hours following a 1-2 hour application
- Tell your healthcare professional if you feel that the effect of EMLA Patch is too strong or too weak

Steps to apply EMLA Patch:



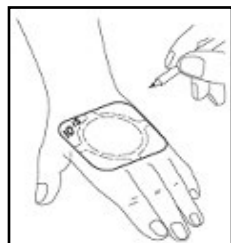
1. Make sure your skin is clear and dry. Take hold of the aluminium flap at the corner of the patch and bend it back.



2. While holding the aluminium flap, take hold of the corner of the tan-coloured patch layer. Pull the two layers apart, separating the adhesive surface from the aluminium paper backing. Do not touch the white, round pad which contains the anaesthetic.



3. Apply EMLA Patch so that the white, round pad containing the anaesthetic covers the area to be treated. Press **firmly** only around the **edges** of the patch to ensure a good adhesion to the skin. Press **gently** on the **centre** of the patch to ensure it comes into contact with the skin. It is important to make sure that the patch is firmly secured. If not, it may not be effective, or others might be accidentally exposed to the medication.



4. Mark the time of application directly on the patch with a ballpoint pen. EMLA Patch must be applied for at least 1 hour before the start of the procedure. Leave the patch on for as long as your healthcare professional recommended, at least for 1 hour. Be careful that the patch doesn't come off during the wait.

5. Remove EMLA Patch and clean the area thoroughly before the procedure. If you are applying the EMLA Patch for a procedure to be performed by a healthcare professional, you should leave it on for the healthcare professional to remove, unless instructed otherwise.
6. Throw away used EMLA Patch by carefully folding it in half so the adhesive side sticks to itself. Dispose of the used patch in the garbage out of the reach and sight of children and pets.

Usual Dose:

The dosing for adults and children is listed below. To help prevent side effects, your healthcare professional may need to adjust the usual dose if you:

- are elderly
- are acutely ill
- have severe liver or kidney disease
- are being treated with other anesthetics or certain heart drugs (e.g. mexilitine, amiodarone)
- have skin conditions such as atopic dermatitis

Adults

Apply the quantity of EMLA Patch prescribed by your healthcare professional to the specific skin area at least 1 hour before the procedure. You will not get any added benefit from leaving EMLA Patch on for longer than 5 hours.

Children

Observe your child closely during and after use of topical anesthetics, as they are at greater risk than adults for serious side effects.

When using EMLA Patch for your child's pain relief, remember it is also very important to provide comfort and emotional support.

The dosing below is based on age. Your healthcare professional may recommend a different dose for your child if their weight is less than what is typical for their age category.

- **Infants Under 3 Months:**
Do not apply the EMLA Patch to infants under 3 months of age unless a healthcare professional tells you to do so. Infants under 3 months of age are at a higher risk than older children for methaemoglobinaemia.

Apply one patch on the specific skin area for 1 hour. Do not use more patches and do not leave EMLA Patch on the skin for longer than 1 hour.

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

- **Infants Between 3 and 12 Months of Age:**
Apply one or two patches on the specific skin area for about 1 hour. Do not use more patches and do not leave EMLA Patch on the skin for more than 4 hours.
- **Children Between 1-6 Years:**
Apply one or more patches on the specific skin area for at least 1 hour. Do not use more than 10 patches and do not leave on the skin for more than 5 hours.
- **Children Between 7-12 Years:**
Apply one or more patches on the specific skin area for at least 1 hour. Do not use more than 20 patches and do not leave on the skin for more than 5 hours.

Overdose:

If you think you, or a person you are caring for, have taken too much EMLA Patch, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using EMLA Patch?

These are not all the possible side effects you may feel when taking EMLA Patch. If you experience any side effects not listed here, tell your healthcare professional.

Your skin where EMLA Patch was applied may stay numb for up to several hours after you take the patch off. Be careful to avoid hurting your skin until your skin isn't numb anymore. This includes scratching, rubbing or exposing your skin to extreme hot or cold temperatures.

The following side effects can happen to the skin where the patch was applied:

- whitening or redness
- slight swelling or puffiness
- initial burning or itching
- tingling of the skin, warmth
- small red dots or purple spots

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Methaemoglobinaemia: brownish or greyish skin especially around lips and nails.			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Eye irritation: if EMLA Patch enters the eye, immediately rinse the eye in water.			✓
Allergic reaction: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat.			✓
VERY RARE			
Central nervous system toxicity: seizures, dizziness, fainting, feeling drowsy, loss of consciousness.			✓
Cardiovascular collapse: severe chest pain and pressure, nausea, vomiting, shortness of breath, trouble breathing, stopping breathing.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep EMLA Patch well out of the reach and sight of children, even after the patch is removed and put in the garbage.
- Store EMLA Patch at room temperature (15-30°C). Protect from freezing.
- Do not use EMLA Patch after the expiry date on the carton. Remember to return any unused EMLA Patch to your pharmacist.

If you want more information about EMLA Patch:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.aspenpharma.ca, or by calling 1-844-330-1213.

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