University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Ibuprofen 400 MG- (Gynaecology Outpatients Department -RDH)

Documentation details

Reference no:	UHDB273
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Valid from:	20/07/2023
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Expiry date:	19/07/2026

Change history

Version number	Change details	Date
1.0	New UHDB Format	30/06/2023

Glossary

Abbreviation	Definition
GOPD	Gynaecology Outpatients Department

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
Melanie McDonagh	Senior Sister Gynaecology Assessment Unit
Joanna Hurcombe	Advanced Pharmacist
Anish Bali	Divisional Medical Director

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
Gynaecology departments ONLY: GOPD at Royal Derby Hospital
Limitations to authorisation
Nil additional to above services and characteristics of staff as per Section 3

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (Pharmacist)	James Hooley	**Signed copy held by Pharmacy**	**20/07/2023**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Advanced Pharmacist Women & Children's	Joanna Hurcombe	Signed copy held by Pharmacy	03/07/2023
Divisional Medical Director	Anish Bali	Signed copy held by Pharmacy	13/07/2023
Gynaecology Matron	Sharon Hill	Signed copy held by Pharmacy	13/07/2023

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	• NMC registered nurse • 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. • 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	Mild to moderate pain including dysmenorrhoea. Pain or inflammation following outpatient procedures.
Criteria for inclusion	Adult patients presenting as above. Patients over 16 years of age, presenting with mild to moderate pain including dysmenorrhoea. Pain or inflammation following outpatient procedures in patients who have given consent to treatment.
Criteria for exclusion	• Previous sensitivity or intolerance to Ibuprofen or any ingredient • Hypersensitivity to Aspirin or other NSAIDs • History of asthma (unless previously tolerated NSAIDs) • Pregnancy • Poor renal function; active or previous peptic ulcer • History of upper gastrointestinal bleeding or perforation related to previous NSAID therapy, renal transplant patients currently taking immunosuppressants, e.g., ciclosporin or tacrolimus. • Currently taking Lithium or Methotrexate (excretion reduced therefore risk of toxicity) • Known hepatic, renal, or cardiac failure. • Cannot swallow, are nil by mouth, or have difficulty swallowing food or drink. Are awaiting a swallow reflex test. • Lacking capacity to consent to PGD. • Undiagnosed medical symptoms • Reservations/concerns by patient about side effects of the treatment • Patients are already taking regular NSAIDs.
Cautions including any relevant action to be taken	*Cautions:* If patient is breastfeeding and infant is not term and healthy, seek specialist advice (doctor or pharmacist). Decision to administer under PGD remains with the practitioner working under this document. If you remain uncertain, contact a prescriber.
Action to be taken if the patient is excluded	• Refer to medical staff for review and prescribing of alternative agent if appropriate. • 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	Ibuprofen tablet 400MG
Legal category	P
Route / method of administration	Oral tablet
Indicate any off-label use (if relevant)	*n/a*
Dose and frequency of administration	400mg as a single dose.
Duration of treatment	**Single dose only.**
Quantity to be supplied (leave blank if PGD is administration ONLY)	*n/a*
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: *Room temperature, stored securely following UHDB Medicines Policy.* *SPC available from the electronic Medicines Compendium website:* www.medicines.org.uk
Drug interactions	If the patient is receiving any concomitant medication or treatment it is the responsibility of the person working under this PGD to ensure that treatment with the drug detailed in this direction is appropriate. Check all concurrent medication with the patient and in the current BNF before supplying. Refer to a doctor if the patient is taking any medication that may interact with the intended treatment. If in any doubt, advice should be sought and recorded before the drug is administered. Known drug interactions (seek advice from a pharmacist): · Mifamurtide (treatment for osteosarcoma) · Quinolone antibiotics (e.g. ciprofloxacin) · Nephrotoxic drugs (including other NSAIDs, many drugs for high blood pressure or drugs to prevent transplant rejection) · Drugs which cause GI irritation (including steroids, SSRIs such as citalopram) · Anticoagulants such as warfarin, enoxaparin and any of the DOACs (apixaban, dabigatran, edoxaban, rivaroxaban) · Lithium · Methotrexate · Antifungal drugs e.g. voriconazole 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	GI disturbance (discomfort, nausea, diarrhoea) and occasionally bleeding or ulceration; hypersensitivity including rash, angioedema and bronchospasm, headache, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, hearing disturbance, photosensitivity and haematuria; blood pressure increase or fluid retention. 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	If required give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	Verbal advice on why drug administered, action of the drug and subsequent management of condition; monitor for sensitivity reactions.
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. 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 and that this was done 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	*Update and include for each revision. In most cases a link to specific records in the examples below will be appropriate* • *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* • *https://medusa.wales.nhs.uk*

7. Registered health professional authorisation sheet

PGD Name [version]: RDH - GOPD - Ibuprofen [v1] PGD ref: UHDB273

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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.