

**EMLA<sup>®</sup> Patch**

lidocaine 2.5% and prilocaine 2.5% Patch

**PART III:  
CONSUMER INFORMATION**

This leaflet is part III of a three-part "Product Monograph" published when EMLA<sup>®</sup> Patch was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about EMLA<sup>®</sup> Patch. Contact your doctor or pharmacist if you have any questions about the drug.

Keep this leaflet to refer to until you have used up all your EMLA Patches.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- EMLA Patch should only be used according to the section **WHAT THE MEDICATION IS USED FOR** because maximum safe doses for other uses are not known.
- If your doctor has not explained how to use EMLA Patch, make sure you read and understand the section, **PROPER USE OF THIS MEDICATION**. Follow the instructions. Ask your doctor or pharmacist to explain the proper use of EMLA Patch if you do not understand these instructions. Serious and life threatening side effects have occurred when EMLA Cream was not used properly.

**WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT EMLA**

EMLA contains 2.5% lidocaine and 2.5% prilocaine.

Be careful to apply no more than the maximum recommended dose of EMLA Patch. Serious side effects from applying too much EMLA Patch can include:

- drowsiness,
- numbness of the tongue,
- brownish or greyish skin especially around lips and nails,
- light-headedness,
- confusion,
- headache,
- sight or hearing problems,
- difficulty breathing,
- vomiting, dizziness,
- weakness,

- unusually slow heart beat,
- fainting,
- nervousness,
- unusual sweating,
- trembling
- seizures

Get medical help right away, if you experience any of these side effects.

**ABOUT THIS MEDICATION**

**WHAT THE MEDICATION IS USED FOR:**

EMLA Patch is used to create a temporary loss of feeling or numbness of small areas of skin (slightly larger than a two dollar coin or "toonie") and can be used:

- prior to getting a needle or having blood taken, and only on healthy, unbroken skin;
- prior to vaccination with only the following vaccines: MMR (Measles-Mumps-Rubella), DPTP (Diphtheria-Pertussis-Tetanus-Poliiovirus), *Haemophilus influenzae b* or Hepatitis B. Since the effect of EMLA on the immune response to any other vaccine is unknown, it cannot be recommended for use with any other vaccine.

**WHAT IT DOES:**

EMLA is the brand name for a topical anesthetic that contains the drugs lidocaine and prilocaine. Topical anesthetics are used to cause a temporary loss of feeling or numbness of the skin at the area where it is applied.

**WHEN IT SHOULD NOT BE USED:**

- if you/your child have methemoglobinemia (a blood disorder);
- on infants who require methemoglobin-inducing agents (e.g., sulfonamides), and are 12 months of age or younger;
- if you are allergic to lidocaine, prilocaine, any other "-caine" type anesthetics, or any of the non-medicinal ingredients in the product (see **WHAT THE NONMEDICINAL INGREDIENTS ARE** section below);
- on infants less than 3 months of age, unless instructed by your doctor.
- for procedures requiring large amounts of EMLA over a large body area that are not conducted in a hospital.

**WHAT THE MEDICINAL INGREDIENT IS:**

lidocaine 2.5% and prilocaine 2.5%

**WHAT THE NONMEDICINAL INGREDIENTS ARE:**

EMLA Patch is composed of a tan-coloured adhesive tape with a round white pad in the centre that contains EMLA. The adhesive tape is protected with a peel-off backing which is removed before the patch is applied.

EMLA Patch also contains carboxypolymethylene, polyoxyethylene hydrogenated castor oil, and sodium hydroxide. The patch adhesive is made from acrylate. The patch does not contain latex.

**WHAT DOSAGE FORMS IT COMES IN:**

EMLA<sup>®</sup> Patch: 1 g patches

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

**EMLA Patch is for use on healthy, unbroken skin. Do not apply to open wounds, nor to burns or rashes or other skin conditions, including diaper rash.**

BEFORE you use EMLA Patch talk to your doctor or pharmacist if:

- if you/your child have glucose- 6-phosphate dehydrogenase deficiency;
- if you/your child have ever had a bad, unusual or allergic reaction to lidocaine or prilocaine, also available under brand names such as Xylocaine<sup>®</sup> (lidocaine) and Citanest<sup>®</sup> (prilocaine);
- if you think you/your child might be sensitive or allergic to other ingredients of the patch (see WHAT THE NONMEDICINAL INGREDIENTS ARE);
- if there is an infection, skin rash or cut at, or near, the area where you want to apply EMLA Patch;
- if you/your child have dermatitis or any other skin problems or diseases;
- if you/your child have severe kidney or liver disease (see PROPER USE OF THIS MEDICATION);
- if you are pregnant, trying to become pregnant or are breastfeeding.

**INTERACTIONS WITH THIS MEDICATION**

Tell your doctor or pharmacist about any other drugs you take, or have recently taken including the ones you can buy without a prescription, including:

- antiarrhythmic drugs for heart problems (e.g. mexilitine, amiodarone);
- other anesthetics;
- other drugs which may trigger methemoglobin formation, including: sulfonamides, acetanilide, aniline dyes, benzocaine (or other “-caine” type anesthetics), chloroquine, dapsone, naphthalene, nitrates or nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenytoin, primaquine, quinine and high doses of acetaminophen.

**PROPER USE OF THIS MEDICATION**

**USUAL DOSE:**

Do not apply the EMLA Patch to infants under 3 months of age unless a doctor tells you to do so. Infants under 3 months of age are at a higher risk than older children for methemoglobinemia. This is a condition in which there is not enough oxygen in the blood, and it can be caused by an overdose of EMLA.

If your doctor tells you to use EMLA Patch, follow your doctor's instructions for use. In any other situation, follow the directions below.

Do not put EMLA Patch near the eyes, as it may cause some irritation. If you accidentally get EMLA in the eye, rinse it well with lukewarm water and protect it until sensation returns.

Do not apply EMLA Patch inside the ear. 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 an EMLA Patch is accidentally swallowed, call your doctor.

Do not re-use EMLA Patch.

The numbing effect of EMLA starts working about 1 hour after it is applied. You may still feel pressure and touch in the area where you apply EMLA. 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.

**Conditions where adjustments in dose may be required:**

- elderly patients
- acutely ill patients
- patients with severe liver disease
- patients with severe kidney disease
- patients also treated with other anesthetics or certain antiarrhythmic drugs (e.g. mexilitine, amiodarone)

EMLA should be used with caution in these patients, who may be more sensitive to the effects of lidocaine and prilocaine.

**Adults**

**Be careful not to apply more EMLA Patch or replace it more frequently than the doctor recommended.**

Serious and life threatening side effects have occurred when EMLA Cream was not used properly and more than the recommended amounts were applied.

EMLA Patch must be applied for at least 1 hour before the procedure. You will not get any added benefit from leaving EMLA Patch on for longer than 5 hours.

**Pediatrics**

**Be careful not to apply more EMLA Patch or replace it more frequently than the doctor recommended.**

**Children should be closely observed during and after use of topical anesthetics, as they are at greater risk than adults for serious side effects, such as methemoglobinemia (a blood disorder that causes the skin, especially around lips and nails, to turn brownish or greyish). See also SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM.**

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

**Infants Under 3 Months (ONLY IF INSTRUCTED BY A DOCTOR):**

Do not use more than one EMLA Patch at the same time. Leave the patch on for 1 hour. 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:**

Do not use more than two EMLA Patches at the same time. Leave the patch on for at least 1 hour. Do not leave EMLA Patch on the skin for more than 4 hours.

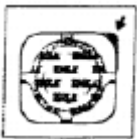
**Children Between 1-6 Years:**

Apply one or more patches to the skin area selected for 1 hour. Do not leave on the skin for more than 5 hours. Apply up to 10 patches.

**Children Between 7-12 Years:**

Apply one or more patches to the skin area selected for at least 1 hour. Do not leave on the skin for more than 5 hours. Apply up to 20 patches.

**INSTRUCTIONS FOR APPLICATION OF 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 EMLA.



3. Apply EMLA patch so that the white, round pad containing EMLA 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 that EMLA 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. Care should be taken that the patch does not become detached during the 1 hour 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 doctor, you should leave it on for the doctor to remove, unless instructed otherwise.

Throw away used EMLA Patch by carefully folding in half so the adhesive side sticks to itself and dispose in the garbage out of the reach of children and pets.

**OVERDOSE:**

In case of EMLA overdose or if you think you, or anyone else, are experiencing any of the side effects described below or methemoglobinemia, contact your doctor, hospital emergency department or regional Poison Control Centre immediately. You may require medical attention.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like any medication, EMLA Patch may result in side effects in some people.

The skin to which EMLA Patch is applied may stay numb for up to several hours after the cream is removed. For this reason, you should be careful to avoid accidental injury to the treated area, such as scratching, rubbing or exposure to extreme hot or cold temperatures, until complete sensation returns.

Mild side effects that are common with use of EMLA are whitening or redness of the skin, slight puffiness, and initial burning or itching on the skin where EMLA is applied. These are normal reactions and will disappear without any treatment.

Allergic reactions to the active ingredients have been seen but are rare.

Medicines affect different people in different ways. Just because side effects have occurred in some patients, does not mean that you will get them. *If any side effects bother you, or if you experience any unusual effects while you are using EMLA, stop using it. Talk to your doctor or pharmacist as soon as possible.*

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency help
		Only if severe	In all cases	
<b>Rare</b>	Methemoglobinemia [reduced oxygen to body tissues causing brownish or greyish skin especially around lips and nails]			X
<b>Rare</b>	Eye irritation			X*
<b>Rare</b>	Allergic reaction			X

\*If EMLA Patch accidentally enters the eye, immediately rinse the eye in water or sodium chloride solution and protect the eye until sensation returns. Contact your doctor or pharmacist.

*This is not a complete list of side effects. For any unexpected effects while taking EMLA Patch, contact your doctor or pharmacist.*

EMLA Patch can cause serious side effects if too much is applied. These include drowsiness, numbness of the tongue, discoloured skin, light-headedness, confusion, headache, sight or hearing problems, difficulty breathing, vomiting, dizziness, weakness, unusually slow heart beat, fainting, nervousness, unusual sweating, trembling or seizures. Stop taking the drug and seek immediate emergency help if you experience any of these side effects. Irritation may occur when eyes are accidentally exposed to EMLA.

If someone using EMLA shows these signs, or any other sign of being unwell, they should seek immediate medical attention.

Methemoglobinemia

EMLA Patch, in extremely rare cases, can affect the level of oxygen that the blood carries, resulting in an increase in the methemoglobin level in your blood. This condition, known as methemoglobinemia, causes the colour of the skin to become brownish or greyish, especially around the lips, fingernails and toenails. If you see this happening, go to the nearest hospital right away.

**HOW TO STORE IT**

Keep EMLA Patch well out of the reach of children. Store EMLA Patch at room temperature. Protect from freezing.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

Call toll-free at: 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

-Fax toll-free to: 1-866-678-6789 or,

-Mail to: Canada Vigilance Program

Health Canada

Postal Locator 0701C

Ottawa ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

**NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.**

**MORE INFORMATION**

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

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: [www.astrazeneca.ca](http://www.astrazeneca.ca) under Patients with Prescriptions, or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries – 1(800) 668-6000, Renseignements – 1(800) 461-3787.

This leaflet was prepared by AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4

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**EMLA<sup>®</sup> Cream**  
lidocaine 2.5% and prilocaine 2.5% Cream

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Keep this leaflet to refer to until you have used up all your EMLA Cream.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- EMLA Cream should only be used according to the section **WHAT THE MEDICATION IS USED FOR** because maximum safe doses for other uses are not known. Applying EMLA Cream on large areas of skin can result in a medical emergency.
- If your doctor has not explained how to use EMLA Cream, make sure you read and understand the section, **PROPER USE OF THIS MEDICATION**. Follow the instructions. Ask your doctor or pharmacist to explain the proper use of EMLA Cream if you do not understand these instructions. Serious and life threatening side effects have occurred when EMLA Cream was not used properly.

### WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT EMLA

EMLA contains 2.5% lidocaine and 2.5% prilocaine.

Be careful to apply no more than the maximum recommended dose of EMLA Cream. Serious and life threatening side effects have occurred when EMLA cream was used on large areas of skin for topical analgesia during cosmetic procedures. Serious side effects from applying too much EMLA Cream can include:

- drowsiness,
- numbness of the tongue,
- brownish or greyish skin especially around lips and nails,
- light-headedness,
- confusion,
- headache,

- sight or hearing problems,
- difficulty breathing,
- vomiting, dizziness,
- weakness,
- unusually slow heart beat,
- fainting,
- nervousness,
- unusual sweating,
- trembling
- seizures

Get medical help right away, if you experience any of these side effects.

### ABOUT THIS MEDICATION

#### WHAT THE MEDICATION IS USED FOR:

EMLA Cream is used to create a temporary loss of feeling or numbness of the skin, and can be used:

- on healthy, unbroken skin before minor skin surgery, or when getting a needle or having blood taken;
- prior to vaccination with only the following vaccines: MMR (Measles-Mumps-Rubella), DPTP (Diphtheria-Pertussis-Tetanus-Poliovirus), *Haemophilus influenzae* b or Hepatitis B;
- on the genital mucosa;
- for the cleansing of leg ulcers.

For best results talk to your doctor before using the cream on the genital mucosa or for leg ulcers.

#### WHAT IT DOES:

EMLA is the brand name for a topical anesthetic that contains the drugs lidocaine and prilocaine. Topical anesthetics are used to cause a temporary loss of feeling or numbness of the skin at the area where it is applied.

#### WHEN IT SHOULD NOT BE USED:

- if you/your child have methemoglobinemia (a blood disorder);
- on infants who required methemoglobin-inducing agents (e.g., sulfonamides) and are 12 months of age or younger;
- if you/your child are allergic to lidocaine, prilocaine, any other "-caine" type anesthetics, or any of the non-medicinal ingredients in the product (see **WHAT THE NONMEDICINAL INGREDIENTS ARE** section below);
- on infants less than 3 months of age, unless instructed by your doctor.
- for procedures requiring large amounts of EMLA over a large body area that are not conducted in a hospital.

#### WHAT THE MEDICINAL INGREDIENT IS:

lidocaine 2.5% and prilocaine 2.5%

**WHAT THE NONMEDICINAL INGREDIENTS ARE:**

EMLA Cream also contains carboxypolymethylene, polyoxyethylene hydrogenated castor oil, and sodium hydroxide.

Tegaderm™ dressings contain polyether polyurethane films, acrylate adhesives and paper liners. These dressings are hypoallergenic and do not contain latex. (Tegaderm™ dressings are supplied with the 5 g EMLA Cream tube only).

**WHAT DOSAGE FORMS IT COMES IN:**

EMLA® Cream: 5 g and 30 g tubes

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

**EMLA Cream is for use on healthy, unbroken skin. Do not apply to open wounds, nor to burns or rashes or other skin conditions, including diaper rash.**

BEFORE you use EMLA Cream talk to your doctor or pharmacist if:

- if you/your child have glucose-6-phosphate dehydrogenase deficiency;
- if you/your child 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);
- if you think you/your child may be sensitive or allergic to other ingredients of the cream or Tegaderm™ dressing (see WHAT THE NONMEDICINAL INGREDIENTS ARE);
- if there is an infection, skin rash or cut at, or near, the area where you want to apply EMLA Cream;
- if you/your child have dermatitis or any other skin problems or diseases;
- if you/your child have severe kidney or liver disease (see PROPER USE OF THIS MEDICATION);
- if you are pregnant, trying to become pregnant or are breastfeeding;
- if you would like to use EMLA Cream prior to treatment of a leg ulcer(s);
- if you would like to use EMLA Cream on the genital area of children.

**INTERACTIONS WITH THIS MEDICATION**

Tell your doctor or pharmacist about any other drugs you take or have recently taken, including the ones you can buy without a prescription, including:

- antiarrhythmic drugs for heart problems (e.g. mexilitine, amiodarone);
- other anesthetics;

- other drugs which may trigger methemoglobin formation, including: sulfonamides, acetanilide, aniline dyes, benzocaine (or other “-caine” type anesthetics), chloroquine, dapsone, naphthalene, nitrates or nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenytoin, primaquine, quinine and high doses of acetaminophen.

**PROPER USE OF THIS MEDICATION**

**USUAL DOSE:**

If your doctor tells you to use EMLA Cream, follow your doctor's instructions for use. In any other situation, follow the directions below.

Do not put EMLA Cream near the eyes, as it may cause some irritation. If you accidentally get EMLA in the eye, rinse it well with lukewarm water and protect it until sensation returns.

Do not apply EMLA Cream inside the ear. Do not put EMLA Cream in the mouth, or swallow it. If EMLA Cream is accidentally swallowed, call your doctor.

Do not re-use EMLA Cream or dressings.

The numbing effect of EMLA starts working about 1 hour after it is applied. You may still feel pressure and touch in the area where you apply EMLA. The numbness of the skin may continue to increase after the cream is removed, and will last for at least 2 hours following a 1-2 hour application.

**Conditions where adjustments in dose may be required:**

- elderly patients
- acutely ill patients
- patients with severe liver disease
- patients with severe kidney disease
- patients also treated with other anesthetics or certain antiarrhythmic drugs (e.g. mexilitine, amiodarone)

EMLA should be used with caution in these patients, who may be more sensitive to the effects of lidocaine and prilocaine.

**Adults**

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

**Serious and life threatening side effects have occurred when EMLA cream was used on large areas of skin for topical analgesia during cosmetic procedures.**

**DOSAGE OF EMLA CREAM ON HEALTHY SKIN**

For minor procedures on skin such as surgical treatment of lesions or when getting a needle or having blood taken, apply a

thick layer of cream, about half of a 5 g tube (2 g), on an area slightly larger than a two dollar coin or "toonie". After covering EMLA Cream with an air-tight dressing, leave on for at least 1 hour. It is important to cover EMLA Cream with an air-tight dressing to ensure that the cream penetrates the skin properly and numbness of the area is felt.

Your doctor may use EMLA Cream on larger areas for such procedures as split-skin grafting. If you are instructed by the doctor to apply EMLA Cream yourself for this procedure, apply a thick layer of cream to the area to be treated (about 1.5 to 2 g/10 cm<sup>2</sup>; 1.5 to 2 g is about half of a 5 g tube; a 10 cm<sup>2</sup> area is a little larger than the size of a two dollar coin or "toonie"). Make sure your doctor has clearly explained the size of the area to be treated. Leave the EMLA Cream on for at least 2 hours.

You will not get any added benefit from leaving EMLA Cream on for longer than 5 hours.

1 g of EMLA cream administered from the 30 g aluminium tube is equivalent to a ribbon of cream of approximately 3.5 cm (or approximately 1.5 inches).

#### **DOSAGE OF EMLA CREAM ON LEG ULCERS**

Talk to your doctor **before** using EMLA Cream on leg ulcers.

For topical anesthesia before cleansing of leg ulcer(s), apply a thick layer of EMLA Cream over the leg ulcer(s), about 1 to 2 g/10 cm<sup>2</sup> (a little larger than the size of a two dollar coin or "toonie"). Use no more than 10 g (two 5 g tubes).

After covering EMLA Cream with an air-tight dressing, leave on the leg ulcer for at least 30 minutes. Leaving EMLA Cream on for 60 minutes may improve the anesthesia. The cleansing of the leg ulcer should begin within 10 minutes after removing the cream.

#### **DOSAGE OF EMLA CREAM ON GENITAL MUCOSA**

Talk to your doctor **before** using EMLA Cream on the genital mucosa. For best results, do not apply EMLA Cream on the genital mucosa until you are with your doctor.

For needle insertion, use half of a 5 g tube (2 g) at the selected site before the procedure.

For the surgical treatment of small lesions, such as the removal of genital warts or when having a biopsy, use about half of a 5 g tube (2 g) per lesion 5 to 10 minutes before the procedure.

You do not need an airtight dressing when using EMLA Cream on the genital mucosa. Your doctor should begin the surgical procedure immediately after removing the cream.

#### **Pediatrics**

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

**Children should be closely observed during and after use of topical anesthetics, as they are at greater risk than adults for serious side effects, such as methemoglobinemia (a blood disorder that causes the skin, especially around lips and nails, to turn brownish or greyish). See also SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM.**

For children under the age of 6: take care not to apply more EMLA Cream or give it more frequently than the doctor recommended. Please make sure that your child does not ingest any of the cream.

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

For minor skin procedures. It is important to cover EMLA Cream with an air-tight dressing to ensure that the cream penetrates the skin properly and numbness of the area is felt.

In children, EMLA Cream should only be applied to healthy, unbroken skin.

Do not apply EMLA Cream to infants under 3 months of age unless a doctor tells you to do so. Infants under 3 months of age are at a higher risk than older children for methemoglobinemia. This is a condition in which there is not enough oxygen in the blood, and it can be caused by an overdose of EMLA.

#### **Neonates Under the Age of 3 Months (ONLY IF INSTRUCTED BY A DOCTOR):**

Apply up to 1 g of cream on a skin area not larger than 10 cm<sup>2</sup> (a little larger than the size of a two dollar coin or "toonie"). After covering EMLA cream with an air-tight dressing, leave on for 1 hour. **DO NOT LEAVE EMLA ON THE SKIN FOR LONGER THAN 1 HOUR.**

#### **Infants Between 3 and 12 Months of Age:**

Apply up to 2 g of cream on a total skin area not larger than 20 cm<sup>2</sup> (a little larger than the size of a credit card). After covering EMLA Cream with an air-tight dressing, leave on for at least 1 hour. Do not leave on the skin for more than 4 hours.

#### **Children Between 1-6 Years:**

Apply up to 10 g of cream on a total skin area not larger than 100 cm<sup>2</sup> (a little larger than the size of two credit cards). After covering EMLA Cream with an air-tight dressing, leave on for at least 1 hour. Do not leave on the skin for more than 5 hours.

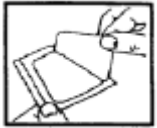
**Children Between 7-12 Years:**

Apply up to 20 g of cream on a total skin area not larger than 200 cm<sup>2</sup> (a little larger than a standard postcard). After covering EMLA Cream with an air-tight dressing, leave on for at least 1 hour. Do not leave on the skin for more than 5 hours.

**INSTRUCTIONS FOR APPLICATION ON INTACT SKIN AND LEG ULCERS**



1. Make sure your skin is clean and dry. Apply cream in a thick layer at the site of the procedure. Do **not** rub the cream into the skin.



2. Cover treated area with an air-tight dressing such as Tegaderm™ or plastic wrap. Tegaderm™ is provided with the 5 g tubes only. If using Tegaderm™ remove the center cut-out piece as shown. Peel the paper liner from the paper-framed dressing.



3. Carefully cover the EMLA cream so that you are left with a thick layer of cream underneath the dressing. Do not spread out the cream. Smooth down the dressing edges carefully and make sure it is secure to prevent leakage. If using plastic wrap, hold the dressing in place with adhesive or medical tape and make sure it is air-tight.



4. If using Tegaderm™, remove the paper frame. The time of application can easily be marked directly on the Tegaderm™ with a ballpoint pen. If using plastic wrap, mark the time of application on the medical tape that is holding the dressing in place.



5. Remove the dressing and clear the area of excess cream thoroughly before the procedure. If you are applying the EMLA cream for a procedure to be performed by a doctor, you should leave the dressing on for the doctor to remove, unless otherwise instructed.

**OVERDOSE:**

In case of EMLA overdose or if you think you, or anyone else, are experiencing any of the side effects described below or methemoglobinemia, contact your doctor, hospital emergency department or regional Poison Control Centre immediately. You may require medical attention.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like any medication, EMLA Cream may result in side effects in some people.

The skin to which EMLA Cream is applied may stay numb for up to several hours after the cream is removed. For this reason, you should be careful to avoid accidental injury to the treated area, such as scratching, rubbing or exposure to extreme hot or cold temperatures, until complete sensation returns.

Mild side effects that are common with use of EMLA are whitening or redness of the skin, slight puffiness, and initial burning or itching on the skin where EMLA is applied. These are normal reactions and will disappear without any treatment. Allergic reactions to the active ingredients have been seen but are rare.

Rare cases of small red dots (petechiae) at the application site have been reported, especially in children with skin problems (atopic dermatitis or mollusca).

Medicines affect different people in different ways. Just because side effects have occurred in some patients, does not mean that you will get them. *If any side effects bother you, or if you experience any unusual effects while you are using EMLA, stop using it. Talk to your doctor or pharmacist as soon as possible.*

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency help
		Only if severe	In all cases	
Rare	Methemoglobinemia [reduced oxygen to body tissues causing brownish or greyish skin especially around lips and nails]			X
Rare	Eye irritation			X*
Rare	Allergic reaction			X

\*If EMLA Cream accidentally enters the eye, immediately rinse the eye in water or sodium chloride solution and protect the eye until sensation returns. Contact your doctor or pharmacist.

***This is not a complete list of side effects. For any unexpected effects while taking EMLA Cream, contact your doctor or pharmacist.***

EMLA Cream can cause serious side effects if too much is applied. These include drowsiness, numbness of the tongue, discoloured skin, light-headedness, confusion, headache, sight or hearing problems, difficulty breathing, vomiting, dizziness, weakness, unusually slow heart beat, fainting, nervousness, unusual sweating, trembling or seizures. Stop taking the drug and seek immediate emergency help if you experience any of these side effects. Irritation may occur when eyes are accidentally exposed to EMLA.

If someone using EMLA shows these signs, or any other sign of being unwell, they should seek immediate medical attention.

**Methemoglobinemia**

EMLA Cream, in extremely rare cases, can affect the level of oxygen that the blood carries, resulting in an increase in the methemoglobin level in your blood. This condition, known as methemoglobinemia, causes the colour of the skin to become brownish or greyish, especially around the lips, fingernails, and toenails. If you see this happening, go to the nearest hospital right away.

**HOW TO STORE IT**

Keep EMLA Cream well out of the reach of children. Store EMLA Cream at room temperature. Protect from freezing.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

Call toll-free at: 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

-Fax toll-free to: 1-866-678-6789 or,

-Mail to: Canada Vigilance Program

Health Canada

Postal Locator 0701C

Ottawa ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

***NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.***

**MORE INFORMATION**

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

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: [www.astrazeneca.ca](http://www.astrazeneca.ca) under Patients with Prescriptions, or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries – 1(800) 668-6000, Renseignements – 1(800) 461-3787.

This leaflet was prepared by AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4

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