1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

EMLA PATCH 25 mg/ 25 mg Transdermal therapeutic system

Lidocaine, Prilocaine

Read all of this leaflet carefully because it contains important information for you

EMLA PATCH is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use EMLA PATCH carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share EMLA PATCH with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve within a few days.

What is in this leaflet

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

EMLA PATCH is local anaesthetic which is used for pain relief on the skin prior to procedures such as needle insertion, minor and superficial skin surgery.

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

Do not use EMLA PATCH:

- if you are hypersensitive (allergic) to lidocaine, prilocaine or any other ingredients of EMLA PATCH, or to any local anaesthetics.
- in infants younger than 12 months who are being treated at the same time with other medicines that affect methaemoglobin levels in the blood. Ask your doctor, pharmacist or other healthcare provider.

Warnings and precautions

Take special care with EMLA PATCH:

- If you have had an allergic, unpleasant or unusual reaction to EMLA PATCH or to any other medicine.
- Do not use EMLA PATCH on areas with skin rash, cuts, grazes or other open wounds. If any of these problems are present, check with your doctor or pharmacist before using the patch.
- Avoid getting EMLA PATCH in the eyes, as it may cause irritation. If you accidentally get EMLA PATCH in your eye, you should immediately rinse it well with lukewarm water or sodium chloride solution and protect it until sensation returns.
- If you have one of the rare metabolic conditions, glucose-6-phosphate dehydrogenase deficiencies or congenital or idiopathic methaemoglobinaemia, as this increases the risk of medicine-induced methaemoglobinaemia (see section 4).

Methaemoglobinaemia is a condition where an excess of haemoglobin has changed into methaemoglobin. If too much methaemoglobin is formed, it becomes more difficult for the blood to provide the body with oxygen.

Children and adolescents

An increase in the fraction of haemoglobin in the blood (methaemoglobin fraction) can be noticeable up to 12 hours after an application of EMLA PATCH in neonates younger than 3 months. Signs include slight discolouration (e.g pale, gray or blue) of the skin and a fast heart beat (tachycardia).

Other medicines and EMLA PATCH

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Dapsone, nitrites, sulphonamides, other local anaesthetics such as tocainide, cimetidine or beta-blockers.

EMLA PATCH with food

Not applicable

Pregnancy, breastfeeding and fertility

There is no experience with safe use of EMLA PATCH during pregnancy.

You can use EMLA PATCH while breastfeeding provided that you do not apply it directly to the breast where it can be swallowed (ingested) by the breastfeeding infant.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice

before using this medicine.

Driving and using machines

EMLA PATCH has no effect on the ability to drive and use machines.

You should not drive, use machinery or perform any tasks that require concentration until you are certain that EMLA PATCH does not adversely affect your ability to do so safely (see section 4).

3. How to use EMLA PATCH

Always use EMLA PATCH exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Your doctor, nurse or other healthcare provider will apply EMLA PATCH or will explain how to use it according to the condition that you are receiving treatment for. The dosage prescribed to you is individualised according to the condition being treated, or for the procedure being done on you.

If you develop any allergic reaction you should remove the patch immediately.

Do not share medicines prescribed for you with any other person.

Adults and adolescents*:*

One or more patches are applied to the skin areas selected for a minimum of 1 hour, maximum 5 hours.

Children:

Newborn infants and infants under the age of 3 months:

One patch is applied to the skin area selected for 1 hour, not more. Not more than one EMLA PATCH should be applied at the same time. The size of the patch makes it less suitable for use on certain parts of the body in neonates and infants.

Infants aged 3 to11 months:

The patch is applied to the skin area selected for 1 hour, maximum 4 hours. Not more than two EMLA patches should be applied at the same time.

Toddlers and children aged 1 to 5 years:

The patch is applied to the skin area selected for 1 hour, maximum 5 hours. Maximum dose: 10 patches.

Children aged 6 to 11 years:

The patch is applied to the skin area selected for 1 hour, maximum 5 hours. Maximum dose: 20 patches.

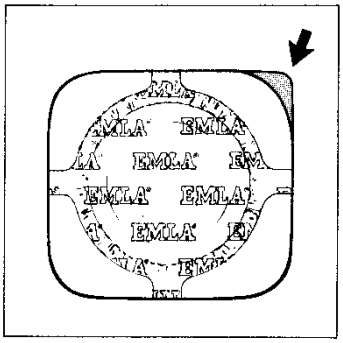
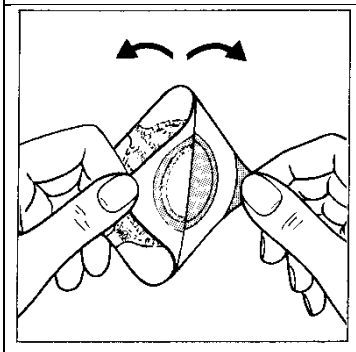
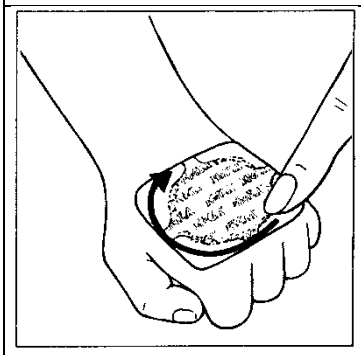
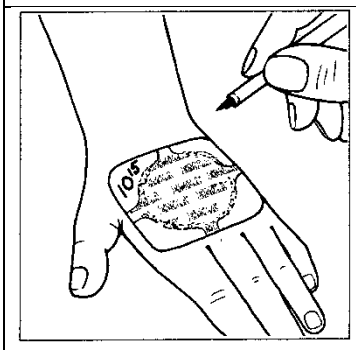
Special skin problems

If you have skin problems such as atopic dermatitis or mollusca, a shorter application time, 15 to 30 minutes, may be sufficient. When mollusca are removed from the skin in children with atopic dermatitis, a 30 minutes application time of EMLA PATCH is recommended.

If you feel that the effect of EMLA PATCH is too strong or too weak, tell your doctor or pharmacist.

DIRECTIONS FOR USE:

EMLA PATCH must be applied at least *1 hour* before the start of the procedure. (If necessary, shave the area prior to application).

	1. Make sure that the area of skin to be anaesthetised is clean and dry. Take hold of the aluminium flap at the corner of the patch and bend it backwards. Next, take hold of the corner of the skin-coloured patch layer.
	2. Pull the two layers apart, separating the adhesive surface from the protective liner, as shown. Make sure that you do not touch the white round pad, which contains EMLA.
	**3.** Do not press on the centre of the patch. This may cause EMLA to spread under the adhesive. **Press firmly around the edges to ensure good adhesion to the skin.**
	4. The time of application may be easily marked directly on the patch (a ballpoint pen may be used for this purpose).

If you use more EMLA PATCH than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Signs of overdosage are: numbness of the lips and around the mouth, light-headedness, dizziness and sometimes blurred vision.

When too much EMLA PATCH have been used, there is a risk of acute methaemoglobinaemia, especially in children and when certain medicines have been taken at the same time. (A small amount of haemoglobin is normally present in the blood in a modified form called methaemoglobin. Methaemoglobinaemia is a condition where an excess of haemoglobin has changed into methaemoglobin. If too much methaemoglobin is formed, it becomes more difficult for the blood to provide the body with oxygen.)
Methaemoglobinaemia is characterised by a slate-grey cyanosis (a bluish-grey discoloration of the skin).

If you forget to use EMLA PATCH

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

EMLA PATCH can have side effects.
Not all side effects reported for EMLA PATCH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EMLA PATCH, please consult your healthcare provider for advice.
If any of the following happens, stop using EMLA PATCH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,

These are all very serious side effects. If you have them, you may have had a serious reaction to EMLA PATCH. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Methaemoglobinaemia (bluish grey discolouration of the skin).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Cases of small red dots (petechiae) at the application site, especially in children with skin problems (atopic dermatitis or mollusca).

Less frequent side effects

- Eye irritation when the eyes accidentally have been exposed to EMLA PATCH.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/Publications/Index/8.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of EMLA PATCH.

5. How to store EMLA PATCH

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not store in a fridge or freezer.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EMLA PATCH contains

The active substances are 25 mg of lidocaine and 25 mg of prilocaine.

The other ingredients are carbomer, macrogolglycerol hydroxystearate, sodium hydroxide (for pH adjustment) and purified water.

Adhesive: Acrylate

What EMLA PATCH looks like and contents of the pack

EMLA PATCH consists of 2 main parts: an occlusive dressing (user part) and a protective liner (closure part).

The user part is composed of an absorbent white or off-white circular cellulose disc with a diameter of 3,5 cm, affixed to a thin, flexible backing (aluminium/plastic laminate) equipped with an adhesive tape around the cellulose disc. The cellulose disc is impregnated with 1 g of EMLA 5 % emulsion.

The closure part is composed of a closure laminate (aluminium/plastic laminate) comprising a recessed portion for the cellulose disc and a release liner for the adhesive. There is a hermetic peel-off seal between the backing and the closure laminate around the cellulose disc.

EMLA PATCH is in cardboard boxes containing 2 patches per box.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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30/4/0478

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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