

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using LMX4®?

LMX4® contains the active ingredient lidocaine (lignocaine). LMX4® is used for topical anaesthesia of intact skin prior to superficial skin procedures, including insertion of IV catheters and blood sampling.

For more information, see Section 1. Why am I using LMX4®? in the full CMI.

2. What should I know before I use LMX4[®]?

Do not use if you have ever had an allergic reaction to LMX4® or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use LMX4®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LMX4® and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use LMX4®?

- Adults, the elderly and children 1 year of age and older: Apply up to 1g to 2.5g of cream onto the skin where venous cannulation or venipuncture will occur.
- Full term neonates and infants up to 1 year of age: Apply up to 1g of cream onto the skin where venous cannulation or venipuncture will occur. Not more than 1g of cream should be applied to infants below the age of 1 year.

More instructions can be found in Section 4. How do I use LMX4®? in the full CMI.

5. What should I know while using LMX4[®]?

Things you must do	 Remind any doctor, dentist or pharmacist you visit that you are using LMX4®. Remember to apply LMX4® on intact skin at least half an hour (30 minutes) before your procedure is due.
Things you must not do	 Do not apply LMX4® to damaged or diseased skin. LMX4® is for external use only. Do not use LMX4® to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you.
Things to be careful of	 Be careful not to let LMX4® get into your eyes. Be careful not to inadvertently injure the anaesthetised area where LMX4® has been applied.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how LMX4® affects you.
Looking after your medicine	 Keep the cream in the carton until it is time to use it Keep it in a cool dry place where the temperature stays below 25°C. Do not freeze, do not refrigerate.

For more information, see Section 5. What should I know while using LMX4®? in the full CMI.

6. Are there any side effects?

Local reaction such as itching, swelling, paleness, redness or a burning sensation are common side effects of LMX4®. They are usually mild and short-lived. A rash at a spot where LMX4® is not being used or difficulty breathing, are very serious side effects which may require urgent medical attention or hospitalisation.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

LMX4®

WARNING: FOR EXTERNAL USE ONLY. DO NOT APPLY NEAR EYES. NOT TO BE USED ON BROKEN SKIN. Do not apply to large areas of the body except on the advice of a healthcare practitioner. If skin irritation occurs, stop immediately and seek medical attention. Also contains benzyl alcohol as a preservative.

LMX4®

Active ingredient(s): *lidocaine (lignocaine)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using LMX4°. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LMX4°.

Where to find information in this leaflet:

- 1. Why am I using LMX4®?
- 2. What should I know before I use LMX4®?
- 3. What if I am taking other medicines?
- 4. How do I use LMX4[®]?
- 5. What should I know while using LMX4[®]?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using LMX4®?

LMX4® contains the active lidocaine (lignocaine). LMX4® belongs to a group of medicines called local anaesthetics. It works by numbing the area where the cream has been applied.

LMX4® is used for topical anaesthesia of intact skin prior to superficial skin procedures, including insertion of IV catheters and blood sampling.

Ask your doctor if you have any questions about this medicine.

Your doctor may have given it for another reason.

LMX4® is not addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

2. What should I know before I use LMX4[®]?

Warnings

Do not use LMX4® if you or your child have an allergy to:

- LMX4®, or any of the ingredients listed at the end of this leaflet.
- Any medicine containing lignocaine.
- Any other similar medicines (other local anesthetics, for example those used at the dentist).
- Adhesives or sticking plasters

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- · Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the hody
- Rash, itching or hives on the skin

Do not use this medicine on premature babies.

Safety and effectiveness in infants who are not full term, have not been established.

Do not use LMX4® after the expiry date printed on the pack or if the packing is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should use LMX4®, talk to your doctor.

Before you start to use it

Tell your doctor if you or your child have allergies to any other medicine, foods, preservatives, or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- You are acutely ill or elderly (you will be more sensitive to lignocaine)
- You have severe liver (hepatic) disease

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

The ingredients in LMX4® have been used for many years and no ill effects have been shown if they are used while you are pregnant.

Only very small amounts of LMX4® get into the blood, so even though your baby can take LMX4® from breast milk if

LMX4[®]

you are breast feeding, it is unlikely to cause any problems.

If you have not told your doctor about any of the above, tell him/her before you start using LMX4[®].

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you or your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and LMX4® may interfere with each other. These include:

- Medicines used to treat arrhythmia (irregular heartbeat) such as tocainide, mexiletine and amiodarone.
- Other local anaesthetics.

These medicines may be affected by LMX4® or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

4. How do I use LMX4®?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the package leaflet, ask your doctor or pharmacist for help.

How much to use

- 1g is approximately equal to 5cm length of cream squeezed from the 5g tube and 3.5cm from the 30g tube.
- Adults, the elderly and children 1 year of age and older:

Apply 1g - 2.5g of the cream to cover an area of skin 2.5×2.5 cm.

Full term neonates and infants up to 1 year of age:
 No more than 1g of cream should be applied

When to use LMX4®

- Apply LMX4® at least 30 minutes before you are due for the procedure.
- Depending on the procedure, your doctor may advise for the cream to be left on for a longer time if you choose not to occlude the cream with a dressing.
 Refer to package leaflet for more information.

How to use LMX4®

- Apply a small amount of cream and if required or not using an occlusive dressing gently massage it into the skin
- Then apply the specified amount of cream (refer above 'How much to use') to the area undergoing the procedure.
- The cream can then be left uncovered or covered with a dressing for the time specified below.
- Adults, the elderly and children 12 years of age and older:
 - Do not leave on the skin for longer than 5 hours
- Full term neonates, infants and children under 12 years of age:

Do not leave on the skin for longer than an hour.

Refer to package leaflet for detailed directions for use.

If you forget to use LMX4®

Apply LMX4® as soon as you realise you have forgotten.

If it is less than 30 minutes before your procedure, talk to your doctor.

If you use too much LMX4®

If you think that you have used too much LMX4®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Overdose with LMX4® cream is unlikely. However, if you use too much you may feel nervous, dizzy, have blurred vision and shaky hands.

5. What should I know while using LMX4®?

Things you must do

- Remember to apply LMX4® on intact skin at least half an hour (30 minutes) before your procedure is due.
- Depending on your procedure this time may vary and your doctor will advise you of this.
- If you do not, you or your child's appointment may have to be delayed, or the procedure may hurt more than it would otherwise.
- Be sure to follow the instruction in the package leaflet on how to apply LMX4® cream carefully.
- Make sure the dressing covering the cream is firmly fixed, especially on young children.
- If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.

Remind any doctor, dentist or pharmacist you visit that you are using LMX4®.

Things you must not do

- Do not apply LMX4® to damaged or diseased skin. LMX4® is for external use only.
- Do not use LMX4® to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

- Be careful not to let LMX4® get into your eyes.
 It may cause eye irritation. If LMX4® does get into your eyes, immediately rinse them with large amounts of water and contact your doctor or pharmacist for advice.
- Be careful not to inadvertently injure the anaesthetised area where LMX4® has been applied.
 Be careful not to scratch, rub or accidently expose the treated area to extreme cold or heat until complete sensation has returned.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LMX4® affects you.

Looking after your medicine

• Keep the cream in the carton until it is time to use it.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 25°C. Do not freeze, do not refrigerate. Do not store LMX4®:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

Ask your pharmacist what to do with any LMX4® that is left over or you find it has expired.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well while using LMX4®.

This medicine helps most people during superficial skin procedures, including insertion of IV catheters and blood sampling, but it may have unwanted side effects in a few people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Common side effects

Common side effects	What to do
Local reaction • itching • swelling • paleness • redness • burning sensation	Speak to your doctor or pharmacist if you have any of these common side effects and they worry you. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
• a rash at a spot where LMX4® is	Remove LMX4®
not being used	and call your
difficulty breathing	doctor straight
	away, or go
	straight to the
	Emergency
	Department at
	your nearest
	hospital if you
	notice any of
	these serious
	side effects.
	You or your
	child may need
	urgent medical
	attention or
	hospitalisation.

Tell your doctor or pharmacist if you notice anything else that may be making you or your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

LMX4[®]

What LMX4® contains

Active ingredient	lidocaine (lignocaine) 40mg/g
(main ingredient)	
Other ingredients	benzyl alcohol
(inactive ingredients)	carbomer 940
	cholesterol
	lecithin – hydrogenated
	polysorbate 80
	propylene gycol
	triethanolamine
	dl-alpha tocopheryl acetate
	water-purified

Do not take this medicine if you are allergic to any of these ingredients.

What LMX4® looks like

LMX4® is a white to off-white, yellowish cream.

LMX4® cream is registered with the following packs:

Aust R 126095

- Carton containing one 5g tube
- Carton containing 5x5g tubes
- Carton containing one 15g tube
- Carton containing one 30g tube

Aust R 208815

Carton containing 5x5g tubes with 10 occlusive dressings

Some packs may not be currently marketed.

Who distributes LMX4®

Dermocosmetica
Unit 8, 14-16 Lens Street
Coburg North, VIC 3058
Australia

This leaflet was prepared in November 2020.