Great Ormond Street Hospital for Children NHS Trust
Supply and administration of medicines under Patient Group Directions

This direction covers: Topical local anaesthetic Tetracaine 4% gel (Ametop®) and
Topical local anaesthetic Lidocaine 2.5% + Prilocaine 2.5% cream (EMLA®) (medicine(s))

For the treatment of: Pain caused by arterial or venipuncture or cannulation; renal biopsy
Punch skin biopsy in patients with Epidermolysis Bullosa (EB) (clinical condition(s))

How the condition will be confirmed: Need for procedure

A patient will be excluded if:

- Under 1 month of age (for Ametop®)
- Pre-term newborn infants i.e. gestational age less than 37 weeks (for EMLA®)
- Known hypersensitivity to local anaesthetics or previous reactions to the medicines/excipients
- Methaemoglobinaemia and in infants/neonates between 0 and 12 months of age receiving treatment with methaemoglobin-inducing agents (e.g. sulphonamides, aniline dyes, benzocaine, chloroquine, dapsone, metoclopramide, nitrates/nitrites, nitrofurantoin, nitroprusside, para-aminosalicyclic acid, phenobarbitone, phenytoin, primaquine, quinine) [for EMLA®]

The arrangement for excluded patients is: Referral to the medical practitioner
The arrangement for patients who refuse this treatment is: Referral to the medical practitioner

Registered professional staff type authorised to supply and administer medicines under this direction:
Nurse on Part 8 or Part 15 of NMC Register
Radiographers (state registered)

Non registered but competent staff, authorised to supply and administer medicines under this direction:
Assistants who have been trained, assessed and are competent in phlebotomy
Nuclear Medicine Technologists
The registered professional responsible for supervising these staff is:
Registered nurse (Children), ARSAC Licence holder (medical practitioner)

Understanding the clinical condition: the specialist qualification, training, experience and competence required is:
Nurse on Part 8 or 15 of the NMC Register and Radiographers who have completed the GOSH PGD Local Anaesthetic Training workbook and
who are trained in the care of patients with Epidermolysis Bullosa (if the procedure is undertaken in this group of patients)

Understanding the medicines: the specialist qualification, training, experience and competence required is:
Nurse on Part 8 or 15 of the NMC Register and Radiographers who have completed the GOSH PGD Local Anaesthetic Training workbook and read the Summary of Product Characteristics for each of the medicine

Arrangements for staff training: Practice educator for the unit/department
Arrangements for staff re-training: Senior Nurse for the unit/department

This direction has been approved by: Drug & Therapeutics Committee on 15th April 2003 and 17th Feb 2005 for the procedure in patients with Epidermolysis Bullosa and Oct 2009

and:	and:	and:	authorised by:
Dr Phil Anchiff Chairman, DTC	Judith Ellis Chief Nurse	Judith Cope Chief Pharmacist	Dr Barbara Buckley Co-Medical Director
Date implemented: October 2009		Review date: OCT 2011	**After this date the direction is not valid.**

Every medicine supplied or administered under this direction, must be recorded against the patient name and number, together with the name/signature/date of the person providing the medicine.
A common form of record is the inpatient prescription chart.

The person providing patient care under this direction, must report any adverse reaction to the medical practitioner in charge.

MEDICINES TO BE SUPPLIED OR ADMINISTERED UNDER THIS PATIENT GROUP DIRECTION:

1	2	3	4	5	6	7	8	9	10	11
name and legal status	dose or dose range & route	criteria for selecting dose	frequency & minimum/maximum duration	total no. doses or drug quantity	follow-up treatment which may be required	advice to the patient or carer	Potential adverse reactions/warnings & what to do	concurrent medication which may be a particular problem	any special facilities or supplies required in the clinical area	What to refer to the medical practitioner in charge
Tetracaine 4% gel (Ametop®) P	> 1 mth: 1 tube (~ 1 gram) Topical onto **intact skin** covered with an occlusive dressing	1 g is sufficient to cover and anaesthetize an area of up to 30 cm^2 (6 x 5 cm) Smaller areas of anaesthetized skin may be adequate in infants and small children	If more than 1 site is necessary (e.g. where cannulation is difficult) the maximum doses are > 1 mth but < 5 yr: 1 tube at a time but split over 2 separate sites > 5 yr: max of 5 tubes (~ 5 g) to separate sites at the same time Adequate anaesthesia achieved after a 30 minute application time for venepuncture, and 45 minutes for venous cannulation	Can be repeated after a minimum of 5 hrs if required. Maximum cumulative dose in a 24 hr period are > 1 mth but < 5 yrs: 2 tubes > 5 yrs: 7 tubes	None	Redness, swelling, itch may occur at the site of application Slight redness is common due to vasodilation Anaesthesia remains for 4 – 6 hrs	More severe erythema, oedema and/or itching confined to the site of application have rarely been reported In rare instances, blistering of the skin at the site of application – remove the gel immediately and treat the affected area symptomatically e.g. cool pack Document in notes Although the systemic availability of tetracaine by percutaneous absorption is low, caution in patients with epilepsy	None known	Clinical emergency equipment Oxygen as first line treatment for systemic toxicity	Severe adverse reactions Patients excluded from PGD or refusal to comply with therapy

Note:

For patients with Epidermolysis Bullosa: Apply topical onto intact skin covered with an occlusive dressing stuck onto an opened piece of soft gauze (**non-adherent side of film placed** over the cream and the gauze secured with a soft conforming bandage)

MEDICINES TO BE SUPPLIED OR ADMINISTERED UNDER THIS PATIENT GROUP DIRECTION:

1	2	3	4	5	6	7	8	9	10	11
name and legal status	dose or dose range & route	criteria for selecting dose	frequency & minimum/maximum duration	total no. doses or drug quantity	follow-up treatment which may be required	advice to the patient or carer	Potential adverse reactions/warnings & what to do	concurrent medication which may be a particular problem	any special facilities or supplies required in the clinical area	What to refer to the medical practitioner in charge
Lidocaine 2.5% + Prilocaine 2.5% cream P	Term newborn to 3 mths or < 5 kg: 1 gram to a max area of 10 cm^2 for 1 hour >3 mths & > 5 kg: 2 gram Topical onto **intact skin** covered with an occlusive dressing	Cream applied to a circular area with a diameter of about 18 mm (a 1 pence coin) & depth of about 5 mm is equal to 1 g of EMLA cream For higher levels of accuracy, a syringe can be used where 1 ml = 1 gram Care in applying to patients with atopic dermatitis & shorter application time may be sufficient	Term newborn to 3 mths or < 5 kg: Only 1 single dose in any 24 hour period >3 - 12 mths & > 5 kg: Up to 2 g of cream to a max area of 20 cm^2, for 1 to 4 hours > 1 – 6 yrs: Up to 10 g of cream to a max area of 100 cm^2, for 1 to 5 hours > 7 yrs: Up to 20 g of cream to a max area of 200 cm^2, for 1 to 5 hours	> 3 mths: Maximum of 2 doses, at least 12 hours apart in any 24 hour period	None	Redness, slight swelling or pale skin may occur at the site of application	A mild burning or itching sensation when the cream is applied on the skin Seek help immediately if • symptoms of toxicity e.g. feeling light-headed or dizzy, tingling of skin around the mouth and numbness of tongue, abnormal taste, blurred vision, ringing in the ears • the skin becomes bluish-grey due to a lack of oxygen Document in notes	Amiodarone, Lidocaine, Flecainide, Mexiletine, - closer monitoring of patient	Clinical emergency equipment Oxygen as first line treatment for systemic toxicity	Severe adverse reactions Patients excluded from PGD or refusal to comply with therapy Requiring two applications in those < 3 mths

Note:

For patients with Epidermolysis Bullosa: Apply topical onto intact skin covered with an occlusive dressing stuck onto an opened piece of soft gauze (**non-adherent side of film placed** over the cream and the gauze secured with a soft conforming bandage)