

PACKAGE LEAFLET: INFORMATION FOR THE USER

LMX4, Lidocaine 4%w/w Cream

Read all of this leaflet carefully before you or your child start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as instructed for your treatment.

- Keep this leaflet. You may need to read it again.
- Ask your doctor, nurse, or other trained person involved in your treatment if you need more information or advice.
- If you get any side effects, talk to a doctor, nurse or other trained person involved in your treatment. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What LMX4 is and what it is used for
2. What you need to know before you use LMX4
3. How to use LMX4
4. Possible side effects
5. How to store LMX4
6. Contents of the pack and other information

1. WHAT LMX4 IS AND WHAT IT IS USED FOR

This medicine is called: LMX4, Lidocaine 4%w/w Cream

Each gram of cream contains 40mg of the active ingredient lidocaine.

LMX4 is a type of medicine called a local anaesthetic, used to numb an area of the body.

LMX4 temporarily numbs the surface of the skin. It can be used to provide pain relief when a needle is inserted into the skin for clinical purposes, such as into a vein (venipuncture or venous cannulation). It may also be used to numb the skin prior to administration of painful topical treatments on larger surface areas of intact skin.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LMX4

Do not use LMX4:

- If you are allergic (hypersensitive) to lidocaine or any of the other ingredients.
- If you are allergic to any similar local anaesthetics.

Take special care with LMX4:

Talk to your doctor, nurse or other trained person involved in your treatment before use if:

- You are acutely ill, debilitated or elderly (you will be more sensitive to lidocaine).
- You have a history of being sensitive to the ingredients of any medicines, particularly other local anaesthetics.
- You have a severe liver (hepatic) disease.

Other medicines and LMX4:

Tell your doctor, nurse or other trained person involved in your treatment if you have recently used any other medicines, with or without a prescription, but specifically:

- LMX4, lidocaine or any other local anaesthetic.
- Any medicine used to prevent or treat an irregular heart beat, such as tocainide, mexiletine or amiodarone.
- The beta-blocker propranolol, for the treatment of hypertension.

- Cimetidine, for the treatment of heartburn or stomach ulcers.
- If you are about to receive a vaccination with live vaccine (e.g. tuberculosis vaccine). Live vaccines should not be administered in areas where LMX4 has been applied as the effect of the vaccine may be affected.

Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask for advice before taking this medicine.

LMX4 contains:

- This medicine contains 75mg propylene glycol in each 1g. Propylene glycol may cause skin irritation. Because this medicine contains propylene glycol, do not use it on open wounds or large areas of broken or damaged skin (such as burns) without checking with your doctor or pharmacist. Do not use on infants below one month.
- This medicine contains 15mg benzyl alcohol in each 1g. Benzyl alcohol may cause allergic reactions or mild irritation.

3. HOW TO USE LMX4

Always use LMX4 exactly as instructed in this leaflet. Ask the doctor, nurse or other trained person involved in your treatment immediately if you have any questions.

How you use LMX4 depends upon why you are using the product. Make sure you follow the correct dosage. If you require further advice the doctor, nurse or other trained person involved in your treatment can either apply the cream for you, or show you where and how you should use the cream.

Precautions when using LMX4:

- For external use only. Do not exceed the recommended dose.
- Do not apply to raw or blistered skin, in the ear, inside the nose, in the mouth, to the anus (back passage), where there is a skin rash or eczema, or where there are cuts, grazes or wounds.

- Avoid getting LMX4 cream in your eyes, as it may cause irritation. If you accidentally get any in your eye, immediately rinse it well with lukewarm water or sodium chloride (salt) solution and protect it until sensation returns.

- **LMX4 blocks all sensations in the treated area. Avoid scratching, rubbing and exposure to extreme hot and cold until the anaesthetic effect has worn off.**

Dosage and how to apply LMX4 to provide pain relief when inserting a needle into the skin and a vein:

1g of cream is approximately equal to a 5cm length of cream squeezed from the 5g tube or 3.5cm squeezed from the 30g tube.

Adults, including the elderly, and children over 1 year of age:

1g to 2.5g of cream, to cover an area of skin 2.5cm x 2.5cm (1"x1") where the needle will be inserted. Do not leave on the skin for longer than 5 hours.

Infants over 3 months but below 1 year of age:

No more than 1g of cream should be applied. Do not leave on the skin for longer than 4 hours.

Infants over 1 month but below 3 months of age: No more than 1g of cream should be applied. Do not leave on the skin for longer than 1 hour.

Do not use on infants below one month old.

1. Apply LMX4 at least 30 minutes before the procedure starts.
2. Using the quantity stated above, apply the cream in a uniform layer to the skin.
3. If told to do so, cover the cream with a dressing, to prevent it being accidentally rubbed off the skin.
4. Shortly before the procedure is due to begin, remove the dressing and remove the cream thoroughly with a gauze swab.

Dosage and how to apply LMX4 to provide anaesthesia prior to administration for painful topical treatments on larger surface areas of intact skin:

1g of cream is approximately equal to a 5cm length of cream squeezed from the 5g tube or 3.5cm squeezed from the 30g tube.

Adults and the elderly aged 18 years and over:

Use 1.5g to 2g on each 10cm² area of skin, to cover a maximum total area of 900cm² (approximately equal to a back or thigh). Do not exceed the recommended dose.

1. Apply LMX4 approximately 30 to 60 minutes before the procedure starts.
2. Using the quantities stated above, apply the cream in a uniform layer to the skin.
3. Ensure the cream is not accidentally rubbed off the skin.
4. Shortly before the procedure is due to begin, remove the cream thoroughly with a gauze swab.

The cream should not be reapplied for at least 12 hours after it has been removed.

Do not use on patients below 18 years of age for large surface areas.

If you use more LMX4 than you should:

Overdose is unlikely, but talk to a doctor, nurse or other trained person involved in your treatment straight away, even if you do not feel any symptoms. An overdose may include using more than the recommended amount, applying the cream to large areas or using the cream for longer than recommended. The following overdose symptoms may be experienced: blurred vision, dizziness or drowsiness, difficulty breathing, trembling, chest pain or an irregular heartbeat.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

An allergic reaction is rare, affecting up to 1 in 1000 people. Symptoms may include a rash, swelling, very low blood pressure or anaphylactic shock. If you experience an allergic reaction or anaphylactic shock, remove the cream and seek medical advice immediately.

Skin irritation, redness, itching, dryness or rash at the site of application are common side effects which may affect up to 1 in 10 people.

You may experience eye irritation if the cream is applied to or around the eye. Refer to 'Precautions when using LMX4' in Section 3 for what to do immediately after accidental eye exposure.

Reporting of side effects:

If you get any side effects, talk to a doctor, nurse or other trained person involved in your treatment. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the MHRA's Yellow Card Scheme, available at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LMX4

Keep this medicine out of the sight and reach of children.

Use within 6 months of opening.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of the month.

Do not throw away medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What LMX4 contains:

The active substance is lidocaine. 1g of cream contains 40mg of lidocaine.

The other ingredients are benzyl alcohol, carbomers, cholesterol, phospholipon 80H (hydrogenated soy lecithin), polysorbate 80, propylene glycol, trolamine, vitamin E acetate and purified water.

What LMX4 looks like and contents of the pack:

LMX4 is a white to off-white cream presented in a 5g or 30g tube. It may be packed into a carton that also contains dressings that can be used to cover and protect the cream after it has been applied to the skin.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:
Ferdale Pharmaceuticals Ltd,
Wetherby, West Yorkshire,
LS23 7FX, UK.

Manufacturer:

Laleham Health and Beauty Ltd,
Sycamore Park, Mill Lane
Alton, Hampshire,
GU34 2PR, UK

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