TOPICAL ANAESTHETIC FOR THERAPIST USE

DOSAGES AND PROTOCOLS

Training Protocol For LMX4 Cream Administration By Trained Therapists

- Indications LMX4 cream should be used for
- LMX4 Cream should be used on adults to provide surface anaesthesia of intact skin prior to painful skin treatments
- LMX4 contains lidocaine 4% in a liposomal cream, the liposomes help facilitate the penetration of the lidocaine in to the dermis and the site of nerve endings where it acts by causing a reversible block to conduction along the nerve fibres.

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Exclusion Criteria Regarding LMX4 Cream

•LMX4 Cream should not be used, or further medical advice should be sought, in the following circumstances

- Hypersensitivity to lidocaine or other amide-type local anaesthetics or any of the excipients.
- Do not apply to wounds, irritated skin, atopic dermatitis, eyes or ears, mucous membranes.
- Pregnancy: Lidocaine should only be used during pregnancy if clearly needed. Lidocaine can cross the placental barrier.
- Lidocaine is excreted in human milk. Therefore, caution should be exercised when LMX 4 is administered to a nursing mother since the milk: plasma ratio of lidocaine is 0.4.
- Patients on class 1 anti-arrhythmic drugs since the toxic effects are additive and generally synergistic

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- For medical dermal needle injection procedures apply 2.5g of cream on to the skin to cover 2.5cm x 2.5cm or 6.25cm^2 areas where the procedure will occur. This can be covered with an occlusive dressing. The cream should be left in place for a minimum of 30 minutes and up to a maximum of 5 hours.
- For painful treatments on larger surface areas of intact skin apply 1.5 to 2.0g of cream to a 10cm^2 area of skin up to a maximum area of 900cm^2.. Apply for 30 to 60 minutes, occlude cream if required.

  Typical estimated larger quantities would be:
- 30g-40g/200cm^2 (approximately 10cm x 20cm, or 1x 30g tube covering a face)
- 45g-60g/300cm^2 (approximately 10cm x 30cm, or 1.5 to 3 x 30g tubes covering an arm)
- 135g-180g/900cm^2 (approximately 30cm x 30cm, or 4.5 to 6 x 30g tubes covering a torso or back)
- Max. dose 6 x 30g tubes on an area 30cm x 30cm. LMX4 Cream should not be reapplied for 12 hours following its removal, giving a maximum of 2 doses in any 24 hours.

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LMX4 Cream Application & Removal

•LMX4 Cream should be applied to intact skin:

- The LMX4 cream should be applied evenly at the specified dosage with a uniform thickness across the area where the topical treatment will occur. The cream can be occluded under a non-absorbent dressing to ensure the cream remains undisturbed until adequate analgesia has been achieved.
- Prior to starting the procedure, the LMX4 Cream should be thoroughly removed and the area prepared in the usual manner.
- The procedure should be initiated shortly after the cream has been removed.
- In the unlikely event of an allergic or hypersensitive response to application of the cream remove and wash the area. Document in patients notes and seek further medical help if problem persists.

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Patient Advice and Warnings

•LMX4 has been shown in clinical studies to well tolerated on the skin, causing significantly less redness compared to topical anaesthetics containing Tetracaine and significantly less blanching compared to topical anaesthetics containing Prilocaine.

- However dermal application of lidocaine may cause transient local blanching followed by transient erythema / redness.

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Patient Advice and Warnings

•When lidocaine is used, the patient should be aware that the production of dermal analgesia may be accompanied by the block normal sensations in the treated skin. For this reason, the client should avoid inadvertent trauma to the treated area by scratching, rubbing, or exposure to extreme hot or cold temperatures until complete sensation has returned.

•Overdose with LMX 4 cream is unlikely but signs of systemic toxicity would be consistent with those of lidocaine.

- Blurred vision, dizziness or drowsiness, difficulty breathing, trembling, chest pain, or irregular heartbeat. If any of these occur seek emergency medical help.

Extra points from Lisa Mason to be included

I've added my previous comments about topical anaesthetics below and worth noting that Ferndale recommend referring the to the products as "topical anaesthetics for surface anaesthesia of the skin" and stating that they are applied to intact skin so there does not become some confusion if the information is passed along an information chain with subcutaneous local anaesthetics.

Previous comments - As P medicines, the licensed topical anesthetics do not need a prescription but they should only be sold to a consumer by a pharmacy, so a clinic should not retail the product (unless they are a Dr or Dentist, who are legally able to sell), it's use should be part of the provision of the treatment. The criteria under which a non-HCP could use such a product is as a business that utilizes the product during the conduct of their business in line with it's approved indications, method of administration and warnings etc.