Patient Group Direction

For the supply of

Ibuprofen 10% gel

By community pharmacists providing the

NHS Wales Clinical Community Pharmacy Service for

the treatment of acute lower back pain without radiculopathy

in Powys Teaching Health Board

Operational from: 1st July 2023

Review Date: 31st March 2026

Version number: 1.0

PGD for the supply of ibuprofen 10% gel for the treatment of acute lower back pain by pharmacists delivering the Common Ailment Service component of the Clinical Community Pharmacy Service

Reference:	Ibuprofen 10% gel PGD
Version no:	1.0
Valid from:	1st July 2023
Review date:	31st March 2026
Expiry date:	30th June 2026

Welsh Medicines Advice Service has developed this PGD for local authorisation

Those using this PGD must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not *alter, amend* or *add* to the *clinical* content of this document. Such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of this PGD should be addressed to: welshmedicines.information@wales.nhs.uk

Change history:

Version number	Change details	Date
1.0	Original PGD template developed	21st February 2023

[1] this includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178 and 2015 No.323).

1. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Advisory Group (CPCAG) in accordance with the PGD Policy.

This section MUST REMAIN when a PGD is adopted by an organisation

Expert panel

Name	Position	Designation
Alya Al-Affan	Main author	Formulary and PGD Lead for the Common Ailments Service, Welsh Medicines Advice Service, Cardiff and Vale UHB
Louise Allen	CPCAG reviewer	Head of Community Pharmacy, Primary, Community and Intermediate Care, Cardiff and Vale UHB
Jason Carroll	CPCAG reviewer	Pharmacy Team Leader – Community Services, Cwm Taf Morgannwg UHB
Dr. Ceri Todd	Medical Reviewer	Group Medical Director, Primary Care, Therapies Service, Swansea Bay UHB

Date CPCAG approval of PGD: 1st June 2023

2. Organisational authorisations

The PGD is not legally valid until it has had the authorisation of the Local Health Board in which the community pharmacy using it operates.

It is the responsibility of the Local Health Board, to ensure that all legal and governance requirements are met. The Local Health Board accepts governance responsibility for the appropriate use of the PGD.

Powys Teaching Health Board authorises this PGD for use by community pharmacies within its area that have been commissioned to provide the Common Ailments Service component of the Clinical Community Pharmacy Service. This authorisation is limited to those pharmacists that meet the requirements set out within the PGD.

Local Health Board approval (legal requirement) as per health board policy			
Role	**Name**	**Sign**	**Date**
Lead Doctor for PTHB	Dr Kate Wright	DocuSigned by: Kate Wright 1F267952823F473...	8/31/2023
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	8/24/2023
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	8/31/2023
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	8/25/2023

Local enquiries regarding the use of this PGD may be directed to welshmedicines.information@wales.nhs.uk

Appendix B provides a practitioner listing sheet. Individual practitioners must be listed by name to work to this PGD. Alternative practitioner listing sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner listing sheet as included at the end of this PGD.

3. Characteristics of Staff

Qualifications and professional registration	This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC).
Additional requirements	Pharmacists must: ➢ be employed by, or providing services on behalf of a pharmacy listed in the All Wales Pharmacy Database (AWPD) for the Clinical Community Pharmacy Service. ➢ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it by completing Appendix B. ➢ be familiar with the medicine and alert to changes in the Summary of Product Characteristics (SmPC). ➢ have access to the Patient Group Direction and associated resources (including the service specification and the clinical guidance document supporting the PGD) and must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). ➢ be named in the All Wales Pharmacy Database for the Common Ailment component of the Clinical Community Pharmacy Service. ➢ have met the training requirements for the service as set out by HEIW (Health Education and Improvement Wales). ➢ be familiar with the British National Formulary (BNF) and SmPC entries for ibuprofen 10% gel. ➢ have awareness of the adverse drug reactions associated with ibuprofen 10% gel. **The pharmacist must be listed by name, under the current version of this PGD that has been issued by the local health board in which area they are operating before working under its authority.**
Ongoing training and competency	Pharmacists must: ➢ undertake regular CPD and maintain own level of competence and knowledge in this clinical area to provide the service. ➢ be aware of any updates made to the products in the SmPC and BNF. ➢ be aware of any updates to relevant national and local guidelines. ➢ as registered professionals, be professionally accountable and must work within their competence. A record of any training and competency assessments undertaken must be maintained.

4. Clinical condition

Clinical condition or situation to which this PGD applies	For the treatment of acute lower back pain without radiculopathy, in accordance with the community pharmacy Common Ailment Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	Ibuprofen 10% gel can be supplied to individuals aged 18 years and over, presenting with symptoms of acute lower back pain (less than 6 weeks since the start of onset of pain) and: ➢ non-pharmacological approaches to control pain have not succeeded ➢ they have no contraindications to ibuprofen 10% gel – see SmPC ➢ where informed consent has been given (patient, parent/guardian, carer)
Criteria for exclusion[2]	Ibuprofen 10% gel should not be supplied to individuals if - ➢ symptoms associated with back pain could be limb or life threatening and (individual needs to be advised to call 999 or got to A&E if experiencing these): ○ is progressive, persistent, or suggests neurological deficit ○ involves new onset pain, tingling, weakness or numbness in both legs ○ involves numbness or tingling around the genitals or buttocks (saddle anaesthesia or paraesthesia) ○ is associated with recent onset of sexual or erectile dysfunction ○ involves recent-onset bowel/bladder dysfunction (loss of control or retention, impaired/altered sensation) ○ involves chest pain ○ started after trauma or strenuous lifting in people with osteoporosis ○ involves sudden onset of severe central spinal pain relieved by lying down ○ involves new onset of a lump or structural deformity of the spine ○ point tenderness over a vertebral body ➢ signs or risk factors of infection could be the cause of the back pain; consider this if: ○ an individual has a fever, is systemically unwell or has had a recent infection ○ an individual has a history of intravenous drug use ○ immunosuppression likely (e.g. due to cancer treatment/high doses of oral steroids/other immunosuppressants, or conditions that lower the immune system, like HIV infection) ○ an individual has diabetes mellitus

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required.

	➢ lower back pain in combination with the factors below could be a sign of cancer: o age over 50 years o gradual onset of symptoms o history of cancer o severe, unrelenting pain o localised spinal tenderness o unexplained weight loss o has pain which is made worse when sneezing, coughing or defecating ➢ the individual: o is under 18 years of age o is pregnant or may be pregnant o is breastfeeding o has pain which is stopping day-to-day activities o has osteoporosis o has unilateral leg pain radiating below the knee to the foot or toes o is worried about pain/struggling to cope o has no symptomatic improvement after 3–4 weeks conservative back pain home treatment/therapy o has a lump or swelling on their back or their back has changed shape o has symptoms lasting more than 3 months o has pain which is coming from the top of the back (between shoulders), rather than the lower back o has an active or history of peptic ulceration or active gastrointestinal bleeding defined as two or more distinct episodes of proven ulceration or bleeding o has a history of gastro-intestinal bleeding or perforation relating to previous NSAID therapy o is taking an anticoagulant, aspirin, clopidogrel or other NSAID (for more detail see drug interactions section below) o has a history of kidney problems o has a history of asthma, unless the individual has tried an NSAID before without any ill effects o is using an occlusive dressings Ibuprofen 10% gel should not be supplied to individuals: ➢ if the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the patient to use it ➢ to individuals who are unable to administer or use the product effectively themselves or who do not have a parent/guardian/carer to administer or apply the medication for them ➢ if individual does not agree to share relevant clinical information

	➢ to individuals with known hypersensitivity to ibuprofen 10% gel or any of the excipients – see SmPC
Cautions (including relevant actions to be taken)	Please refer to the SmPC for ibuprofen 10% gel for full details of special warnings and precautions for use. ➢ Asthma: individuals with asthma should only be offered treatment if they have been given/used ibuprofen before and had no signs/symptoms of worsening asthma. ➢ Individuals should not smoke or go near naked flames when using this product- risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.
Cautions (including relevant actions to be taken) (continued)	➢ Possible photosensitivity reactions may occur if individuals are excessively exposed to sunlight on area of skin treated. ➢ For external use only. ➢ Avoid contact with eyes, mucous membranes and inflamed or broken skin. ➢ Apply with gentle massage only. ➢ The product should be discontinued if a rash develops. ➢ Ibuprofen 10% gel contains 1.25 mg benzyl alcohol in each 125 mg dose which is equivalent to 0.01 mg/mg. Benzyl alcohol may cause allergic reactions. See also drug interactions section below for additional cautions.
Action to be taken if the individual is excluded or declines treatment	➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, record the reason and advise of the consequences of not receiving treatment. Document the advice given alongside details of any referral made and their (patient, parent, guardian) intended actions. ➢ If appropriate, patients may be offered a suitable alternative to ibuprofen 10% gel from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to their GP if appropriate and/or provide them with information about further options. ➢ Where there are safeguarding concerns, seek advice from local safeguarding services.
Further advice	Further information can be found in the SmPC, BNF and the All Wales Common Ailments Service Formulary.

5. Description of treatment

Name, strength & formulation of drug	Ibuprofen 10% gel
Legal category	POM
Black triangle▼	No
Off-label use	No
Route / method of administration	Topical
Dose and frequency of administration	**Individuals aged 18 years and over:** Squeeze 2 cm to 5 cm of gel (equivalent to 50 mg-125 mg ibuprofen) and lightly rub into the affected area until absorbed. The dose should not be repeated more frequently than every 4 hours and no more than 4 times in a 24 hour period. N.B. Patients should not apply more than 500 mg ibuprofen (approximately 5 g gel) in any 24 hour period.
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied/administered	Appropriately labelled pack to provide treatment for FOURTEEN days. 1 x 100 g pack to provide 14 days treatment at a dose of maximum four times daily application.
Drug interactions (continued over page)	**Contraindications** ➢ Anticoagulants (e.g. warfarin). Ibuprofen can enhance the effects of anticoagulants. The SmPC states the chance of this occurring with a topical preparation is extremely remote. ➢ Aspirin, clopidogrel or other NSAIDs (including other forms of ibuprofen). May result in an increased incidence of adverse effects. **Caution** ➢ Medicines to lower blood pressure. The SmPC states the chance of this occurring with a topical preparation is extremely remote.
Drug interactions (continued)	The BNF for ibuprofen states: ○ Since systemic absorption can follow topical application, the possibility of interactions should be borne in mind. The SmPC and the BNF should be referred to prior to supply of the medication.
Identification & management of adverse reactions	If the patient experiences any of the following they must discontinue treatment: ➢ difficulty breathing or swallowing

	➢ swelling of the mouth, face, lips, tongue or throat (severe allergic reaction symptoms) ➢ severe itching of the skin, with a rash or raised lumps, hives or blisters The following side effects have been reported as: Not known (cannot be estimated from the available data) ➢ Gastrointestinal: dyspepsia and abdominal pain ➢ Renal impairment in an individual with a history of kidney problems ➢ Photosensitivity reactions N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.
Patient or carer advice/follow up	Supply the marketing authorisation holder's patient information leaflet (PIL). Inform the individual or their carer: ➢ to report any red flag signs or symptoms and/or seek a follow-up with the GP if symptoms persist or are worsening after 4-6 weeks. **Patient education** ➢ Signpost to patient website such as NHS Choices for further information. This includes self-management advice including exercises and stretches for back pain (see link below). ➢ Encourage return to day-to-day activities/work as soon as possible. Normal back movements may produce some pain, but this should not be harmful if activities are resumed gradually. ➢ Advise on expected time course of pain. ➢ Advise individual to seek help for depression/other psychological conditions that may worsen symptoms. **Lifestyle** ➢ Weight loss (if appropriate). ➢ Keep as active as possible and exercise regularly to reduce the risk of recurrent episodes. ➢ Avoid occupational hazards/activities which may worsen symptoms e.g. heavy lifting. **Non-pharmacological options** ➢ Heat application from various products (e.g. a hot water bottle/patch) may allow a short-term reduction in pain and stiffness for individuals presenting with acute/subacute lower back pain. Ibuprofen 10% gel should not be used underneath

	anything that produces heat directly to the skin as absorption can be increased, possibly resulting in negative effects. ➢ Massage, if recommended by a trained professional (e.g. a physiotherapist), may improve short-term symptoms. ➢ A physiotherapy consultation is an option an individual may wish to seek privately or via GP if indicated. **Signposting** Inform the individual or their carer: ➢ NHS Choices has a section on back health that individuals can be signposted to. It includes useful exercises you may wish to highlight: https://www.nhs.uk/livewell/backpain/pages/backpainhome.aspx ➢ the national charity Backcare website has various leaflets, including top 10 tips for back pain, back pain in the workplace and exercises for back pain: www.backcare.org.uk ➢ the Chartered Society of Physiotherapy (www.csp.org.uk) list a number of patient resources in their web section “Back pain”.
	➢ Keele University’s STarT Back resources: https://startback.hfac.keele.ac.uk/patients/#:~:text=This%20is%20where%20the%20STarT,treatment%20matched%20to%20their%20condition ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme. This includes any possible side effects not listed in the PIL. ➢ to seek medical advice if their condition deteriorates and/or they become systemically unwell. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on back pain for more information.
Records	The consultation details including any medication supplied under this PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred into Choose Pharmacy as soon as practically possible following the consultation. If the patient is excluded, a record of the reason for exclusion and any specific advice that has been given must be documented within the consultation notes.

Appendices

Appendix A: *Key references*

- British National Formulary (BNF) – current edition. Available from: https://bnf.nice.org.uk/ [accessed 20 March 2023]
- Summary Product Characteristics (SmPC). Available from: https://www.medicines.org.uk/emc [accessed 20 March 2023]
- Patient Group Directions. Medicines practice guideline [MPG2]. Updated March 2017. Available from: http://www.nice.org.uk/guidance/mpg2/resources [accessed 20 March 2023]
- General Pharmaceutical Council. In Practice: Guidance on Consent. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 20 March 2023]
- General Pharmaceutical Council. In Practice: Guidance on Confidentiality. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 20 March 2023]
- All Wales Medicines Strategy Group. All Wales Common Ailments Formulary. February 2018. Available from: https://awttc.nhs.wales [accessed 20 March 2023]
- National Institute for Health and Care Excellence: Clinical Knowledge Summaries. Back pain-low (without radiculopathy). Last revised November 2022. Available from: https://cks.nice.org.uk [accessed 04 May 2023]
- Yellow Card Reporting. Available from: http://yellowcard.mhra.gov.uk [accessed 20 March 2023]
- NHS 111 Wales Health A-Z. Available from: https://111.wales.nhs.uk [accessed 20 March 2023]
- NHS Medicines A-Z. Available from: https://www.nhs.uk [accessed 20 March 2023]

Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of:
Ibuprofen 10% gel by community pharmacists under the Clinical Community Pharmacy Service, Common Ailment Service (acute lower back pain without radiculopathy) commissioned by Powys Teaching Health Board

Patient Group Directions do not remove inherent professional obligations or accountability.

Once completed and approved, health professionals wishing to use the PGD must sign up to the PGD for the local health board in which they will be providing services. Only pharmacists who are accredited in line with the National Service Specification can operate under the PGD.

This Patient Group Direction is to be read, agreed and signed by all registered healthcare professionals authorised to operate the PGD. By signing this document, the professional operating the PGD confirms that they have read and understood the content of this PGD and are willing and competent to work under it within their professional code of conduct. One copy should be given to each named pharmacist and a signed copy must be kept within the pharmacy by the nominated member of staff with responsibility for PGDs. This will usually be the Superintendent Pharmacist or Responsible Pharmacist.

Name and address of pharmacy:

For registered professional

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.

Name of registered pharmacist	Signature	GPhC number	Date