Patient Group Direction For The Application Of EMLA® Cream By Approved Healthcare Professionals Working Within NHS Grampian
Prior to Intravenous Cannulation Or Venepuncture

Lead Author:
Medicines Management Specialist Nurse

Consultation Group:
See relevant page in the PGD

Approver:
NHSG Medicines Guidelines and Policies Group

Signature:


Identifier:
NHSG/PGD/Emla/ MGPG966

Review Date:
August 2020

Date Approved:
August 2018

Expiry Date:
August 2021

NHS Grampian have authorised this Patient Group Direction to help patients by providing them with more convenient access to an efficient and clearly defined service within the NHS Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed
Version 6
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2018</td>
<td>June 2016</td>
<td>2 Yearly update to new PGD template.</td>
<td></td>
</tr>
<tr>
<td>May 2018</td>
<td>June 2016</td>
<td>Changed from PoM to P medicine.</td>
<td>Legal status</td>
</tr>
<tr>
<td>May 2018</td>
<td>June 2016</td>
<td>Statement added regarding the removal of the cream prior to cannulation or venepuncture.</td>
<td>Route/Method of administration</td>
</tr>
<tr>
<td>May 2018</td>
<td>June 2016</td>
<td>Time the cream was applied added.</td>
<td>Route/Method of administration</td>
</tr>
<tr>
<td>July 2018</td>
<td>June 2016</td>
<td>Supply removed from the PGD.</td>
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<tr>
<td>July 2018</td>
<td>June 2016</td>
<td>Information regarding application on newly shaven skin added.</td>
<td>Precautions and special warnings</td>
</tr>
<tr>
<td>July 2018</td>
<td>June 2016</td>
<td>Information regarding the application of EMLA® Cream to patients with atopic dermatitis added.</td>
<td>Precautions and special warnings</td>
</tr>
<tr>
<td>July 2018</td>
<td>June 2016</td>
<td>Information regarding patients treated with anti-arrhythmics of class III added after the removal of the concurrent medications/drug interactions section.</td>
<td>Precautions and special warnings</td>
</tr>
<tr>
<td>July 2018</td>
<td>June 2016</td>
<td>Instructions regarding the removal of the cream after 5 hours if it has not been removed before this time added.</td>
<td>Route/Method of administration</td>
</tr>
<tr>
<td>August 2018</td>
<td>June 2016</td>
<td>Dosing information including total dosages changed to reflect current SmPC.</td>
<td>Dose/Maximum total dose</td>
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</table>

**NHS Grampian Identifier:** NHSG/PGD/Emla/MGPG966  
**Replaces:** NHSG/PGD/Emla/MGPG795, Version 5  
**Keyword(s):** PGD Patient Group Direction EMLA Cream SSU Short Stay Unit Nurse

**Policy Statement:** It is the responsibility of individual healthcare practitioner and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.
Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of patient safety. The expiry date should not be more than 3 years from the date the PGD was authorised.

Document: Drafted: April 2018  
Completed: August 2018  
Approved: August 2018 (published – October 2018)
Organisational Authorisation

This PGD is not legally valid until it has had organisational authorisation.

PGD Developed/Reviewed by

| Medical Practitioner | Name: Dr Andrew Bayliss  
Health Board: NHSG  
Title: Consultant Anaesthetist  
Contact email: abayliss@nhs.net  
Signature: |
|----------------------|------------------------------------------------------------------|
| Senior representative of the professional group who will provide care under the direction. | Name: Frances Adamson  
Health Board: NHSG  
Title: Medicines Management Specialist Nurse  
Contact email: f.adamson@nhs.net  
Signature: |
| Lead Author (if different from above) | Name:  
Health Board:  
Title:  
Contact email:  
Signature: |
| Pharmacist | Name: Thomas Allen  
Health Board: NHSG  
Title: Rotational Pharmacist  
Contact email: Thomas.allen5@nhs.net  
Signature: |

Authorised on Behalf of NHSG by

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Chair Name</th>
<th>Signature</th>
<th>Date Signed</th>
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<tr>
<td>NHS Grampian Medicines Guidelines and Policies Group</td>
<td>Lesley Thomson</td>
<td></td>
<td>September 2018</td>
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</tbody>
</table>
Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Frances Adamson</td>
<td><strong>Lead Author:</strong> Medicines Management Specialist Nurse</td>
</tr>
<tr>
<td>Thomas Allen</td>
<td><strong>Pharmacist:</strong> Surgical Rotational Pharmacist</td>
</tr>
<tr>
<td>Dr Andrew Bayliss</td>
<td><strong>Medical Practitioner:</strong> Consultant Anaesthetist, ARI</td>
</tr>
<tr>
<td>Anne Gourlay</td>
<td>Senior Charge Nurse Day Surgery Unit</td>
</tr>
<tr>
<td>Lisa Grant</td>
<td>Senior Staff Nurse Day Surgery Unit</td>
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</table>
Patient Group Direction For Use Within NHS Grampian

Patient Group Direction For The Application Of EMLA® Cream By Approved Healthcare Professionals Working Within NHS Grampian Prior to Intravenous Cannulation Or Venepuncture

Clinical indication to which this PGD applies

<table>
<thead>
<tr>
<th>Definition of situation/condition</th>
<th>This Patient Group Direction (PGD) will approved healthcare professionals working within NHSG to administer EMLA® to patients. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC) and individual Summary of Product Characteristics (SmPC).</th>
</tr>
</thead>
</table>
| Inclusion criteria              | • Adults and children over 1 year of age who require to undergo intravenous cannulation or venepuncture and for whom undertaking a procedure involving needles is impossible or extremely difficult as a result of a true needle phobia or a painful cannulation experience in the past.  
• Use in preoperative patients should be discussed with the anaesthetist and the vein(s) to be treated agreed and marked. |
| Exclusion criteria              | • Children under 1 year of age.  
• Patients who are pregnant or breast feeding.  
• Patient with glucose-6-phosphate dehydrogenase deficiency or congenital/acquired methaemoglobinemia.  
• Patients taking medicines which may cause an increase in methaemoglobin plasma levels e.g. sulphonamides (see current BNF and SmPC for details).  
• Areas where there are open wounds.  
• Areas of atopic dermatitis.  
• Instances where application to large areas of skin >10cm² and where large doses of EMLA® cream are required, i.e. skin grafts.  
• Mucous membranes.  
• Areas near the eyes or ears.  
• Patients who have known anaphylactic hypersensitivity to the anaesthetics of the amide type or any of the components of EMLA® cream. |
### Precautions and special warnings

EMLA® cream contains polyoxyethylene hydrogenated castor oil which may cause skin reactions.

The healthcare professional must verbally check patient allergies and previous usage of EMLA® cream or any other amide type anaesthetics with the patient, e.g. bupivacaine, mepivacaine, etc. They should check the patient’s records (if available) for any documentary evidence regarding its use in the past.

Due to the potentially enhanced absorption on newly shaven skin, it is important to adhere to the recommended dosage, area and time of application.

Take care to avoid accidental eye exposure.

Care should be taken when applying EMLA® Cream to patients with atopic dermatitis. A shorter application time, 15-30 minutes, may be sufficient.

Patients treated with anti-arrhythmics of class III (e.g. amiodarone) should be carefully monitored and ECG monitoring considered, as cardiac effects may be additive.

### Action if excluded from treatment

Medical advice should be sought – refer to General Practitioner/Consultant (relevant medical practitioner).

The reason why the patient was excluded under the PGD will be documented in the appropriate patient record.

### Action if treatment is declined

The patient should be advised of the risks and consequences of not receiving treatment.

Refer to General Practitioner/Consultant (relevant medical practitioner).

Record outcome in Patient Medication Record if appropriate, or relevant patient record.

### Consent

Prior to the administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG consent policy.
Description of treatment available under the PGD

| Name form and strength of medicine | EMLA® cream. EMLA® is a white soft cream containing the active ingredients lidocaine 2.5% w/w and prilocaine 2.5% w/w. It is available in the following preparations:  
  - Pre-medication pack containing 5 x 5g tubes EMLA® and 12 occlusive dressings.  
  - Pack containing 1 x 5g tube of EMLA® and 2 occlusive dressings.  
  - 1 x 30g tube with enclosed spatula.  
  - 1 x 5g tube. |
| Legal status | EMLA® cream is a Pharmacy Medicine (P). |
| Dosage/Maximum total dose | Adults and adolescents 12 years of age and over: 2g (approx half a 5 g tube) for 1 - 5 hours.  
Child 1 – 11 years: 1g for 1 – 5 hours.  
Detailed information on dose, including pictorial guidance on how to apply the cream is given in the Patient Information Leaflet (PIL) supplied with this medicine.  
N.B. Estimating the dose:  
Cream applied to a circular area with a diameter of about 18mm (a 1 pence coin) and depth of about 5mm is equal to 1g of EMLA® cream.  
Maximum total dose for adults and adolescents over 12 years: 4g  
Maximum total dose for a child 1-11 years: 2g |
| Frequency of dose/Duration of treatment | Every 12 hours for a maximum of 2 doses in a 24 hour period. |
| Maximum or minimum treatment period | 24 hours maximum. |
| Route/Method of administration | Where appropriate for pre-operative application, discuss with the anaesthetist regarding the choice of vein(s) to be covered. These may be pre-marked by the anaesthetist. |
- Apply a thick layer of cream in a mound as per the dosage outlined above to a suitable skin site, e.g. the dorsum of the hand or anterior cubital fossa ensuring that an obvious and prominent vein is covered. Do not rub the cream in.
- Cover with the supplied occlusive dressing.
- Apply the cream for a minimum of 1 hour and a maximum of 5 hours before the procedure.
- The time the cream was applied should be annotated on the occlusive dressing without obscuring the site.
- Procedures on intact skin should begin soon after the occlusive dressing is removed.
- Prior to venepuncture or cannulation all cream should have been absorbed. Any remaining cream should be wiped off with a clean tissue or gauze.
- The cream should be removed after 5 hours and re-applied if necessary if it is not removed before this time.

<table>
<thead>
<tr>
<th>Quantity to be administered</th>
<th>See Dosage/Maximum total dose section above.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage requirements</td>
<td>Do not store above 30°C. Do not freeze.</td>
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<tr>
<td>Follow-up (if applicable)</td>
<td>Not Applicable.</td>
</tr>
<tr>
<td>Advice to patient (Verbal)</td>
<td>Advice should be given on what to expect and what to do for major and minor reactions. Reassure patients who are anxious about the procedure to be undertaken. Patients should be advised about the potential side effects and length of time that the cream needs to be applied to be effective.</td>
</tr>
<tr>
<td>Advice to patient (Written)</td>
<td>The Patient Information Leaflet (PIL) contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Copies of PIL and SmPC for medicines can be found at <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a> or <a href="http://www.mhra.gov.uk/spc-pil/index.htm">http://www.mhra.gov.uk/spc-pil/index.htm</a>.</td>
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</table>
**Identifying and managing possible adverse reactions**

Transient paleness, redness and oedema at the application site are very common. Allergic reactions, including anaphylactic shock have been reported rarely.

Corneal irritation after accidental eye exposure.

**This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.**

BNF/BNFC:  
[https://www.bnf.org](https://www.bnf.org)

SmPC/PIL and Risk Minimisation Materials:  
[https://www.medicines.org.uk/emc/](https://www.medicines.org.uk/emc/)  
[https://www.medicines.org.uk/emc/rmm-directory](https://www.medicines.org.uk/emc/rmm-directory)

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report the reaction to the MHRA using the Yellow Card System.  
[https://yellowcard.mhra.gov.uk/](https://yellowcard.mhra.gov.uk/)

**Facilities and supplies required**

The following should be available at sites where the medication is to be administered:

- Appropriate storage facilities
- An acceptable level of privacy to respect patient’s right to confidentiality and safety
- Resuscitation equipment
- Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection
- Access to medical support (this may be via the telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities
- Copies of the current PGD for the medicine specified in the PGD.

**Characteristics of staff authorised to administer medicine under PGD**

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Registered Nurses and Midwives as registered with the Nursing and Midwifery Council (NMC). Registered Radiographers as registered with the Health and Care Professionals Council (HCPC).</th>
</tr>
</thead>
</table>
### Specialist competencies

**Approved by the organisation as:**
- Competent to assess the patient’s capacity to understand the nature and purpose of the administration in order for the patient to give or refuse consent
- Aware of current treatment recommendations and be competent to discuss issues about the drug with the patient
- Competent in the administration of the drug.

### Ongoing training and competency

**All professionals working under this PGD must:**
- Have attended basic life support training which is required to be updated annually
- Have undertaken the NHS e-anaphylaxis training session or equivalent (including annual updates) which covers all aspects of the identification and management of anaphylaxis
- Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct
- Must be familiar with the SmPC for all medicines administered in accordance with this PGD.

### Professional managers/Lead Nurses will be responsible for:

- Ensuring that the current PGD is available to staff providing care under this direction.
- Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.
- Maintain up to date record of all staff authorised to administer drug specified in PGD.

### Documentation

### Authorisation of administration

Nurses and midwives working within NHS Grampian can be authorised to administer the drug specified in this PGD by their Clinical Manager or Consultant.

Radiographers working within NHS Grampian can be authorised to administer the drug specified in this PGD by their Unit Clinical Director.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). This should be held in the individual practitioners records, or as agreed locally.
A Certificate of Authorisation ([Appendix 2](#)) signed by the authorising doctor/manager and staff working to the PGD, should be held as agreed locally.

**Record of administration**

An electronic or paper record for recording the screening of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:

- Date and time of administration
- Patients name
- Patient Date of birth and CHI
- Details of parent/guardian, or person with parental responsibility where applicable
- Exclusion criteria, record why the drug was not administered
- Consent to the administration (if not obtained elsewhere)
- Signature and name in capital letters of practitioner who administered the drug
- Record of any adverse effects (advise patient’s doctor).

These records should be retained:

**For children and young people**, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment.

**For 17 years and over** retain for 6 years after last date of entry, for 3 years after death, or in accordance with local policy, where this is greater than above.

**Audit**

All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each H&SCP/practice/service will be responsible for auditing completion of drug forms and collation of data.

**References**


Appendix 1

Health Care Professional Agreement to Administer Medicines Under Patient Group Direction

I:  ____________________________________________ (Insert name)

Working within: ___________________________________ e.g. H&SCP, Practice

Agree to administer medicines under the direction contained within the following Patient Group Direction

**Patient Group Direction For The Application Of EMLA® Cream By Approved Healthcare Professionals Working Within NHS Grampian Prior to Intravenous Cannulation Or Venepuncture**

I have completed the appropriate training to my professional standards enabling me to administer medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor out with the recommendations of the Patient Group Direction.

Signed:  ____________________________________________

Print Name:  ____________________________________________

Date:  ____________________________________________

Professional Registration No:  ____________________________________________
Health Professionals Authorisation to Administer Medicines Under Patient Group Direction

The lead nurse/professional of each clinical area is responsible for maintaining records of their clinical area where this PGD is in use, and to whom it has been disseminated.

The manager who approves a healthcare professional to administer medicines under the patient group direction, is responsible for ensuring that he or she is competent, qualified and trained to do so and for maintaining an up-to-date record of such approved persons in conjunction with the Head of Profession.

The healthcare professional who is approved to administer medicines under the direction is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her code of professional practice and conduct.

Patient Group Direction For The Application Of EMLA® Cream By Approved Healthcare Professionals Working Within NHS Grampian Prior to Intravenous Cannulation Or Venepuncture

Local clinical area(s) where these healthcare professionals will operate under this PGD:

<table>
<thead>
<tr>
<th>Name of Healthcare Professional</th>
<th>Signature</th>
<th>Date</th>
<th>Name of Manager</th>
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