University Hospitals of Derby and Burton NHS Foundation Trust

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PATIENT GROUP DIRECTION (PGD)

Supply & Administration of Prochlorperazine for the management of hyperemesis - *(GAU & EPAU at RDH and QHB)*

Documentation details

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Change history

Version number	Change details	Date

Glossary

Abbreviation	Definition
GAU	Gynaecology Assessment Unit
EPAU	

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
Anushka Tirlapur	Professional & Specialty Lead Consultant
Harriet Hughes	Advanced Pharmacist, Women's and Children's
Sharon Hill	Gynaecology Matron
Melanie McDonagh	Senior Sister Gynaecology Assessment Unit
Josh Dhamrait	Pharmacist

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	n/a	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
Obstetrics and gynaecology departments ONLY: - GAU at Royal Derby Hospital - EPAU at Queens Hospital Burton
Limitations to authorisation

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (Pharmacist) *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held in Pharmacy**	

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Professional & Specialty Lead Consultant	Anushka Tirlapur	Signed copy held by Pharmacy	05/07/2022
Gynaecology matron	Sharon Hill	Signed copy held by Pharmacy	29/06/2022
Advanced Pharmacist, Women's & Children's	Harriet Hughes	Signed copy held by Pharmacy	22/06/2022

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	• NMC registered nurse • NMC registered midwives Registered professional with current professional registration operating within their usual scope of practice.
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 • Training in use of the PGD, clinically assessing and classifying patients who meet an inclusion or exclusion criteria. • IM injection - training session. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Competency assessment	• Approved drug assessment. • To undertake appropriate training in carrying out a clinical assessment, of patients, leading to diagnosis that requires treatment according to the indications listed in the PGD. • Has undertaken appropriate training for working under Patient Group. Directions for the supply and administration of medicines.
Ongoing training and competency	• Annual Medicines Safety Training (essential to role) • 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 authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required. • 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	Patients presenting to GAU/EPAU with nausea and vomiting **in confirmed pregnancy**, with reduced tolerance to food and/or drink. Refer to clinical guideline for the day case management of nausea and vomiting of pregnancy/hyperemesis gravidarum.
Criteria for inclusion	**Prochlorperazine Maleate – *(5-10mg Oral Tablet)*:** - Patients over 16 years old presenting with the above condition **AND** consenting for administration. **Prochlorperazine *(Buccastem®) – (3mg buccal tablets):*** - Patients over 16 years old presenting with the above condition

	AND consenting for administration. - Unable to tolerate swallowing medication, food or drink. **Prochlorperazine Maleate – *(12.5mg IM injection)*:** - Patients over 18 years old presenting with the above condition **AND** consenting for administration. *Short term Prochlorperazine is acceptable to those breastfeeding as per Specialist Pharmacy Service. However please note that sedation in the infant and suppression of lactation may theoretically occur with frequent or high-dose use.*
Criteria for exclusion	**Prochlorperazine Maleate – *(Oral Tablet)*:** - Previous sensitivity or intolerance to the drug or any ingredient – See Summary of Product Characteristics - Women who suffer from glaucoma, hepatic disease, renal disease or Parkinson's disease. - Patients under 16 years of age. - Cannot swallow, are nil by mouth, or have difficulty swallowing food or drink' are awaiting a swallow reflex test. - Non competent patient's e.g. vulnerable adult; undiagnosed medical symptoms; reservations/concerns by patient about side effects of the treatment. - Patient has been given Prochlorperazine 6mg in the previous 12 hours (and/or 24mg total in previous 24 hours) - Consent to treatment not gained. **Prochlorperazine *(Buccastem®) – 3mg buccal tablets:*** - Previous sensitivity or intolerance to the drug or any ingredient – See Summary of Product Characteristics - Women who suffer from glaucoma, hepatic disease, renal disease or Parkinson's disease. - Patients under 16 years of age. - Non competent patient's e.g. vulnerable adult; undiagnosed medical symptoms; reservations/concerns by patient about side effects of the treatment. - Patient has been given Prochlorperazine 6mg in the previous 12 hours (and/or 24mg total in previous 24 hours). - Consent to treatment not gained. **Prochlorperazine Maleate – *(12.5mg IM injection)*:** - Previous sensitivity or intolerance to the drug or any ingredient – See Summary of Product Characteristics. - Women who suffer from glaucoma, hepatic disease, renal disease or Parkinson's disease. - Patients under 18 years of age. - Non competent patient's e.g. vulnerable adult; undiagnosed medical symptoms; reservations/concerns by patient about side effects of the treatment. - Patient has been given Prochlorperazine 6mg in the previous 12 hours

	- Consent to treatment not gained.
Cautions including any relevant action to be taken	**Cautions:** Blood dyscrasias; cardiovascular disease; conditions predisposing to seizures; depression; diabetes (may raise blood glucose); epilepsy; history of jaundice; myasthenia gravis; Parkinson's disease (may be exacerbated) (in adults); photosensitisation (may occur with higher dosages); severe respiratory disease; susceptibility to angle-closure glaucoma. **Actions required:** For doctor review if GAU/ EPAU nursing staff are concerned about the patient's condition or she has failed to respond to this medication in the past or has suffered side effects with this medication in the past.
Action to be taken if the patient is excluded	- For doctor review. - For nursing staff to continue to manage patient following the clinical guidelines for the hyperemesis clinic. Identify and document reason for exclusion and discuss with patient/carer.
Action to be taken if the patient or carer declines treatment	Document refusal, action taken, and advice given in nursing documentation and refer to medical staff if appropriate.
Arrangements for referral for medical advice	Nursing staff to contact the gynaecology SHO/Registrar on duty for review.

5. Description of treatment

Name, strength & formulation of drug	➢ Prochlorperazine Maleate 5mg Oral Tablet ➢ Prochlorperazine (Buccastem®) 3mg Buccal Tablets: ➢ Prochlorperazine Maleate 12.5mg IM Injection
Legal category	POM
Route / method of administration	➢ Prochlorperazine Maleate 5mg **Oral** Tablet ➢ Prochlorperazine (Buccastem®) 3mg **Buccal** Tablets: ➢ Prochlorperazine Maleate 12.5mg **intramuscular** Injection
Indicate any off-label use (if relevant)	*NIL*
Dose and frequency of administration	**Oral: *5-10mg 8 hourly*** Maximum of one dose to be given in hyperemesis clinic without a prescription. **Buccal: *3mg twice daily*** – Maximum of one dose to be given in hyperemesis clinic without a prescription. **IM: *12.5mg 8 hourly*** – Maximum of ONE dose to be given in hyperemesis clinic without a prescription.
Duration of treatment	**Oral*:*** up to 5 days' supply to take home (or one full pack of 28 tablets). Where TTO pack is unavailable, patient must be sent to pharmacy with a prescription for supply. **Buccal: *3mg twice daily* –** up to 5 days' supply to take home. Where TTO pack is unavailable, patient must be sent to pharmacy with a prescription for supply. **IM: *12.5mg 8 hourly* –** ONE dose only in hyperemesis clinic.
Quantity to be supplied (leave blank if PGD is administration ONLY)	Labelling must meet the requirements outlined in Trust PGD Policy and associated training. The Pharmacy department over-label packs to meet legal requirements for supply. If you do not hold these appropriately over-labelled packs in stock, then a supply to patients is not appropriate.
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: **Prochlorperazine Maleate 5mg Oral Tablet:** - No special requirements

	Prochlorperazine Maleate (Buccastem®) 3mg Buccal Tablets: - No special requirements **Prochlorperazine Maleate 12.5mg IM Injection:** - Keep the ampoules in the outer carton to protect from light. - Do not store above 25°C.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk Where unsure, contact pharmacist for further information or advice.
Adverse reactions	Extrapyramidal symptoms including tremor, dystonia (abnormal face and body movements), dyskinesia; restlessness, tardive dyskinesia (rhythmic, involuntary movements of tongue, face, and jaw), increase prolactin concentration, drowsiness; apathy; agitation, excitement and insomnia; convulsions; dizziness; headache; confusion; palpitations; arrhythmias; gastro-intestinal disturbances; nasal congestion; antimuscarinic symptoms (such as dry mouth, constipation, difficulty with micturition, and blurred vision; very rarely, precipitation of angleclosure glaucoma); venous thromboembolism; blood dyscrasias (such as agranulocytosis and leucopenia), photosensitisation, contact sensitisation and rashes, and jaundice (including cholestatic); corneal and lens opacities, and purplish pigmentation of the skin, cornea, conjunctiva, and retina; respiratory depression.
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	If required, provide marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	- Monitor for sensitivity reactions; may cause drowsiness, dizziness, dry mouth, insomnia, agitation, mild skin reactions. - Drowsiness may affect performance of skilled tasks (.e.g. driving).

	- Extrapyramidal reactions are very unlikely at the recommended dosage, but include acute dystonic reactions (facial and skeletal muscle spasm and oculogyric crisis with abnormal movement of the eyeball) - Seek medical advice in the event of an adverse reaction.
Records	- Nursing documentation and patient pathway. State 'administered under PGD' with name and signature of an authorised nurse. A second check should be obtained from a qualified healthcare practitioner before administration. - EPMA: Document the utilisation of the medicine under PGD by ordering the appropriate drug order item against the correct patient. Document the administration of the medicine. *The above records should capture all of the following information:* - 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 and that this was done via Patient Group Direction (PGD) -

6. Key references

Key references	• *Electronic Medicines Compendium http://www.medicines.org.uk/* • *Electronic BNF https://bnf.nice.org.uk/* • *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2* • *Specialist Pharmacy Service Safety in Lactation: Drugs used in nausea and vertigo – https://www.sps.nhs.uk/*

7. Registered health professional authorisation sheet

PGD Name [version]: GAU and EPAU – Prochlorperazine [v1] PGD ref: UHDB190

Valid from: 05/07/2022 Expiry date: 04/07/2025

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.