University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply and Administration of Paracetamol 500mg tablets By Registered UHDB Staff in Adult UHDB services

Documentation details

Reference no:	UHDB037
Version no:	1.0
Valid from:	16/09/2021
Review date:	16/03/2024
Expiry date:	15/09/2024

Change history

Version number	Change details	Date
1	New template – Extended for all UHDB staff on any site	January 2021

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 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 <u>can</u> be implemented in all adult services where training and resources have been allocated by senior staff to do so (see policy and limitations below if in doubt).
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 in Pharmacy	**23/08/2021**

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 in Pharmacy	**18/08/2021**
Medical Director or deputy *Doctor*	**Magnus Harrison**	Signed copy held in Pharmacy	**18/08/2021**
Chief Nurse or Deputy *Registered Professional representing users of the PGD*	**Catherine Winfield**	Signed copy held in Pharmacy	**11/08/2021**

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 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	Mild to moderate pain / headache and/or pyrexia
Criteria for inclusion	• Patients over 16 years presenting with the above symptoms; • Patient must be able to take medicine orally
Criteria for exclusion	• Pain or pyrexia in the absence of known cause or diagnosis • Previous sensitivity or intolerance to the drug or any ingredient; • Patient under 40kg – refer to prescriber. • patients under 16 years old; • Cannot swallow (or awaiting swallow assessment), are nil by mouth, or have difficulty swallowing food or drink • Severe hepatic impairment • Alcoholic liver disease • Patients who have taken any product containing Paracetamol within the previous 4 hours (or where timing of previous dosing cannot be confirmed). • Patients taking imatinib (used in a range of cancer and haematology conditions)
Cautions including any relevant action to be taken	In the following cases, this PGD should be used for administration only (up to maximum number of doses specified below) and should not be supplied to the patient: • Severe renal disease* • Mild to moderate hepatic impairment - • chronic alcohol consumption • chronic dehydration • chronic malnutrition • Patients taking warfarin or other coumarin anticoagulants *UHDB renal service have approved administration of paracetamol under PGD within the dosing structure in this document – if referring on to a prescriber for continued prescription, ensure you inform them of impaired renal function
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 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	Immediate medical advice should be sought in the event of an overdose, even if patient feels well, because of the risk of delayed & serious liver damage. 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	Paracetamol 500mg tablets (includes soluble formulations)
Legal category	GSL / P
Route / method of administration	Oral
Indicate any off-label use (if relevant)	No off-label usage
Dose and frequency of administration	• >50kg: One or Two tablets (500mg – 1000mg) 4-6 hourly up to maximum of 4grams in 24 hours • 40-50kg: One tablet (500mg) 4-6 hourly up to a maximum of 3 grams in 24 hours Always check pre-admission / pre-attendance dosing and factor this in to the maximum daily dose limits for the patient's weight.
Duration of treatment	ADMINISTRATION for inpatient, outpatient, triage use: Maximum of three doses before a prescription is obtained. SUPPLY: Up to 7 days
Quantity to be supplied (leave blank if PGD is administration ONLY)	SUPPLY of a discharge pack is only appropriate: - In nurse or practitioner-led clinics or pathways (i.e. areas where prescribers are not involved in the preparation of discharge summaries/prescriptions). - After considering if the patient has a supply at home or can buy over the counter. A prescription charge should be levied in clinical areas who are required to issue NHS prescription charges. Over the counter supplies of paracetamol are cheaper for the patient; signpost where possible **Supply whole packs only up to a maximum of 7 days supply.** 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: Store below 25°C in a dry place. Protect from light.
Drug interactions	• Imatinib – refer to prescriber – do not authorise PGD use of concomitant paracetamol and imatinib)see exclusions) • Check other analgesia, especially patients on compound analgesic preparations which may contain Paracetamol; Check that the patient has not already received the maximum daily dose of Paracetamol (see 'Dose & Frequency section above) and has

	not had a dose of Paracetamol within the last four hours; • Warfarin, phenindione & acenocoumarol: prolonged use of Paracetamol may enhance anticoagulant effects – see cautions section above. • Pharmacy advice on scheduling doses should be sought if a patient is on concomitant Cholestyramine, as administration of this drug within 2 hours prior to a dose of Paracetamol may reduce the effectiveness of the Paracetamol. 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	Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia, neutropenia, pancytopenia, leukopenia and agranulocytosis but these were not necessarily causality-linked to Paracetamol Very rare cases of serious skin reactions have been reported. 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.
Patient advice / follow up treatment	Monitor for sensitivity reactions; Verbal advice on why drug administered, action of the drug and subsequent management of condition; not to take more than max recommended dose in 24 hours (see 'Dose & Frequency section above); not to take any other medicines/over-the-counter products containing Paracetamol; report effectiveness or any untoward effects to nursing staff if still within the hospital or discuss with a community pharmacist.
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 implemented 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	• *Electronic Medicines Compendium http://www.medicines.org.uk/* https://www.medicines.org.uk/emc/product/5916/smpc accessed 18/03/21 • *Electronic BNF https://bnf.nice.org.uk/ accessed 18/03/21*

7. Registered health professional authorisation sheet

PGD Name [version]: Oral Paracetamol [v1] PGD ref: UHDB037

Valid from: 16/09/2021 Expiry date: 15/09/2024

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.