LMX4®

Topical Anaesthetic Cream

Lignocaine (Lidocaine) 4% w/w

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about LMX4®. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you or your child using LMX4® against the benefits they expect it will have for you or your child.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What LMX4® is used for

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

It belongs to a group of medicines called local anaesthetics.

It works by numbing the area where the cream has been applied.

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.

Before you use LMX4®

When you must not use it

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

- any medicine containing lignocaine
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines (other local anaesthetics, for example those used at the dentist).
- Adhesives or sticking plasters 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 body
- · 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 packaging 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 medicines, 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

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 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®.

Taking other medicines

Tell your doctor or pharmacist if you or your child is taking any other medicines, including any that you get 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.

How to 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 cm x 2.5 cm.

Full term neonates and infants up to 1 year of age:

No more than 1g of cream should be applied.

How to use it

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.

Refer to package leaflet for detailed directions for use.

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 1 hour.

Do not apply to large areas of the body except on advice of a healthcare practitioner.

When to use it

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.

If you forget to use it

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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, and 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much LMX4®. 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.

When you are 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 instructions 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.

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 scratch, rub or accidently expose the treated area to extreme cold or heat until complete sensation has returned.

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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

 any local reaction such as itching, swelling, paleness, redness or a burning sensation

The above list includes the more common side effects of your medicine. They are usually mild and short-lived

If any of the following happen, remove LMX4® and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- a rash at a spot where LMX4® is not being used
- · difficulty breathing

The above list includes very serious side effects. You or your child may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you or your child feel unwell.

Other side effects not listed above may also occur in some people.

After using LMX4®

Storage

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.

Do not store LMX4® or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

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

Product description

What it looks like

LMX4® is a white to off-white, vellowish cream

LMX4® cream is registered with the following packs:

- carton containing one 5g tube
- carton containing 5x5g tubes
- carton containing one 15g tube
- carton containing one 30g tube
- carton containing 5x5g tubes with 10 occlusive dressings

Some packs may not be currently marketed.

Ingredients

lg of LMX4® contains 40mg of lignocaine as the active ingredient.

It also contains:

- benzyl alcohol
- carbomer 940
- cholesterol
- · lecithin hydrogenated

- polysorbate 80
- · propylene glycol
- triethanolamine
- · dl-alpha tocopheryl acetate

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Ferndale Laboratories Michigan 48220 Detroit, USA.

Supplier

LMX4® is suppled in Australia by: Perrigo Australia 25- 29 Delawney Street, Balcatta WA 6021 Australia.

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