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GIG CYMRU NHS WALES | Bwrdd Iechyd Addysgu Powys / Powys Teaching Health Board

Protocol

for the administration

of Pharmacy (P) and General Sales List (GSL) classified

Ibuprofen preparations

to

patients aged 2 years of age or over with mild to moderate pain

by Registered Nurses

in MIU and Outpatient Departments

in Powys Teaching Health Board

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Scope:	PTHB wide	

Do not print this document. The latest version will be accessible via the intranet. If the review date has passed please contact the Author for advice.

Disclaimer

Powys teaching Health Board is the operational name of Powys teaching Local Health Board
Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

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Protocol authorisation

Name	Job title and organisation	Signature	Date
Chief Pharmacist Jacqueline Seaton	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	6/6/2022

Appendix A provides a Staff Permitted to use Protocol Signature Sheet. Individual practitioners must be authorised by name to work to this protocol.

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Version Control

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue	May 2022

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ENGAGEMENT & CONSULTATION

Key Individuals/Groups Involved in Developing this Document

Role / Designation
Senior Pharmacist Governance and Training
Advanced Clinical Pharmacist – Medicines Management & Medicines Optimisation

Circulated to the following for Consultation

Date	Role / Designation
5/07/2021 & 5/01/2022	Judith Jamieson-Senior Nurse OPD
May 2022	Jo Wolfenden – MIU Lead Nurse
May 2022	PGD Working Group

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Evidence Base
Please list any National Guidelines, Legislation or Health and Care Standards relating to this subject area • Royal Pharmaceutical Society: Professional Guidance on the Administration of Medicines in Healthcare Settings (2019) • British National Formulary, current online edition. • Electronic Medicines Compendium. • NICE CKS Scenario: Analgesia - mild to moderate pain • NICE CKS NSAIDs prescribing issues

IMPACT ASSESSMENTS

Equality Impact Assessment Summary

	No impact	Adverse	Differential	Positive	Statement
Age	x				Please remember policy documents are published to both the **intranet** and **internet.** The version on the internet must be translated to Welsh.
Disability	x				
Gender	x				
Race	x				
Religion/ Belief	x				
Sexual Orientation	x				
Welsh Language	x				
Human Rights	x				

Risk Assessment Summary

Have you identified any risks arising from the implementation of this policy / procedure / written control document?

No risks identified as long as protocol directive is followed. If yes, note the risk/s and action taken to mitigate.
Protocol awareness training and signature of line manager who must confirm that the registered practitioner is competent to administer ibuprofen under this protocol.

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Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document? No governance issues identified
Have you identified any training and / or resource implications as a result of implementing this? Awareness training will be provided by the Medicines Management Team. Target audience will be registered general nurses or agreed registered allied health professionals working within Powys Community Hospital OPD Units and MIU (Minor Injury Unit) departments. Compliance with this Protocol will be monitored by annual retrospective audit of 10 instances where this Protocol has been used. This audit may be conducted by the department lead or Medicines Management team.

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1. Protocol Statement & Introduction

This protocol provides a clear framework to support registered nurses or registered allied health professionals to **administer** Pharmacy (P) and General Sales List (GSL) ibuprofen to patients in MIU and Outpatients Departments, where the patient does not have ibuprofen available, it is not already prescribed, a PGD is not in place and a doctor or independent prescriber is not available for the respective clinic and in a reasonable timeframe.

This protocol applies to administration of ibuprofen preparations in MIUs or outpatient departments settings by registered nurses (who have the appropriate authorisation – see Appendix A) ONLY.

The most recent and in date final signed version of the protocol should be used.

Patients should be informed that they are being treated within a protocol, and where possible, consent should be obtained before administering.

If used in MIU, this protocol should be used in conjunction with the "Clinical Guidelines for Minor Injuries ".

Supply of ibuprofen preparations (i.e. for the patient to take home) is not permitted by this protocol. If supply is required, refer the patient/carer to purchase over the counter from a community pharmacy or local shop etc.

2. Objective.

The objective of this protocol is to provide a standardised clinical pathway for administration of ibuprofen to patients aged 2 years or older presenting with mild to moderate pain to MIU or Outpatient departments in Powys Teaching Health Board.

3. Definitions and abbreviations.

GSL	General Sales List Medication – can be sold in a variety of retail outlets but may be restricted in terms of pack size and number of packs that can be sold at one time.
MIU	Minor Injuries Unit

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OTC	Over the Counter – where a medicine is available for supply or purchase through a retail outlet such as a supermarket, local shop or petrol station for [GSL] medicines or Community Pharmacy only for a [P] medicine.
P	Pharmacy medicine – can be sold from a registered pharmacy by a pharmacist or someone working under the supervision of a pharmacist
POM	Prescription only medicines – requires a prescription written by an appropriate practitioner before it can be supplied.
PGD	Patient Group Direction – a written direction that allows the supply and/or administration of a specified medicine, by named authorised health professionals, to a well-defined group of patients requiring treatment for a specific condition.
POVA	Protection of Vulnerable Adults
PSD	Patient Specific Direction
SPC	Summary of Product Characteristics available via www.medicines.org.uk. This provides comprehensive information around a medicine's licensed indications, dose, frequencies, information about adverse drug reactions and interactions and advice around administration
STAT	Immediate

4. Role and responsibilities.

4.1. The registered nurse has a responsibility to:

- Assess the patient and plan their care.
- Complete the awareness training in order to ensure they are competent and feel confident when administering ibuprofen preparations, and also be authorised by name as permitted to use this protocol (Appendix A).
- Be familiar with the use of products covered by this protocol, including knowledge of their actions and uses, contra-indications and adverse effects.
- Discuss the treatment to be administered with the patient, if possible and/or with the carer and obtain consent.
- Have current competence in assessing capacity and follow the Mental Capacity Act guidance regarding consent to treatment.
- Administer the medication for the duration of time specified in the protocol and recognise that the authorisation is invalid after this time.

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- Be competent in the recognition and management of recognised adverse reactions, including anaphylaxis.
- Be competent in the administration of adrenaline and have up to date at least Basic Life Support (BLS) skills.
- Ensure that the pack of medication used for administration is legally classified as a P or GSL medicine. This will be noted on the packaging denoted by a box with [P] or [GSL] respectively.
- Record the assessment, any intervention, and arrangements for review in the nursing records, care plan or care pathway.
- Record any medication administered in the patient records.
- Review the patient's response to treatment and monitor clinical observations as appropriate.
- Seek medical advice if the symptoms persist or worsen or if there is an actual or potential reaction to the treatment.
- Recognise their limitations and seek medical advice if they are concerned about the patient's overall condition or if the medication has been ineffective.
- Report any serious adverse drug reactions via the MHRA Yellow Card Scheme and via Once for Wales Reporting System.
- Refer the patient/carer to self-care options for ongoing use and advise that ibuprofen may be purchased from a range of outlets such as a community pharmacy, supermarket, local store and petrol stations.
- Every registered nurse must adhere to their appropriate professional code of conduct and the Royal Pharmaceutical Society Professional Guidance on the Administration of Medicines (2019).
- Each registered nurse is professionally accountable for their individual practice. In a local context, they are required to adhere to Powys Teaching Health Board (PTHB) departmental policies available on the PTHB intranet site.

These tasks cannot be delegated and so the registered nurse making the decision to administer a medicine under this protocol must carry out the administration to the patient.

4.2. The Medicines Management Team has a responsibility to:

- Update and review this protocol and advise on any major changes.
- Ensure safe systems of supply for medicines named in the protocol.
- Audit the use of this protocol through annual audit of OPD records and documentation.

4.3. Line Managers have a responsibility to:

- Ensure the competency of registered nurses administering medicines under this protocol.

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- Ensure awareness training is included as part of the induction process for new appointees.
- Ensure registered nurses have completed the awareness training before they commence administration of any P/GSL medicine included in this protocol.
- Sign off the schedule of staff authorised to use this protocol (Appendix A)

4.4. Head of the department must:

- Ensure all registered staff read and understand this protocol.
- Arrange regular review to monitor compliance with this protocol.

4.5. Senior Nurse:

Has responsibility for:

- Arranging yearly update training
- Arranging rotas

5. Administration of ibuprofen process.

NB. It is the responsibility of the administering practitioner to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice

This protocol details all processes required, including record keeping, in order to safely administer ibuprofen.
If there are any concerns, medical advice should be sought.
Where further treatment is likely to be required, the patient should be signposted appropriately, in accordance with PTHB policies and procedures e.g. self-care advice, or to a community pharmacy, GP practice or A&E, as appropriate.

5.1. Clinical situation and indications.

To administer a stat dose of ibuprofen for the relief of occasional mild to moderate pain.

For use in conjunction with (for adults) or as an alternative to paracetamol – refer to MMPr005 Protocol and to NICE CKS for information on the choice of analgesic and combining analgesics -see Appendix B and https://cks.nice.org.uk/topics/analgesia-mild-to-moderatepain/.

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5.2. Inclusion criteria.

- Adults and Children aged 2 years and over presenting with mild or moderate pain
- Where ibuprofen not available via any other reasonable source of supply.
- Medical and drug history taken, no reason for exclusion.
- Informed consent obtained.
  Refer to PTHB Consent to Treatment and Examination Policy.
  NB: If working in an MIU, this protocol should be used in conjunction with the "Clinical Guidelines for Minor Injuries ".
  In case of any doubt, contact medical team.

5.3. Exclusion criteria.

- Conditions outside of the clinical situations criteria
- No valid consent or patient/representative refuses treatment.
  Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "Action to be taken if patient is excluded or "Action to be taken if patient declines treatment".
- Children aged under 2 years old
- Allergy or hypersensitivity to ibuprofen or any excipients
- A history of hypersensitivity/severe allergic reaction to an NSAID (including aspirin) — for example, asthma, rhinitis, angioedema or urticaria
- Pregnancy after 28 weeks of duration
- Chickenpox infection
- In patients with:
  - Active gastrointestinal (GI) bleeding, or active GI ulcer.
  - A history of GI bleeding related to previous NSAID therapy, or a history of GI perforation related to previous NSAID therapy
  - A history of recurrent GI haemorrhage (two or more distinct episodes), or history of recurrent GI ulceration (two or more distinct episodes)
- Severe heart failure
- Severe hepatic impairment — serum albumin less than 25 g/L or Child-Pugh score of 10 or more
- Severe renal impairment — estimated glomerular filtration rate (eGFR) less than 30 mL/minute/1.73 m2
- Asthmatics (unless they know they can tolerate NSAIDs – see cautions)
- Bleeding disorders or coagulation defects e.g. haemophilia
- If last dose of ibuprofen was taken less than 6 hours ago and total daily dose was reached prior to presentation and assessment.
- Patients taking other NSAIDs (including low dose aspirin or COX-2 inhibitors)

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- Patients with rare hereditary problems involving glucose/galactose or fructose- may be excluded depending on preparation supplied or administered- consult individual SPC for more information
- Patients who have taken any drug interacting with ibuprofen listed below and in the BNF –under NSAIDs; if in doubt seek advice from a doctor or pharmacist and document advice:
  - Anagrelide
  - Anti-platelet drugs (e.g. low dose aspirin, clopidogrel)
  - Ciclosporin
  - Dipyridamole
  - Oral anticoagulants including warfarin, DOACs (dabigatran, apixiban, rivaroxaban, edoxaban), phenidione , acenocoumarol, heparin
  - Corticosteroids
  - Baclofen
  - Deferasirox
  - Caplacizumab
  - Erlotinib
  - Fluconazole
  - Ketorolac
  - Lithium
  - Methotrexate
  - Nicorandil
  - Omega-3-acid ethyl esters
  - Prasugrel
  - Quinolone antibiotics (e.g. ciprofloxacin, levofloxacin, ofloxacin)
  - SSRI antidepressants (e.g. citalopram, escitalopram, fluoxetine, paroxetine, sertraline)
  - Ritonavir
  - Sulfonylureas (e.g. gliclazide, glipizide)
  - Tacrolimus
  - Ticagrelor
  - Venlafaxine
  - Voriconazole
  - Zidovudine

5.4. Action to be taken if patient is excluded.

- Explain reason to the individual, if possible
- Record reason and any advice given and seek medical advice.
- Refer to MMPr005 Protocol for paracetamol for the relief of occasional mild to moderate pain
- Refer to GP or prescriber as appropriate.

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5.5. Action to be taken if the patient/carer/representative declines treatment.

- Explain consequences of refusing treatment.
- If patient has capacity to consent and refuses treatment then follow locally agreed pathway.
- In the unlikley situation, if patient's carer/representative refuses treatment for the patient, the decision would be overridden by a *decision to treat* in the individual's best interests in accordance with the Mental Capacity Act 2005.
- For MIU patients, advise the patient or guardian to seek medical advice, GP as appropriate.
- Document refusal and any advice given. Complete a Discharge Against Advice Form if appropriate.
- Inform or refer to GP/follow local procedures as appropriate.

5.6. Cautions.

- Allergic disorders
- Asthmatics (check whether aspirin or a NSAID has ever precipitated an attack, and if so, do not give). Use with caution in patients with asthma: bronchospasm may occur.
- Breastfeeding –NSAIDs can appear in breast milk in very low concentrations, avoid if possible whilst breastfeeding
- Elderly patients or the very frail who are at increased risk of severe adverse reactions and fatalities
- Patients with systemic lupus erythematosus and mixed connective tissue disorder
- Cerebrovascular disease
- Connective-tissue disorders
- Inflammatory bowel disease — NSAIDs may increase the risk of developing or cause exacerbations of ulcerative colitis or Crohn's disease.
- Ischaemic heart disease.
- Peripheral arterial disease.
- Risk factors for cardiovascular events — for example, hypertension, hyperlipidaemia, diabetes mellitus, smoking.
- Hepatic impairment — dose reductions may be necessary.
- Renal impairment (avoid if possible) — sodium and water retention may occur leading to a deterioration in renal function and, possibly renal failure.
- Patient taking: ACE inhibitors or angiotensin 2 receptor antagonists (increased risk of renal adverse effects), antihypertensive agents (increased BP), diuretics (increased risk of renal impairment), iloprost (increased risk of bleeding), pentoxifylline (increased risk of bleeding)
- Also use with caution in:
  - Patients with complex multiple pathologies, poly-pharmacy or multiple allergies.

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- Women trying to conceive — NSAIDs may impair female fertility. Paracetamol is the analgesic of choice during conception. Refer to **Paracetamol** use guidance.

Seek medical advice and document advice given and action taken.

Refer to BNF/SPC for full list.

5.7. Medication information: Ibuprofen

5.7.1. Legal category:

GSL or P Pharmacy, dependent on pack size (16 tablets– GSL, 24, 36 tablets- P).

5.7.2. Form and strength.

- Tablets 200mg or 400mg
- Oral suspension 100mg/5ml
- Must be [P] or [GSL] legally classified medicines as denoted on the medication pack

NB. Granules, chewable and effervescent tablets are not included in this protocol.

5.7.3. Route of administration

Oral.

5.7.4. Information for administration

- May be given as an alternative to or in combination (in adults) with paracetamol if appropriate – see Appendix B for information on using combinations of analgesics.
- Administer with or after food.

For patients with swallowing difficulties, with NG tubes, discuss the method of administration with Medicines Management.

5.7.5. Dosage

Children under 12 years old:

Age	Weight	Dosage
CHILD 2 – 3 years old	11 – 16 kg	100 mg (5 ml) up to three times daily
CHILD 4 – 6 years old	17 – 22 kg	150 mg (7.5 ml) up to three times daily
CHILD 7 – 9 years old	23 – 31 kg	200 mg (10 ml) up to three times daily
CHILD 10 – 11 years old	32 – 39 kg	300 mg (15 ml) up to three times daily

Adults and children > 12 years old and > 40kg:

400 mg up to three times daily

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*If patient is underweight for their age, use dose appropriate for the weight band.
If patient is overweight for their age, use dose appropriate for the age band.

5.7.6. Frequency of administration.
This protocol allows a single dose of ibuprofen to be administered.

5.7.7. Maximum total dose in 24 hours.
Three doses (at an appropriate dose according to patients age and weight). See Dosage section.

5.7.8. Maximum duration of treatment.
A single dose of ibuprofen can be administered under this protocol.

6. Supply and storage.

Keep container tightly closed. For oral suspension 100mg/5ml there may be a shorter shelf life after opening the bottle- please check manufacturers information on individual product.

Blister packaging and oral suspension- store in original package inside outer carton.

Store in a dry place at a temperature not exceeding 25ºC.

7. Drug interactions.

- Angiotensin-converting enzyme (ACE) inhibitors or an angiotensin-II receptor antagonists (AIIRAs) — concurrent use may increase blood pressure, the risk of renal impairment and rarely hyperkalaemia
- Anticoagulants (for example, warfarin, heparin, DOACs) — all NSAIDs can cause GI irritation and reduce platelet aggregation, which can worsen any bleeding event. Avoid concomitant use if possible.
- Antidepressants — increased risk of upper GI bleeding when some antidepressants (selective serotonin reuptake inhibitors, and serotonin noradrenaline reuptake inhibitors) and an NSAID are taken concomitantly. If an NSAID is considered necessary, weigh the risks and benefits of treatment and consider prescribing gastroprotection.
- Antiplatelets (low dose aspirin, clopidogrel) — NSAIDs may antagonize the antiplatelet effects of aspirin, and increase the risk of GI bleeds when taken concurrently with other antiplatelets. If concomitant use is unavoidable consider prescribing gastroprotection with a PPI.
- Beta blockers — NSAIDs may reduce the efficacy of beta blockers given for heart failure. Consider/advise monitoring blood pressure if an NSAID is started or stopped.
  Note: NSAIDs should generally be avoided in people with heart failure (see exclusion).

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- Corticosteroids — the incidence and/or severity of ulceration associated with NSAIDs, and the possibility of GI bleeding may be increased. Consider giving gastroprotection.
- Ciclosporin — NSAIDs may reduce renal function, and lead to increased ciclosporin levels. If concurrent is necessary, monitor renal function and consider reducing the dose of the NSAID.
- Fluconazole, voriconazole — the peak plasma level of some NSAIDs (for example, ibuprofen) may be increased. Monitor for NSAID adverse effects (for example, dyspepsia, nausea, dizziness). Consider using the lowest NSAID dose and titrate accordingly.
- Lithium — NSAIDs can reduce lithium excretion and increase the risk of lithium toxicity. Avoid concomitant use especially if risk factors for lithium toxicity (such as advanced age or renal impairment) are present, unless lithium levels can be closely monitored, and the dose adjusted accordingly. Advise people to report lithium adverse effects (tremor, dysarthria, ataxia, confusion).
- Loop diuretics (for example, furosemide) — NSAIDs may reduce the antihypertensive effects of loop diuretics and exacerbate congestive heart failure. Consider an alternative non-NSAID analgesic, but if concurrent use is essential, monitor the diuretic effects, renal function and electrolytes closely, and increase the dose of the loop diuretic if required.
- Methotrexate — NSAIDs may reduce the excretion of methotrexate and increase the risk of methotrexate toxicity. Advise people to report symptoms such as sore throat, dyspnoea or cough.
  If high-dose methotrexate is given with an NSAID, monitor methotrexate levels and increase routine methotrexate monitoring (full blood count, liver function tests).
- Nicorandil — there may be an increased risk of GI ulceration, perforation or haemorrhage if taken concurrently with an NSAID. Monitor for GI adverse effects.
- Potassium-sparing diuretics (for example, spironolactone) — concomitant administration with ibuprofen may cause hyperkalaemia. Several cases of acute renal impairment have been reported with concurrent use with NSAIDs. Avoid concurrent use.
- Probenecid — probenecid reduces excretion of NSAIDs. Avoid concurrent use.
- Quinolones (for example, ciprofloxacin) — possible increased risk of convulsions if taken concurrently. This is rare, therefore in most cases, the concomitant use of a quinolone and an NSAID is acceptable. However concurrent use should be avoided in people with epilepsy or people who are predisposed to convulsions. See exclusion criteria.

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- Thiazide-type diuretics — some NSAIDS may reduce the antihypertensive effect of thiazides. If concurrent use is indicated monitor blood pressure regularly and refer patient to prescriber for dose adjustment, if necessary.
- Zidovudine — the risk of haematological toxicity and risk of bleeding may be increased if given concurrently with NSAIDs.

NB: Particular drug interactions exclude patients from treatment under this protocol – see above under criteria for exclusion):-

- Other NSAIDs including cyclooxygenase-2 selective inhibitors: avoid concomitant use of two or more NSAIDs as this may increase the risk of gastrointestinal ulcers and haemorrhage

Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic medications.

NB. Refer to BNF/SPC http://www.medicines.org.uk for full list of potential interactions. Refer for medical advice as appropriate and document advice given.

8. Identification, management of, and reporting of adverse effects

Common:

- Gastrointestinal discomfort
- Skin reactions

Uncommon:

- Hypersensitivity
- Rash (NB. To discontinue treatment)
- Headache
- Nausea
- Asthma

Rare and very rare:

- Angioedema
- Dyspnoea
- Blood disorders
- Fluid retention

Report any suspected adverse reactions to a prescriber.

Refer to the BNF and/or the up to date SPC via www.medicines.org.uk for a comprehensive list of adverse drug reactions.

All significant adverse drug reactions and any administration errors must be recorded via Once for Wales Reporting System incident reporting system.

If serious adverse effects are noted, complete a Yellow Card (found in the BNF) or submit online through the MHRA website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults that may be attributable to the medication should be reported. All suspected adverse reactions in children that may be attributable to the medication should be reported.

9. Anaphylactic reactions.

Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a telephone must be available for immediate use.
In case of anaphylaxis: -

- Refer to adrenaline (epinephrine) PGD0017 Patient Group Directions (PGDs) - Powys Teaching Health Board (nhs.wales) and anaphylaxis policy
- Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E
- Ensure reaction is fully documented in patient notes
- Ensure all patient records are marked **ALLERGIC TO Ibuprofen**

10. Safety Information.

Ensure there is immediate access to resuscitation equipment including adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of administration.

11. Written/verbal advice for patients/carers.

- Advise the person about the adverse effects associated with NSAIDs including the cardiovascular and renal and gastrointestinal (GI) adverse effects. Explain that adverse effects may be minimized by:
  - Using an alternative treatment to an oral NSAID (for example paracetamol, or a topical NSAID if appropriate).
  - Using an NSAID at the lowest effective dose and for no longer than is necessary.
  - Taking an NSAID with or after food.
  - Taking a proton pump inhibitor if they have an increased risk of GI adverse effects.
- If they have continuous pain, they should use ibuprofen regularly (three times a day, or up to the maximum dose and frequency for weight advised in the dosing table)
- Explain the tablets may take 30 minutes to work.
- Explain where to refer to if symptoms persist or worsen.

- If a dose of ibuprofen has been administered, the patient or their carer must be advised not to take another dose for at least six to eight hours, and not to exceed a maximum of three doses in 24 hours (or the maximum dose for weight advised in the dosing table).
- Explain that no other products containing aspirin, ibuprofen or other NSAIDs should be used at the same time. Be particularly careful if buying products over the counter.
- Advise to stop taking if side effects occur and seek medical advice.
- In adults, ibuprofen may be alternated or taken in combination with paracetamol if appropriate – see appendix B
- Shake suspension bottle well (for at least 10 seconds) before use. Demonstrate how to use oral syringe/spoon for measuring dose if thought to be useful for use of selfcare products.
- Provide the Patient Information Leaflet, if appropriate, either via the package insert or print the leaflet from the relevant brand via www.medicines.org.uk

12. Follow up and referral.

As directed by medical staff.

MIU staff to also refer to MIU guidelines.

Give appropriate advice dependant on the clinical condition of the patient and if necessary, transfer to a DGH.

Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk.
Any vulnerable adult or child protection concerns should be referred to Safeguarding and the Minor Injury Unit guidelines, as appropriate followed, along with PTHB safeguarding policies. Consider discussing with GP.

Any safeguarding concerns need to be directed to Safeguarding Hub:

- to generic email address: PowysTHB.Safeguarding@wales.nhs.uk

and

- Central Safeguarding number: 01686 252806.
- Out of hours: 08457 573818.

Advice can also be sought from local Safeguarding Leads:

- CNS for Safeguarding North Powys Office: 01874 442082; mobile: 07964 132698
- CNS for Safeguarding South Powys Office: 01874 442098; mobile: 07973 686520.

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13. Record keeping.

Record consultation details as required by local procedures. Administration of any medication must be clearly recorded in the patients' notes.

The following must be included:

- Symptoms allowing patient to be treated under this protocol.
- Rationale for administering under this protocol, including ruling out access to these medicines by other routes e.g. supply at home, OTC, PGD in place, prescriber available.
- Relevant past and present medical history, including medication history
- That valid informed patient consent to treatment was obtained or a decision to treat was made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent, if appropriate. Record advice given and action taken, if patient excluded or declines treatment.
- Name of individual, address, date of birth
- GP contact details where appropriate
- Any reasons for exclusion or referral, including actions taken.
- Examination finding/s where relevant.
- Any known allergies or previous adverse events and nature of reaction
- Printed name and signature of registered health professional responsible for administration.
- For administration, record:
  - Date and time of administration
  - Name, form, strength and dose of drug administered
  - Weight where dose adjusting the medicine
  - Route of administration
  - Expiry date(s)
- Details of any adverse reactions and actions taken
- Effectiveness of treatment and any adverse reactions experienced.
- If there is handover to any external services - that medication has been given in accordance with this protocol and details of what was given.
- Advice given about the medication including side effects, benefits, and when and what to do if any concerns.
- Any advice received from medical cover and advice given to patient/carer.
- Any advice given to the patient, including self-care/OTC recommendations for ongoing symptoms and when and who to refer to if symptoms are ongoing or worsen. If further doses are required, the patient/carer must be advised when it is safe to consider taking the next dose.

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- Record that medication was administered via a protocol, record protocol title and version number

Records should be signed and securely kept for a defined period in line with local policy.

All records should be clear, legible and contemporaneous.

A record of all individuals receiving treatment under this Protocol should be kept for audit purposes in accordance with local policy.

14. Training.

Initial training:

- Nurses currently registered with the Nursing and Midwifery Council (NMC) and working in a Minor Injury Unit in PTHB or in a PTHB outpatient department.
- The assessment and management of mild and moderate pain.
- The administration of medicines listed in this protocol including knowledge of their actions and uses, contraindications and adverse effects. The registered nurse should also be alert to changes in the BNF and Summary of Product Characteristics.
- The recognition, management and reporting of adverse drug reactions, including anaphylaxis and the administration of adrenaline.
- Up to date BLS skills (ILS for nurses working in MIU).
- Must have current competence in assessing capacity and follow Mental Capacity Act guidance regarding consent to treatment in an emergency situation.
- Must have undertaken and completed Safeguarding of Children, Young People and Vulnerable Adults - Training and Competency Passport, as applicable to the role.

THE DECISION TO ADMINISTER ANY MEDICATION RESTS WITH THE INDIVIDUAL REGISTERED PRACTITIONER WHO MUST ABIDE BY THE PROTOCOL AND ANY ASSOCIATED ORGANISATION POLICIES.

Competency assessment

- Evidence of ongoing protocol training for the administration of medicines to be submitted to Line Manager annually.
- Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly.
- Practitioners must make a self-declaration of competency in their Personal Appraisal and Development Review (PADR).
- Nurses must be authorised by name as an approved practitioner under the current terms of this Protocol before working to it.

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Individuals operating under this protocol are personally responsible for ensuring they remain up to date with the use of the medicines included in the protocol. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the protocol and further training provided as required.

Ongoing training and competency

- Update at least every 2 years, or earlier in response to new local/national guidance on the use of the medicines recommended in this protocol.
- Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, ILS/BLS (as applicable to the role), with evidence of appropriate Continued Professional Development (CPD).
- Compliance with all mandatory NHS training.
- Evidence of appropriate Continued Professional Development (CPD) must be retained and made available on request.

15. Monitoring compliance & audit.

This document will be reviewed in two years.

Compliance with this protocol will be monitored by annual retrospective audit of 10 instances in the MIU/ OPD where this protocol has been used.

This will be undertaken by reviewing any issues for ibuprofen, as stated in the patient records. This audit may be conducted by the departmental manager, unscheduled care lead or medicines management team.

Records will be reviewed for rationale behind administering medication, to check that administration was in accordance with the relevant monograph and that clear documentation is in place and appropriate referral to self-care options have been given.

All incidents involving ibuprofen will be reported via Once for Wales Reporting System and monitored via incident reports.

16. Review

This document will be reviewed after two years or earlier should audit results or changes to legislation/ practice within PTHB indicate otherwise.

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- Competency framework: For health professionals using Patient Group Directions. Implementing the NICE guidance on Patient Group Directions (MPG2). Updated March 2017.
- Royal Pharmaceutical Society: Professional Guidance on the Administration of Medicines in Healthcare settings (2019)
- Alternative mechanisms for the supply and administration of medicines - An introduction to PGDs: definitions and examples of use – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice – December 2020
- NICE CKS Analgesia - mild-to-moderate pain Analgesia - mild-to-moderate pain | Health topics A to Z | CKS | NICE: last revised Nov 2021
- NICE CKS NSAIDS – prescribing issues: last revised April 2020 NSAIDs - prescribing issues | Health topics A to Z | CKS | NICE

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Appendix A. Staff Permitted to use Protocol Signature Sheet

Department name:_____

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this protocol. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named nurse below who has signed the protocol to work under it.

Practitioner: By signing this **protocol** you are indicating that you agree to its contents and that you will work within it. Protocols 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 Protocol and that I am willing and competent to work to it within my professional code of conduct.

Name of health professional	Signature	Senior representative authorising health professional (Authorising Manager)	Date

The authorising manager should retain a copy of the list and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU for audit purposes.
The nurse should retain a copy of the document after signing.

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Appendix B.

Choice of Analgesic – From NICE Clinical Knowledge Summaries (CKS)

Last revised in November 2021

For adults, a stepwise strategy for managing mild-to-moderate pain is recommended.

Summary

- An analgesic is a drug used to relieve pain.
- The analgesics used to relieve mild-to-moderate pain are:
  - Paracetamol.
  - Nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and naproxen.
  - Aspirin (a salicylate NSAID).
  - Weak opioids, such as codeine, dihydrocodeine, and tramadol.
- Fixed-dose combination preparations are also available, including:
  - Paracetamol with codeine.
  - Paracetamol with dihydrocodeine.
  - Paracetamol with tramadol.
  - Aspirin with codeine.
- For adults and children aged over 16 years, a stepwise strategy for managing mild-to-moderate pain is recommended:
  - Step 1 — paracetamol should be used.
  - Step 2 — paracetamol should be substituted with ibuprofen or, if ibuprofen is unsuitable, a weak opioid (such as codeine).
  - Step 3 — paracetamol should be added to ibuprofen or the weak opioid.
  - Step 4 — paracetamol should be continued and ibuprofen replaced with an alternative NSAID.
  - Step 5 — a weak opioid should be started in addition to paracetamol and/or a NSAID.
- When prescribing analgesics:
  - A full therapeutic dose of one drug should be used before considering switching to a different analgesic or adding another analgesic.
  - The underlying cause of the pain should be treated whenever possible.
  - People who experience continuous pain should receive regular analgesia following a full clinical assessment.
  - Combination analgesics should be avoided as first-line treatment. Prescribing single constituent analgesics allows independent titration of each drug.

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- For children under 16 years of age, paracetamol or ibuprofen alone is a suitable first-line choice.
    - If the child does not respond to the first-line analgesic, check their adherence and that an appropriate dose is being taken.
    - If adherence and dose are appropriate, switch analgesic: if paracetamol has been used, ibuprofen should be tried. If ibuprofen has been used, paracetamol should be tried.
    - If the child has not responded sufficiently to the appropriate dose of one drug alone, alternating paracetamol and ibuprofen should be considered.
    - If the child is still in pain or more than short courses of analgesics are required, specialist advice should be sought.

Which analgesic should I prescribe for adults and children aged 16 years and older?

- **In adults and children aged 16 years and older,** a stepwise strategy for managing mild-to-moderate pain is recommended:
    - **Step 1** — start paracetamol.
    - **Step 2** — substitute the paracetamol with ibuprofen. If the person is unable to take a nonsteroidal anti-inflammatory drug (NSAID), use a weak opioid (such as codeine phosphate).
    - **Step 3** — add paracetamol to the ibuprofen or weak opioid.
    - **Step 4** — continue with paracetamol and replace the ibuprofen with an alternative NSAID (such as naproxen).
    - **Step 5** — add a weak opioid to the paracetamol and/or NSAID.
- **When prescribing analgesics:**
    - Ensure a full therapeutic dose of one analgesic is used before switching to (or combining with) another analgesic.
    - Treat the underlying cause of the pain whenever possible.
    - Ensure that people who experience continuous pain receive regular analgesia following a full clinical assessment.
    - Avoid combination analgesics as first-line treatment.
        - Prescribing single-constituent analgesics to allow independent titration of each drug, taking into account local prescribing guidelines.
        - Consider fixed-dose combination analgesics (except those with low-doses of opioids) for people with chronic, stable pain and for people taking a lot of tablets (to reduce the number of tablets taken).

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- Be aware that fixed-dose combination analgesics containing low doses of opioids (such as codeine 8 mg plus paracetamol 500 mg or dihydrocodeine 10 mg plus paracetamol 500 mg) are no more effective than paracetamol alone and can cause opioid adverse effects, such as constipation.