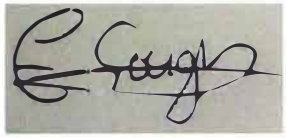
Patient Group Direction For The Administration Of Medicines As Included In The Royal Aberdeen Children's Hospital PGD Formulary By Nurses Working Within NHS Grampian

Lead Author: Staff Nurse, RACH	**Consultation Group**: See relevant page in the PGD	**Approver:** Medicines Guidelines and Policies Group **Authorisation:** NHS Grampian

Signature: 		**Signature:** 

NHSG Identifier: MGPG/PGD/RACH_ Formulary/1396	**Review Date:** June 2025 **Expiry Date:** June 2026	**Date Approved:** June 2023

NHS Grampian have authorised this Patient Group Direction to help individuals 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 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD	
Date of change	**Summary of Changes**	**Section heading**
June 2022	New PGD	

NHGS Identifier: MGPG/PGD/RACH_Formulary/MGPG1396

Keyword(s): Patient Group Direction formulary RACH children ametop chlorphenamine maleate syrup tablets dexamethasone oral solution emla cream

Policy Statement: It is the responsibility of the individual healthcare professionals 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 individual, 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 safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	September 2022
	Completed:	November 2022
	Approved:	June 2023 (published – September 2023)
	Amended and re-authorised:	

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Sarah White **Title:** Consultant in Emergency Medicine **Contact email:** sarah.white52@nhs.scot **Signature:** ..... **Date:** 08/09/2023
Senior representative of the professional group who will provide care under the direction	**Name:** Hazel Anderson **Title:** Senior Charge Nurse **Contact email:** hazel.anderson3@nhs.scot **Signature:** ..... **Date:** 08/09/2023
Lead author	**Name:** Emma Gough **Title :** Staff Nurse **Contact email:** emma.gough@nhs.scot **Signature:** **Date:** 07/09/2023
Pharmacist	**Name:** Sophia Murray **Title :** Pharmacist **Contact email:** sophia.murray@nhs.scot **Signature:** S. Murray ..... **Date:** 12/09/2023

Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		04/09/2023

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.

Name:	Title:
Emma Gough	**Lead Author:** Staff Nurse
Sophia Murray	**Pharmacist:** Pharmacist
Sarah White	**Medical Practitioner:** Consultant in Emergency Medicine
Hazel Anderson	**Senior Representative:** Senior Charge Nurse, ECU
Faith Apostolou	SCN, DCU, RACH
Louise Beattie	Staff Nurse, ECU, RACH
Anna Begg	Staff Nurse, ECU, RACH
Chris Driver	Consultant Surgeon, RACH
Rachel McIntosh	Staff Nurse, ECU, RACH
Kelsey McDonald	Senior Staff Nurse, Surgical Ward, RACH

Patient Group Direction For The Administration Of Medicines As Included In The Royal Aberdeen Children's Hospital PGD Formulary By Nurses Working Within NHS Grampian

Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise nurses working within Royal Aberdeen Children's Hospital (RACH) to administer medicines included in the Royal Aberdeen Children's Hospital PGD Formulary (Appendix 3) to individuals who meet the criteria as described on each individual medicine monograph, according to diagnoses, disease, state and concurrent medicines. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	The medicines specified in Appendix 3 under this PGD must be used **only** for the specific indication(s) and age group listed in the individual drug monographs. Individuals of a different age group, or who are suffering from a condition other than that specified in the monograph, must be referred to an out of hours (OOH) (formally GMED) duty doctor, Advanced Nurse Practitioner or medical professional. Children and young people up to the age of 18 who attend RACH as either an Emergency Department (ED) patient or have been admitted as an inpatient on any ward within RACH. See individual monographs for more information. Prior to the administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current NHSG consent policy.
Exclusion criteria	• Under 3 months of age. • Weighing less than 6kgs. • Previous reactions to any medications listed in the monographs. • Has a known or suspected hypersensitivity to any of the medications or ingredients. • Where there is no valid consent. • The individual meets any of the exclusion criteria listed in the individual monographs.

Precautions and special warnings	The products listed for use under this PGD should only be used for the specific condition and age groups specified. Patients who are suffering from a condition out with the PGD specifications should be seen by medical staff. Medicines included in the PGD should not be used for treatment of patients who have a known or suspected hypersensitivity to the product or any of its ingredients. In the event that a patient suffers an adverse reaction, medical help should be sought immediately.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Inform/refer to the relevant medical practitioner if individual/person with parental responsibility declines treatment. Document that the administration was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	See individual monographs.
Legal status	Medicines in this PGD formulary are either Prescription-only Medicine (POM) or Pharmacy-only Medicine (P).
Dosage/Maximum total dose	See individual monographs.
Frequency of dose/Duration of treatment	See individual monographs.
Maximum or minimum treatment period	See individual monographs.
Route/Method of administration	See individual monographs.
Quantity to be administered	See individual monographs.

Storage requirements	See individual monographs.
Follow-up (if applicable)	Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the medicine first. If necessary a doctor or the individuals GP should be contacted for advice.
Advice (Verbal)	Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions. Advice should be given as detailed in the individual product monographs and manufacturers' product information. If serious adverse or persistent effects occur, the individual/ person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	See individual monographs. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur, give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the medicine is to be administered: • Appropriate storage facilities or pharmaceutical refrigerator • An acceptable level of privacy to respect individual's right to confidentiality and safety

	• Basic airway resuscitation equipment (e.g. bag valve mask, supraglottic airway) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • 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 or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to administer medicine(s) under PGD

Professional qualifications	Registered Nurses as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual/person with parental responsibility • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent to undertake administration of the medicine • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken North of Scotland (NoS) PGD module training on TURAS Learn • Have attended basic life support training either face to face or online and updated in-line with Board requirements • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with Board requirements • To administer dexamethasone and chlorphenamine, nurses must have at least 3 years paediatric clinical experience and deemed to possess suitable knowledge and skills by their SCN • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct

	• Have knowledge and familiarity of the following; o SmPC for the medicine(s) to be administered in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all 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 the medicine(s) specified in this direction.

Documentation

Authorisation of administration	Nurses working in Royal Aberdeen Children's Hospital (RACH) within NHS Grampian can be authorised to administer the medicine(s) specified in this PGD by their Clinical nurse manager/senior charge nurse/ consultant. All authorised staff are required to read the PGD and sign the Agreement to administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed locally.
Record of administration	An electronic or paper record must be completed to allow audit of practice. An electronic/HEPMA record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD. This should include as a minimum: • Date and time of administration • Individuals name and CHI • Exclusion criteria, record why the medicine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained

<table>
<tr><td></td><td>

- The name, dose, form, route (batch number, expiry date and anatomical site where appropriate for injectable medicines) of the medicine administered
- Advice given, including advice given if excluded or declined treatment under this PGD
- Signature and name in capital letters of the healthcare professional who administered the medicine, and who undertook the assessment of the individual's clinical suitability for the administration of the medicine
- Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner).

Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:

- Secondary Care Medical Notes
- HEPMA
- Individual service specific systems.

Local policy should be followed with respect to sharing information with the individual's GP practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.
</td></tr>
<tr><td>Audit</td><td>All records of the medicine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.</td></tr>
<tr><td>References</td><td>Electronic Medicines Compendium
http://www.medicines.org.uk

<table>
<tr><th>Medicine</th><th>Date of revision of text</th><th>Date accessed</th></tr>
<tr><td>EMLA® Cream 5% (Aspen)</td><td>23/12/2016</td><td>20/04/2023</td></tr>
<tr><td>Ametop® Gel 4% (Alliance Pharmaceuticals)</td><td>14/09/2020</td><td>20/04/2023</td></tr>
<tr><td>Dexamethasone 2mg/5ml Oral solution (Wockhardt UK)</td><td>31/12/2020</td><td>20/04/2023</td></tr>
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	<table><tr><th>Medicine</th><th>Date of revision of text</th><th>Date accessed</th></tr><tr><td>Chlorphenamine (Piriton) 2mg/5mL syrup (Haleon UK Trading Limited.)</td><td>17/04/2023</td><td>20/04/2023</td></tr></table> British National Formulary and British National Formulary for Children https://about.medicinescomplete.com/ accessed 20/04/2023.

Appendix 1

Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Medicines As Included In The Royal Aberdeen Children's Hospital PGD Formulary By Nurses Working Within NHS Grampian

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2

Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD 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.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD 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 individual code of professional practice and conduct.
Patient Group Direction For The Administration Of Medicines As Included In The Royal Aberdeen Children's Hospital PGD Formulary By Nurses Working Within NHS Grampian
Local clinical area(s) where the listed healthcare professionals will operate under this PGD: **Emergency Care Unit (ECU)** **Day Case Unit (DCU)/Outpatient Department (OPD)** **High Dependency Unit (HDU)** **Medical Ward** **Surgical Ward**

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Administration Of Medicines As Included In The Royal Aberdeen Children's Hospital PGD Formulary By Nurses Working Within NHS Grampian					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3

Medicines as Included in the Royal Aberdeen Children's Hospital PGD Formulary

Contents **Page No**

Ametop® Gel (Tetracaine) 4% w/w 1.5g tube	
Legal Status	P (Pharmacy Only)
Indication	Topical anaesthesia before venepuncture or venous cannulation.
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Avoid use if known or suspected hypersensitivity to the active substance (tetracaine), to local anaesthetics of the ester type, or to any of the excipients. • Not to be used on broken skin, mucous membranes or to the eyes/ears. • Not to be used during pregnancy or while breastfeeding.
Precautions and Special Warnings	• Only to be applied to intact, normal skin. • Not to be taken enterally. • Not to be instilled into the middle ear or used for procedures which might involve penetration into the middle ear. • Repeated exposure to Ametop® Gel may increase the risk of sensitisation reactions to tetracaine. • Use gloves when applying Ametop® Gel to minimise risk/exposure. • Although the systemic availability of tetracaine by percutaneous absorption of Ametop® Gel is low, caution should be exercised in patients with epilepsy. • Ametop® Gel contains Sodium methyl-p-hydroxybenzoate (E219) and Sodium propyl-p-hydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).
Dose/Maximum total dose	Child 3 months to 4 years: Apply contents of up to 1 tube (can be applied at separate sites at a single time) to site of venepuncture or venous cannulation and cover with occlusive dressing; remove gel and dressing after 30 minutes for venepuncture and after 45 minutes for venous cannulation.

Ametop® Gel (Tetracaine) 4% w/w 1.5g tube	
	Child over 5 years: Apply contents of up to 5 tubes (approximately 5g) (can be applied at separate sites at a single time) to site of venepuncture or venous cannulation and cover with occlusive dressing; remove gel and dressing after 30 minutes for venepuncture and after 45 minutes for venous cannulation. **Application can be repeated after minimum of 5 hours.** **Maximum total dose allowed under this PGD is Children under 5: Maximum total dose 2 tubes in 24 hours.** **Children over 5: Maximum total dose 7 tubes in 24 hours.**
Frequency of dose/Duration of treatment	See above information for duration of application. It is not necessary to apply Ametop® Gel for longer than 30-45 minutes and anaesthesia remains for 4-6 hours in most patients after a single application.
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of Administration	Topical
Quantity to be administered	See dose/maximum dose section above.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Erythema and itching to application site.
Advice	Advise individual/person with parental responsibilityto inform staff if gel leaks from the occlusive dressing. Ask to report any side effects such as skin redness or itchiness.

Ametop® Gel (Tetracaine) 4% w/w 1.5g tube	
Follow up (If applicable)	Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.
Storage	Store at 2 - 8°C Do not freeze Protect from heat Single use only – any unused medicinal product should be disposed of in accordance with waste guidance.

Chlorphenamine maleate 2mg/5mL Syrup or Chlorphenamine 4mg tablets	
Legal Status	P (Pharmacy Only)
Indication	Symptomatic relief of allergy such as hay fever, urticaria, food allergy, drug reactions. Relief of itch associated with chicken pox, vasomotor rhinitis, angioneurotic oedema, serum reactions and insect bites.
Inclusion Criteria	As per main PGD inclusion criteria. Children 1 year of age and over.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Children presenting with anaphylaxis requiring immediate medical attention. • Known or suspected hypersensitivity to antihistamines and any ingredients. • Patients with epilepsy. • Patients with renal or hepatic impairment. • Patients with rare fructose intolerance, glucose malabsorption or sucrose isomaltase insufficiency. • Patients who have been treated with monoamine oxidase inhibitors (MAOIs) within the last fourteen days. • Children under 1 year of age. • Pregnancy of breastfeeding.
Precautions and Special Warnings	Chlorphenamine, in common with other drugs having anticholinergic effects, raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and asthma; hepatic impairment; renal impairment. Children are more likely to experience the neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness). The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients. The effects of alcohol may be increased and therefore concurrent use should be avoided.

Chlorphenamine maleate 2mg/5mL Syrup or Chlorphenamine 4mg tablets	
	Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines. Concurrent use with drugs which cause sedation such as anxiolytics and hypnotics may cause an increase in sedative effects, therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines. Piriton syrup contains 6.3% v/v ethanol (alcohol), i.e. up to 497mg per 10mL (4mg), equivalent to 12.6mL beer, 5.3 mL wine per 10mLs. Other brands of chlorphenamine may also contain alcohol. Check ingredient list in SmPC for individual brand for full information Piriton Syrup® contains 2.36g of sucrose per 5mL. This should be taken into account in patients with diabetes mellitus. Long term use increases the risk of dental caries and it is essential that adequate dental hygiene is maintained. Methyl, ethyl and propyl hydroxybenzoates (E218, E214 and E216) may cause allergic reactions (possibly delayed).
Dose/Maximum total dose	Child 12 -23 months - 1mg (2.5mL syrup) Child 2-5 years - 1mg (2.5mL syrup) Child 6-11 years - 2mg (half tablet or 2.5mL syrup) Child 12-17 years - 4mg (1 tablet or 10mL syrup) **Note:** Only the syrup is to be administered to individuals less than 6 years of age **Maximum total dose allowed under this PGD is ONE dose as per age.**
Frequency of dose/Duration of treatment	ONE dose to be given under PGD.
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of Administration	Oral

Chlorphenamine maleate 2mg/5mL Syrup or Chlorphenamine 4mg tablets	
Quantity to be administered	One Dose
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: • Abnormal coordination • Blurred vision • Disturbance in attention • Dizziness • Dry mouth • Fatigue • Headache • Nausea • Sedation • Drowsiness.
Advice	Drowsiness may affect performance of skilled tasks (e.g. cycling or driving).
Follow up (If applicable)	Advise of the possible adverse effects and advise to seek medical attention in the event of a suspected adverse reaction.
Storage	Store below 25°C. Protect from light. Discard syrup bottle 3 months after opening.

Dexamethasone 2mg/5mL Oral Solution	
Legal Status	POM (prescription only medication)
Indication	Mild croup which is defined as a score of 0-2 using the Westley croup score.
Inclusion Criteria	As per main PGD inclusion criteria and additionally; Children who present with a mild stridor or “barking cough” who are over 6 months of age.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Severe stridor or airway compromise. • Any history or suspicion of inhaled foreign body • Less than 6 months of age old • Hypersensitivity to dexamethasone or any of the excipients listed. • Systemic infection unless specific anti-infective therapy is employed. • Systemic fungal infections. • Stomach ulcer or duodenal ulcer • Infection with tropical worms. • Patients with rare hereditary problems of fructose intolerance should not take this medicine.
Precautions and Special Warnings	Please refer to SmPC for full information on precautions and special warnings. Some brands may contain alcohol. Check ingredients list for full information.
Dose/Maximum total dose	150micrograms/Kg as a single dose **Maximum total dose allowed under this PGD is ONE dose of 150micrograms/kg**
Frequency of dose/Duration of treatment	150micrograms/kg as a single dose
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.

Dexamethasone 2mg/5mL Oral Solution	
Route/Method of Administration	Oral
Quantity to be administered.	150micrograms/Kg single oral dose.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: The usual side effects of short-term dexamethasone treatment (days/weeks) include weight gain, psychological disorders, glucose intolerance and transitory adrenocortical insufficiency.
Advice	N/A
Follow up (If applicable)	Advise of the possible adverse effects and to seek medical advice in the event of a suspected adverse reaction or reoccurrence of croup symptoms.
Storage	Do not store above 25°C. Do not refrigerate. The storage at temperatures higher than 25°C could allow precipitation inside the solution. Do not use the product if solid particles are observed inside the solution. This product is sensitive to light. Store in the original package. Once bottle opened, discard after period specified by manufacturer.

EMLA® Cream 5% (Lidocaine 2.5% w/w & Prilocaine 2.5% w/w) 5g tube	
Legal Status	P (Pharmacy medicine)
Indication	Topical anaesthesia before minor skin procedure including venepuncture.
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Known or suspected hypersensitivity to lidocaine and/or prilocaine or local anaesthetics of the amide type or to any of the excipients. • Do not use on areas with skin rash, eczema, cuts, grazes or other open wounds. • Do not use in or near the eyes. • Do not use inside nose, mouth or ear. • Not to be applied to the genital skin of children below 12 years due to insufficient data on absorption. • Do not use in newborn infants/infants up to 12 months of age receiving concomitant treatment with methaemoglobin-inducing agents.
Precautions and Special Warnings	Care should be taken when applying EMLA® Cream to patients with atopic dermatitis. A shorter application time, 15-30 minutes, may be sufficient. Application times of longer than 30 minutes in patients with atopic dermatitis may result in an increased incidence of local vascular reactions, particularly application site redness and in some cases petechia and purpura. If eye contact occurs, the eye should immediately be rinsed with water or sodium chloride solution and protected until sensation returns. 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. EMLA® Cream contains macrogolglycerol hydroxystearate, which may cause skin reactions. **Paediatric population** If the recommended dose is exceeded the patient should be monitored for system adverse reactions secondary to methaemoglobinaemia.

EMLA® Cream 5% (Lidocaine 2.5% w/w & Prilocaine 2.5% w/w) 5g tube	
Dose/Maximum total dose	Child 3-11 months: Apply up to 2g for maximum 1 hour before procedure, to be applied under occlusive dressing. Child 1-5 years: Apply up to 10g for 1-5 hours before procedure, a thick layer should be applied under occlusive dressing. Child 6-11 years: Apply up to 20g for 1-5 hours before procedure, a thick layer should be applied under occlusive dressing. Over 12 years: Apply 2g (approx. half a 5g tube) for 1-5 hours before procedure. **Maximum total dose allowed under this PGD is ONE application.**
Frequency of dose/Duration of treatment	See above information for duration of application.
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of Administration	Topical
Quantity to be administered	One application per venepuncture/cannulation episode.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: • An initially mild sensation of burning, itching or warmth at the treated area. • Application site erythema, oedema and pallor. • Small dot shaped bleeding on the treated area (particularly on children with eczema after longer application times) during treatment of the skin. • Irritation of the eye if EMLA® Cream accidently comes into contact with them during treatment of the skin.

EMLA® Cream 5% (Lidocaine 2.5% w/w & Prilocaine 2.5% w/w) 5g tube	
Advice	Advise patients to let staff know if cream leaks from occlusive dressing. Ask patients to report any side effects such as skin redness or itchiness.
Follow up (If applicable)	N/A
Storage	Do not store above 30°C and do not freeze. Do not use after expiry date.