University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of NAPROXEN ORAL TABLETS

By Registered Nurses, Emergency Nurse Practitioners (ENP), Emergency Care Practitioners (ECP) and Emergency Physiotherapy Practitioners (EPP) In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals

Documentation details

Reference no:	UHDB237
Version no:	1
Valid from:	04/01/2023
Review date:	04/07/2025
Expiry date:	03/01/2026

Change history

Version number	Change details	Date

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
Dr Thungala	Doctor
James Kerr	Pharmacist
Alannah Davies	Representative of RNMHP Group

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
In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals
Limitations to authorisation
Nil

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held by Pharmacy**	**04/01/2023**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Pharmacist *Clinical Pharmacist from PGD working group*	**James Kerr**	**Signed copy held by Pharmacy**	**22/12/2022**
Consultant *Doctor*	**Dr. Thungala**	**Signed copy held by Pharmacy**	**04/01/2023**
Interim Matron Acute Medicine QHB *Registered Professional representing users of the PGD*	**Danielle Murphy**	**Signed copy held by Pharmacy**	**03/01/2023**

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	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 - Deemed competent by their line manager to undertake the clinical assessment of a patient leading to a diagnosis that requires treatment according to the indications listed in this PGD and Trust clinical guidelines
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 the senior individual responsible for authorising individuals to act under the PGD and further training 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 registered healthcare practitioner will ensure Anaphylaxis/CPR training is kept updated yearly. - The registered healthcare professional must actively take part in CPD and annual individual performance reviews. -Regular training and updating in safeguarding children and vulnerable adults as per trust policy
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	**Pain and inflammation caused by:** - Acute gout - Acute musculoskeletal disorders - Ankylosing spondylitis - Direct trauma including recent surgery - Dysmenorrhoea - Osteoarthritis (degenerative arthritis) - Rheumatoid arthritis
Criteria for inclusion	• Patients between ages of 16 and 65 years of age who have pain with inflammation
Criteria for exclusion	• Patients under 16 years of age of over 65 years of age • Pregnancy • Breastfeeding • Hypersensitivity to naproxen or any of the ingredients • Hypersensitivity reactions to ibuprofen, aspirin or other NSAIDs • Patients currently taking regular NSAIDs or COX2 specific inhibitors • Severe heart failure, hepatic failure or renal failure • History of/ or active GI bleed or ulceration • Acute asthma or asthmatics who have never used NSAIDs safely before • Ulcerative or acute inflammatory conditions of the anus, rectum or sigmoid colon • Haemorrhoids or predisposition to rectal bleeding • Disorders of the coagulation or treatment with anticoagulants or antiplatelets
Cautions including any relevant action to be taken	• Patients treated with NSAIDs long-term should undergo regular medical supervision to monitor for adverse events. • Severe gastrointestinal side effects may occur in patients who use prostaglandin synthetase inhibitors. • Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with naproxen after careful consideration. Similar consideration should be made before initiating longer-term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking). • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Action to be taken if the patient is excluded	• **Refer to a Doctor (e.g. GP or A&E) for further assessment**
Action to be taken if the patient or carer declines treatment	• Discuss need for treatment • Document advice given • Advise patient on alternative treatment

Arrangements for referral for medical advice	• Refer to GP or, patient to self-refer for assessment, alternatively 111 service

5. Description of treatment

Name, strength & formulation of drug	Naproxen Oral Tablets 250mg
Legal category	POM
Route / method of administration	**PO** **Oral tablets**
Indicate any off-label use (if relevant)	*None*
Dose and frequency of administration	**Acute Musculoskeletal disorders and dysmenorrhea:** 500mg initially then 250mg every 6-8 hours as required, maximum dose after first day is 1.25g daily **Acute gout:** Initially 750 mg, then 250 mg every 8 hours until attack has passed. **Pain and inflammation in rheumatic disease:** 0.5–1 g daily in 1–2 divided doses. BNF Online accessed at: https://bnf.nice.org.uk/drugs/naproxen/
Duration of treatment	Administration in department and then short term supply (see max quantity below which will provide approx 7-14 days' supply).
Quantity to be supplied (leave blank if PGD is administration ONLY)	One pack of pre-labelled 28 Naproxen 250mg tablet to be supplied to patient, any further requirement should be sought from a prescriber.
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 and protect from light. Do not refrigerate or freeze.
Drug interactions	**Antacid or colestyramine:** can delay the absorption of naproxen but does not affect its extent. Naproxen should be taken at least one hour before or four to six hours after colestyramine. **Food:** Concomitant administration of food can delay the absorption of naproxen but does not affect its extent. **Other analgesics including cyclooxygenase-2 selective inhibitors:** Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk of adverse effects **Anti-hypertensives:** Reduced anti-hypertensive effect. Concomitant administration of naproxen with beta blockers may reduce their antihypertensive effect and may increase the risk of renal impairment

	associated with the use of ACE inhibitors or angiotensin II receptor antagonists. **Diuretics:** Caution is advised when Naproxen is co-administered with diuretics as there can be a decreased diuretic effect. The natriuretic effect of furosemide has been reported to be inhibited by some drugs of this class. Diuretics can increase the risk of nephrotoxicity of NSAIDs. **Cardiac glycosides:** NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels. **Lithium:** Inhibition of renal lithium clearance leading to increases in plasma lithium concentrations has also been reported following administration of these agents. **Methotrexate**: Caution is advised where methotrexate is given concurrently because of possible enhancement of its toxicity, since naproxen, among other non-steroidal anti-inflammatory drugs, has been reported to reduce the tubular secretion of methotrexate in an animal model. **Ciclosporin**: Increased risk of nephrotoxocity. **Mifepristone**: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone. **Corticosteroids**: As with all NSAIDs, caution should be taken when co-administering with cortico-steroids because of the increased risk of gastrointestinal ulceration or bleeding. **Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs):** Increased risk of GI bleeding when anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs) are combined with NSAIDs. **Anti-coagulants :** It is considered unsafe to take NSAIDs in combination with anti-coagulants such as warfarin or heparin unless under direct medical supervision, as NSAIDs may enhance the effects of anti-coagulants **Effect of high plasma protein binding of Naproxen on other drugs:** Due to the high plasma protein binding of naproxen, patients simultaneously receiving hydantoins, anticoagulants, other NSAIDs, aspirin or a highly protein-bound sulphonamide should be observed for signs of overdosage of these drugs. Patients simultaneously receiving Naproxen and a hydantoin, sulphonamide or sulfonylurea should be observed for adjustment of dose if required. No interactions have been observed in clinical studies with naproxen and anticoagulants or sulfonylureas, but caution is nevertheless advised since interaction has been seen with other non-steroidal agents of this class. **Probenecid**: Probenecid given concurrently increases naproxen plasma levels and extends its half-life considerably. **Zidovudine:** There is an increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an

	increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen. **Bisphosphonates**: concomitant use of bisphosphonates and NSAIDs may increase the risk of gastric mucosal damage. **Quinolone antibiotics**: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions. **Tacrolimus:** Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus. **Acetylsalicylic acid:** Clinical pharmacodynamic data suggest that concomitant naproxen usage for more than one day consecutively may inhibit the effect of low-dose acetylsalicylic acid on platelet activity and this inhibition may persist for up to several days after stopping naproxen therapy. The clinical relevance of this interaction is not known.
Adverse reactions	**Frequency not known:** • GI disturbance, GI ulceration or GI bleeding (particularly in the elderly) • Hypersensitivtiy reactions include rashes, angioedema and bronchospasm there is a risk of anaphylaxis. Note these may occur in patients with no previous history of previous reactions. • Headaches, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, tinnitus, photosensitivity, haematuria. • Dyspepsia, nausea, vomiting, diarrhoea, abdominal pain, irritation of the gastric mucosa causing ulceration or bleeding. • May worsen control of asthma and hypertension • Can precipitate renal failure/heart failure/colitis. **Rarely** - Alveolitis, blood disorders, pulmonary eosinophilia, pancreatitis, visual disturbances, toxic epidermal necrolysis, Steven Johnson Syndrome, aseptic meningitis, interstitial fibrosis and papillary necrosis leading to renal failure. *See manufacturers leaflet or SPC for a full list of side effects.*
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. • If Anaphylaxis occurs treat as per local emergency protocols and transfer to A&E via 999 if appropriate to area.

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	• Advise on duration of treatment and maximum doses for condition • Report any reactions, especially GI, skin or allergic type reactions. • Undesirable effects may be minimised by using the minimum effective dose for the shortest possible duration necessary to control symptoms. Tablets should be taken with food to reduce likelihood of GI reactions • Patients who experience dizziness, drowsiness, fatigue and visual disturbances while taking NSAIDs should not drive or operate machinery.
Records	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	• *Electronic Medicines Compendium: Available at: https://www.medicines.org.uk/emc/product/6034/smpc#CLINICAL_PRECAUTIONS, Accessed 15/7/22* • *Electronic BNF, Available at:* https://bnf.nice.org.uk/drugs/naproxen/, *Accessed 15/7/22* • *NICE guidelines. Available at:* https://cks.nice.org.uk/topics/nsaids-prescribing-issues/, *Accessed 15/7/22* • *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]: Emergency Department, Ambulatory Care QHB and MIU SJCH and SRP – Naproxen Oral Tablets [v1]

PGD ref: **UHDB237**

Valid from: 04/01/2023 Expiry date: 03/01/2026

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.