University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Ametop Gel 4% w/w (Tetracaine)
By Registered UHDB Staff in Adult & Paediatric UHDB services

Documentation details

Reference no:	UHDB249
Version no:	1
Valid from:	22/02/2023
Review date:	22/08/2025
Expiry date:	21/02/2026

Change history

Version number	Change details	Date
1	New template – Extended for all UHDB staff on any site	17/11/22

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD (or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
James Hooley	Medicines Safety Officer (Pharmacist)
Core Adult PGD list maintained by Medicines Safety Group.	Note: No PGD working group convened as this PGD is created by merging detail from multiple authorised PGDs (adult and paediatric) in active use across UHDB which have been developed previously with nursing and medical input.

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
N/A	-	-

2. Organisational authorisations

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

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
All UHDB staff providing UHDB services (includes UHDB staff/services undertaken on non-UHDB premises) This is a core PGD and can be implemented in all adult and paediatric services where training and resources have been allocated by senior staff to do so (see policy and limitations below if in doubt). **Note for paediatrics:** Within the paediatric BU, the administration of Ametop may be delegated to health care support workers (HCSW) who are following 'PROTOCOL for the administration of Ametop gel 4% (Tetracaine)'. The registered professional is responsible for all clinical checks and documentation and may only delegate to HCSWs who have been trained and authorised to work under the protocol. Delegation of administration is not legally permissible under routine PGDs. However, in this instance this medicine is not a prescription only medicine and is being administered (not supplied). The delegation has therefore been authorised by UHDB providing the registered professional is authorised to use this PGD and the HCSW is authorised to use the protocol named above.
Limitations to authorisation
It is the responsibility of the practitioner working under this PGD to ensure that this PGD is in place in the area they are practising at the time of use. In most cases, this is implicit when a senior manager requests the staff to undertake training and then authorises them in section 7 of this document. However, when working in alternative areas (e.g. internal bank or redeployment) it is important that the practitioner confirms with a departmental manager in the new department that the core PGDs are in-use in their area.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Chief Pharmacist	**Clive Newman**	**Signed copy held by Pharmacy**	22/2/2023

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (pharmacist) *Clinical Pharmacist from PGD working group*	**James Hooley**	**Signed copy held by Pharmacy**	**19/12/2022**
Medical Director or Nominated Deputy *Doctor*	**James Crampton**	**Signed copy held by Pharmacy**	**24/12/2022**
Executive Chief Nurse or nominated deputy *Registered Professional representing users of the PGD*	**Garry Marsh**	**Signed copy held by Pharmacy**	**20/02/2023**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	All Divisions, Adult and Paediatric Areas, registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction.
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with either the authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	Annual Medicines Safety Training (essential to role) Review/repeat initial training above when this PGD is revised
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Percutaneous local anaesthetic to produce anaesthesia of the skin prior to venepuncture or venous cannulation.
Criteria for inclusion	**All Services:** • Adults and children aged 1 month* and over, requiring surface anaesthesia of the skin • For use on intact, normal skin • **Midwifery services only** may also treat during pregnancy / breastfeeding *For premature babies, Ametop is only to be used once baby is 4 weeks beyond expected delivery date (44 weeks' 'gestation').
Criteria for exclusion	Hypersensitivity to the active substance, to local anaesthetics of the ester type, or to any of the excipients Children under 1 month (or premature babies who are not yet at least 4 weeks' beyond expected delivery date). Pregnancy or Breastfeeding excluded EXCEPT for use of this PGD by midwives or other registered staff working within midwifery services. DO NOT apply on the following: • damaged or broken skin • skin with rash, eczema or inflamed area • mucus membrane • scabs • wounds • eyes • ears • lips, mouth or tongue • inside nose • genitals • rectum/anus
Cautions including any relevant action to be taken	• Repeated exposure - repeat use of Ametop gel may increase the risk of sensitisation reactions to tetracaine. • Epilepsy – systemic absorption is very low with Ametop. Use minimal amount of Ametop. Counsel and consent patient/carer this can still be used within its license. Consider referral to prescriber if patient has uncontrolled epilepsy.
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment • Refer to medical staff or prescriber for review and prescribing of alternative agent if appropriate.
Action to be taken if the patient or carer declines treatment	• Document advice given • Advise patient on alternative treatment • Refer to medical staff if appropriate.

Arrangements for referral for medical advice	Contact your ward or clinic medical team in the first instance except in the event of anaphylaxis/cardiac arrest when you should follow your local medical emergency procedures (e.g. 2222 / 3333 / 999 procedures)

5. Description of treatment

Name, strength & formulation of drug	Tetracaine (Ametop) 4% gel (1 tube = approximately 1gram)
Legal category	P
Route / method of administration	• Topical route • Wear finger cot or rubber gloves during application and removal of Tetracaine gel. • Apply the contents of the tube to the centre of the area to be anaesthetised and cover with an occlusive/transparent dressing. • One tube is sufficient to cover and anaesthetise an area of up to 30sq.cm (6x5cm). • Do not rub in • Remove gel with a gauze swab and prepare the site with an antiseptic wipe after 30 minutes for venepuncture and 45 minutes for venous cannulation **Paediatric Business Unit only**: administration may be delegated to fully trained/authorised HCSW as per section 2
Indicate any off-label use (if relevant)	Manufacturer advises not preferable to use in pregnancy and to avoid in breastfeeding. However, BNF states not known to be harmful in breastfeeding. UHDB have had midwifery PGD (including pregnancy inclusion) for many years. In 2022 this was supported as routine practice for continuation of use under PGD by Dr Raouf (Obstetrician) and by Midwifery Matron Sarah Evans and Lead Midwife Claire Brackenbury. Therefore use in pregnancy and breastfeeding is supported within this PGD within the midwifery specialist service only.
Dose and frequency of administration	**Paediatric Business Unit only**: administration may be delegated to fully trained/authorised HCSW as per section 2 **All other areas:** administration must be undertaken by the practitioner working under this PGD Children aged 1 month to 4 years • Apply contents of up to ONE tube to site(s) of venepuncture or venous cannulation and cover with occlusive dressing. The gel may be applied to more than one site, but only 1 tube should be used • Remove gel and dressing after 30 minutes for venepuncture and after 45 minutes for venous cannulation

	• Application of gel can be repeated after a minimum of 5 hours • Maximum cumulative dose in 24 hours should not exceed 2 tubes Adults and children 5 years or over • Apply the contents of up to 5 tubes to site(s) 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 of gel can be repeated after a minimum of 5 hours • Maximum cumulative dose in 24-hour period should not exceed 7 tubes Tetracaine is effective for 4-6 hours after a single application.
Duration of treatment	Maximum of two applications, 5 hours apart as above (and not exceeding the 24 hour maximum). A prescription must be obtained for any treatment beyond these first two applications. 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.
Quantity to be supplied (leave blank if PGD is administration ONLY)	Administration PGD only
Storage	Stock must be securely stored according to UHDB medicine policy and in conditions in line with SPC as detailed below: • Store at 2 – 8 degrees C. Do not freeze. • May be stored at room temp (up to 25°C) for up to 1 month. Any tubes being stored at room temp should be clearly marked with revised expiry date
Drug interactions	The following interactions have been identified and should be considered where it is known a patient is on the following medicines: • None known NOTE: The BNF does list theoretical interactions for tetracaine with other drugs, however, this is unlikely to be significant with normal topical use, as there is minimal systemic absorption. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	• Redness of the skin at application site - common • Itching and swelling at application site – uncommon • More severe redness, swelling and/or itching at application site - rare • Blistering of the skin at application site – very rare • Hypersensitivity, cardiac, respiratory, or CNS reactions are unlikely with normal usage as there is a minimal absorption following topical application. Only likely if excessively absorbed.

	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product. For children there is option to direct parent or guardian to: • Medicine for Children leaflet which can be obtain on https://www.medicinesforchildren.org.uk/medicines/tetracaine-gel-for-local-anaesthesia/
Patient advice / follow up treatment	Report any discomfort at the site after application If blistering occurs, remove the tetracaine gel immediately and treat symptomatically The treated skin may feel numb for 4 – 6 hours after application Advise to seek advice from a healthcare professional if an adverse event occurs
Records	For inpatients, the record of administration must be documented in the ePMA system or medicines chart used in your area. For other areas, an ePMA system should be used if in-use in your area as this will ensure all legal criteria are fulfilled and auditable. Otherwise, records can be made in the medical notes or within the patient pathway (e.g. in daycase or triage where a pathway booklet is in use) but must include the legal requirements below. Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered via Patient Group Direction (PGD)

	Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• *https://www.medicines.org.uk/emc/product/9055* • *https://bnf.nice.org.uk/drugs/tetracaine/* • Tetracaine gel for local anaesthesia – Medicines For Children

7. Registered health professional authorisation sheet

PGD Name [version]: Ametop Gel 4% w/w (Tetracaine) Adult & Children [v1.0]
PGD ref: UHDB249
Valid from: 22/02/2023 **Expiry date:** 21/02/2026

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional
By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

Patient group directions do not remove inherent professional obligations or accountability.
It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.