

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the administration of

EMLA Cream 5%

by registered **Nurse** to

**produce surface anaesthesia of the skin prior to a
medical procedure involving needle insertion**

Version number: EMLA PGD 2015 v1

PGD Development- EMLA Cream 5% to produce surface anaesthesia prior to a medical procedure involving needle insertion

| | Name | Job title | Organisation |
|--|-----------------|---------------------------------|----------------|
| Lead author | Helen Dingle | Prescribing Adviser | North West CSU |
| Lead doctor (or dentist) | | | |
| Lead pharmacist | Caroline Crouch | Medicines Management Pharmacist | North West CSU |
| Representative of other professional group using PGD | | | |

PGD Signatories

| PGD signatories- | |
|------------------|--|
| Lead Doctor | Name: Dr Saket Jalan Position: CCG Prescribing Lead Signature: _____ Date: _____ |
| Lead Pharmacist | Name: Steve Riley Position: Senior Prescribing Adviser Signature: _____ Date: _____ |
| Lead Nurse | Name: Sue Smith Position: Lead Nurse Quality and Patient Safety Signature: _____ Date: _____ |

PGD Authorisation

| | |
|---------------------------------|---|
| Organisational Authorisation by | Name: Lorna Quigley Position: Director of Quality and Patient Safety Signature: _____ Date: _____ |
| Optional local Signatory | Name: Position: Signature: _____ Date: _____ |

Training and competency of registered health Professionals

| | Requirements of registered health professionals working under the PGD |
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| Qualifications and professional registration | Registered Nurse having valid registration with the Nursing and Midwifery Council (NMC) and working within Wirral CCG The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards of Administration for nurses |
| Initial training | <ul style="list-style-type: none"> Received training to undertake supply and administration of medicines under Patient Group Directions. Received specific training in the use of this PGD The nurse should have achieved the competency levels specified in the NICE Competency Framework for Health Professionals using Patient Group Directions |
| Competency assessment | Maintenance of own level of updating with evidence of continued professional development (PREP requirements) |
| Ongoing training and competency | <ul style="list-style-type: none"> Annual update on resuscitation skills and the management of anaphylaxis in the community. Able to provide evidence of continued professional development i.e. meeting Post-Registration Education & Practice (PREP) requirements |

Change history

| Version number | Change details | Date |
|----------------|---|------------|
| May 2015 | Reviewed to <ul style="list-style-type: none"> BNF May 2015 accessed 13 May 2015 Summaries of Product Characteristics SPCs in the Electronic Medicines Compendium eMC | 13/05/2015 |
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Clinical condition

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| Clinical condition or situation to which this PGD applies | Local anaesthetic for topical use to produce surface anaesthesia of the skin prior to a medical procedure involving needle insertion |
| Inclusion criteria | <ul style="list-style-type: none"> • Individual undergoing a medical procedure involving painful needle insertion • Valid consent |
| Exclusion criteria | <ul style="list-style-type: none"> • Known hypersensitivity to anaesthetics of the amide type or any component of EMLA cream • Individuals with anaemia, glucose-6-phosphate dehydrogenase deficiency or hereditary or idiopathic methaemoglobinaemia or patients on concomitant therapy known to produce such conditions e.g. sulphonamides • Prior to injections of intracutaneous live vaccines • No valid consent |
| Cautions (including any relevant action to be taken) | <ul style="list-style-type: none"> • EMLA cream contains polyoxyethylene hydrogenated castor oil which may cause skin reactions • Do not store above 30°C, do not freeze |
| Arrangements for referral for medical advice | If deferred ensure arrangements are put in place for a further appointment. |
| Action to be taken if the patient is excluded | If excluded refer to GP for advice and treatment. |
| Action to be taken if the patient declines treatment. | If declines, discuss with patient and refer to GP for treatment if necessary. If procedure continues without EMLA Cream, obtain written refusal and record in notes. Document refusal. |

Details of the medicine

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| Name, form and strength of medicine | EMLA Cream 5% (Lidocaine 2.5%, Prilocaine 2.5%) |
| Legal category | GSL |
| Black triangle | No |
| Indicate any <u>off-label use</u> (if relevant) | N/A |
| Route/method of administration and dose | <p>Topical application of approximately 2g. (approx half a 5g tube) EMLA Cream 60 minutes prior to the procedure, applied under occlusive dressing.</p> <p>For babies and children up to the age of 12, the maximum dose is 1.0g/10cm².</p> <p>Not to be applied to wounds, mucous membranes or areas of atopic dermatitis or to genital mucosa or eyes or ears.</p> |
| Dose and frequency | As above and as a single dose. Maximum treatment period 1 hour. |
| Quantity to supply/administer | One dose |
| Adverse effects | <p>Transient paleness, redness and oedema have been reported. In rare cases local anaesthetics have been associated with allergic reactions including anaphylactic shock. Rare cases of discrete local lesions at the application site in children with atopic dermatitis or mollusca contagiosa</p> <p>Corneal irritation after accidental eye exposure</p> |
| Drug Interactions Please refer to current SPC or BNF for full details | <p>Methaemoglobinaemia may be accentuated in patients on concomitant therapy known to produce such conditions e.g. sulphonamides</p> <p>Cardiac effects of anti-arrhythmic drugs such as amiodarone may be additive</p> |
| Records to be kept | <p>Record fully in clinical record / GP records and as required in patient held records</p> <ul style="list-style-type: none"> • State PGD has been followed and record treatment plan, including dose and route of administration in patient's notes • Patient's name and date of birth • Date and time given • Brand, batch and expiry date of products used • Signature and name of the person supplying or administering the medication • Advice given • An electronic or manual record of all individuals receiving treatment under this PGD should be kept for audit purposes. • Any serious adverse events that may be attributable to any product named in this PGD, should be reported to the MHRA using the yellow card system and documented in the medical records. The GP should also be informed. |

Reference Number: EMLA PGD 2015 v1

 Valid from: 1st June 2015

 Expiry date: 31st May 2017

Patient information

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| Information to be given to patient or carer | <ul style="list-style-type: none">• Care should be taken to avoid EMLA Cream coming into contact with the eyes, if contact with eyes occurs, immediately rinse the eye with water• Care should be taken to avoid EMLA Cream coming into contact with the middle ear• Numbness will last for several hours, contact practice if sensation does not return to affected area• Advise on possible side effects and their management |
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Appendices

Appendix A Key references

1. Summary of Product Characteristics for Emla 5% Cream
<http://www.medicines.org.uk/emc/search>
2. Current BNF chapter 15.2
<https://www.medicinescomplete.com/mc/bnf/current/index.htm>
3. NICE Good Practice Guidance on Patient Group Directions and the Competency framework for healthcare professionals using Patient Group
<http://www.nice.org.uk/mpc/goodpracticeguidance/GPG2.jsp>

Appendix B

Health professionals' agreement to provide EMLA Cream 5% to produce surface anaesthesia prior to a medical procedure involving needle insertion

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| Practitioner | I have read and understood the Patient Group Direction and agree to supply and/or administer this medicine only in accordance with this PGD |
| Name | |
| Signature | |
| Date | |

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| Senior Representative (Clinical) | I give authorisation on behalf of Wirral CCG for the named Health Care Professional who has signed this PGD to administer the medication as prescribed within this direction. |
| Name | |
| Signature | |
| Date | |