PATIENT GROUP DIRECTION (PGD)

for administration and supply of

Oral Naproxen

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

1	**The reference code for this PGD is:**	**QHB/ED/MIU/naproxen**	**Version:**	**3**
	The original signed hardcopy of this document is kept in the location in which it is used and an electronic copy of the current version can be found on the intranet Pharmacy >PGDs			

Extended to 29/12/2022 - agreed at PGD Governance Sept 2022

2	**Valid from:**	30th September 2019	**Expiry date:**	29th September 2022
	Outside of these dates this PGD is not a valid legal document and Health Professional approvals are invalid. 'Valid from' must be after authorisation date in section 7 so may be left blank until section 7 is completed. Expiry date must be 3 years or less from valid from date.			

3	**Lead Author:**	**Name**		**Designation**		
		Nadine Watson		**Clinical Education Practitioner ED**		
	This person, normally a member of the development group in section 5, is responsible for review and renewal of the PGD before its expiry date. If this responsibility is transferred to another individual please amend below and inform Pharmacy so the database can be updated.					
	Amended Lead Author	**Name**		**Designation**		
	Date amended:		Amended by:		Pharmacy informed on:	

4	**Post in the above service area authorised to approve named Health Professionals to work under this PGD:**			
	Matron for ED			
	Before using this PGD the Health Professional must be approved by the above post holder, complete Appendix B and have their name added to the approved list of staff for this PGD - appendix A. If this post changes or the responsibility is transferred to another post please amend below.			
	Amended Post:			
	Date amended:		Amended by:	

5	**Development group**		
Designation	**Name**	**Signature**	**Date**
Doctor	**Dr Sarah Pearson**		25/9/19
Pharmacist	**Lisa Nock**		26/9/19
Representative of RNMHP group	**Sara Wheeler**	Swheeler	25/9/19
The above persons have drafted and peer reviewed this document. The Doctor and the Pharmacist take joint responsibility for the clinical and pharmaceutical information contained in it. The representative of the RNMHP is the person agreeing this PGD is suitable for use in the specified group of staff in the specified service or area or location.			

6	**Consultation group** – the following were consulted during the development of this PGD
Designation	**Name**
Reviewed and approved by PGD subgroup on	

7	**Authorised on behalf of UHDB NHS Foundation Trust by:**		
Designation	**Name**	**Signature**	**Date**
Medicines Safety officer	**James Hooley**		20/9/19
This person has established that the legal requirements, local policy and governance arrangements for PGD development have been met in the production of this document and authorise its use in this Trust. For persons allowed to authorise see the guidance document.			

Record of review during life of this PGD which did not require any changes.		
Date of review	**Reason for review**	**Reviewed by**

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8	**Name, strength and formulation of drug**	Naproxen 250mg and 500mg tablets
9	**Clinical Situation for which medicine is to be used**	Pain and inflammation caused by: - Acute gout - Acute musculoskeletal disorders - Ankylosing spondylitis - Direct trauma including recent surgery - Dysmenorrhoea - Osteoarthritis (degenerative arthritis) - Rheumatoid arthrits
10	**Inclusion Criteria**	Patients between the age of 16 years and 65 years who have pain with inflammation.
11	**Exclusion criteria including any contraindications to use**	- Under 16 years or over 65 years - Active, or history of, GI bleeding or ulceration - Hypersensitivity to naproxen or other ingredients - Hypersensitivity reactions to ibuprofen, aspirin or other NSAIDs - Patients currently taking regular NSAIDs or COX2 specific inhibitors. - Severe heart failure - Severe liver disease - Severe renal impairment (eGFR <30ml/min) - Pregnancy (third trimester) and breastfeeding - 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 coagulation or treatment with anticoagulants or antplatelets
12	**Reasons for seeking further advice or referral to Doctor including any cautions to use**	- Renal or hepatic impairment - Pregnancy – first and second trimester - Uncontrolled hypertension - Congestive heart failure - Established Ischaemic heart disease

		- Peripheral arterial disease - Cerebrovascular disease - Patients with SLE and mixed connective tissue disorders (increased risk of aseptic meningitis) - Concurrent treatment with any of the medicines listed in section 16 (drug interactions)
13	**Dosage**	**Acute Musculoskeletal disorders and dysmenorrhoea:** 500mg initially then 250mg every 6-8 hours **Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis:** 250 – 500 mgmg every 12 hours **Acute gout:** 750mg initially then 250mg every 8 hours
14	**Route of administration**	Orally, preferably after food
15	**Administration frequency and duration**	See dosage
16	**Drug interactions**	- ***Other NSAID, cyclooxygenase 2 (COX2)selective inhibitors or corticosteroids*** Increased risk of adverse effects - ***Antihypertensive agents*** Effect of propranolol and other beta blockers can be reduced - ***ACE inhibitors and Angiotensin II inhibitors*** Increase nephrotoxic risk, reduced antihyperntensive effect - ***Anticoagulants and anti-platelets*** Increased risk of bleeding - ***Biphosphonates*** Increased risk of GI mucosal damage - ***Ciclosporin*** Increased risk of nephrotoxic effects - ***Digoxin*** May increase plasma levels and toxic effects - ***Diuretics*** Increased risk of nephrotoxicity and reduced diuretic effect - ***Lithium*** Reduced excretion - ***Methotrexate*** Reduced excretion - ***Pentoxifyline*** Increased risk of bleeding - ***Probenecid*** Reduces excretion of Naproxen - ***Quinolone antibiotics*** Increased risk of convulsions - ***SSRIs*** Increase risk of GI bleeding - ***Sulphonamides and hydantoins*** –increased levels and risk of overdosage when given with naproxen - ***Tacrolimus*** Increased risk of nephrotoxicity - ***Zidovudine*** Increased risk of haematological effects
17	**Warnings / potential adverse reactions**	- GI disturbance, GI ulceration or GI bleeding (particularly in the elderly) - Hypersensitivity 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, and 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, Stevens 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
18	**Identification and management of adverse reactions (including reporting)**	Monitor for signs of hypersensitivity reactions and anaphylaxis and refer urgently. Treatment for anaphylaxis should be available when administered on-site. Serious or unusual adverse reactions that could conceivably be attributable to the drug should be reported to a Doctor. Complete and submit a yellow card and incident form as appropriate. *www.mhra.gov.uk/yellowcard*
19	**Advice to be given to patients**	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. The tablets should be taken with food to reduce the likelihood of GI reactions. Patients who experience dizziness, drowsiness, fatigue and visual disturbances while taking NSAIDs should not drive or operate machinery.
20	**Follow up arrangements**	To see GP if symptoms persist
21	**Additional information**	Can be combined with paracetamol and/or codeine for increased analgesic effect.
22	**Supply criteria and quantity**	The triage nurse will NOT supply, only administer. If ongoing treatment is necessary the ENP / ECP /EPP can supply: One pack of overlabelled 28 Naproxen 250mg tablets The following must be added to the label before supply - Patient's name - Date of supply - Issuing department ie. "ED QHB" - The dose indicated for the patient according to section 13. All packs must contain the manufacturer's leaflet. One prescription charge per item should be levied if a patient normally pays for prescriptions.

23	**Legal classification**	POM	If CD include justification
24	**Off label use**	No	If yes include justification
25	**Black triangle drug**	No	If yes include justification
26	**Reference to national or local policies or guidelines**	BNF 76	
27	**Sources used in the development of this PGD**	SPC Naproxen 250mg tablets Accord Healthcare Limited Updated 1604/07/18 https://www.medicines.org.uk/emc/medicine/25766	

28	**Records required**
	- date and time of administration - details of medicine, such as name, strength, dose, frequency, quantity, route and site (if by injection) of administration - an annotation that administration or supply is by using a PGD - name and signature (which may be an electronic signature) of the health professional supplying or administering the medicine - relevant information that was provided to the patient or their carer - Circumstances if consent to treatment was not obtained

29	**Training and competency requirements**
	1. Completion of the ESR online PGD training 2. Understanding of the content and context of the PGD 3. The practitioner will have had completed the Trust IV training where necessary for their role, and attended training updates as required (at least every 3 years) Or: 4. The practitioner will have completed the recognition and treatment of anaphylaxis online training and updated 3 yearly. 5. Triage Competency

30	**Professional responsibility**
	- The Registered Healthcare Professional will undertake training and will ensure he/she is competent in all aspects of this treatment. - The nurse / practitioner will have due regard for their professional bodies standards for conduct, performance and ethics, the NMC standards for medicines management and the NMC guidelines for records and record keeping, the Trust Medicines Management Policy plus other relevant Department of Health Guidelines

Changes from previous version:

Section		Changed on new version
8	Drug description	
9	Clinical Situation	
10	Inclusion Criteria	
11	Exclusion criteria	
12	Reasons for referral	
13	Dosage	
14	Route / method of admin	
15	Administration	
16	Drug interactions	
17	Warnings / potential ADRs	
18	Management of ADRs	
19	Advice for patients	
20	Follow up arrangements	
21	Additional information	
22	Supply criteria & quantity	
23	Legal classification	
24	Off label use	
25	Black triangle drug	
27	References	Updated
29	Training	Updated to take into account on line training
30	Professional responsibility	Updated to include all Registered Healthcare Professionals

Appendix A -
List of approved staff

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

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Name	Signature	Approved by

The approver is the post holder specified in section 4.
Each Health Professional should complete the form in appendix A and the training specified in section 29 before being approved to work under this PGD
When completed this appendix is not on the intranet.
When completed this appendix should be kept with a copy of the PGD in the location of the service.
Hiss access to record administration must be requested from Systems Support

Appendix B – PGD staff approval

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

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Registered Healthcare Professional:

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work under it within my professional code of conduct

Signed ..... Date:.....

Name:.....

Designation:.....

Approver:

Having confirmed the competence of the above named person, I, as the postholder specified in section 4, approve their authorisation to practice under this PGD and have added their name to the list of approved Health Professionals for this PGD (appendix A).

Signed ..... Date:.....

Name:.....

Designation:.....

The Health Professional should keep this document, together with a copy of the PGD and any relevant training or competency documents in their portfolio. When completed this appendix is not on the intranet.