Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

National reference: CYM-25025

Local reference: PGD 0231A

Community Pharmacy Common Ailments Service

Patient Group Direction

for the supply of

omeprazole 20 mg gastro-resistant capsules

in [Powys Teaching Health Board]

Operational from: 01 November 2025

Review Date: 31 March 2028

Expiry Date: 31 October 2028

Version number: 2.0

PGD for the supply of omeprazole for the treatment of dyspepsia by pharmacists delivering the Common Ailments Service component of the Clinical Community Pharmacy Service

Reference:	Omeprazole 20 mg gastro-resistant hard capsule PGD
Version no:	2.0
Valid from:	01 November 2025
Review date:	31 March 2028
Expiry date:	31 October 2028

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	13 March 2023
2.0	PGD reviewed and updated to align with other national PGD templates. Acknowledgement of contribution by clinician reference group and community pharmacy user group added. PGD exclusion criteria aligned to updated back pain and dyspepsia formulary monograph. Information regarding gastroprotection treatment for back pain removed.	19 August 2025

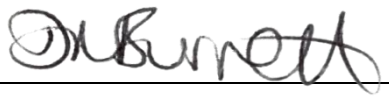
[1] this includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178 and 2015 No.323).

1. PGD development

This PGD has been developed by the following health care professionals on behalf of NHS Wales.

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

PGD Development

Name	Designation	Signature
Main author – Dianne Burnett	Director, Welsh Medicines Advice Service, Cardiff and Vale UHB.	
Expert reviewer – Richard Evans	Community Pharmacy Advisor, Aneurin Bevan UHB.	
Expert reviewer – Clare Tibbatts	Consultant Gastroenterologist, Aneurin Bevan UHB.	

This PGD has been peer reviewed by the Community Pharmacy Clinical Advisory Group (CPCAG) in accordance with the WMAS PGD Policy and ratified by the All-Wales PGD Advisory Board.

Expert Panel – Community Pharmacy Clinical Advisory Group

Name	Designation
Adam Mackridge	Strategic Lead Pharmacist for Community Pharmacy, Betsi Cadwaladr UHB and Chair of Community Pharmacy Clinical Advisory Group (CPCAG).
Louise Allen	Head of Community Pharmacy, Primary, Community and Intermediate Care (PCIC), Cardiff and Vale UHB.
Amy David	Primary Care Pharmacist, Swansea Bay UHB.
Meryl Davies	Lead Antimicrobial Pharmacist Primary and Community Care, Health Protection Team, Public Health Wales.
Emlyn Pritchard	Head of Primary Care Medicines Management, Powys THB.
Rachel James	Advanced Pharmacist Medicines Management, Hywel Dda UHB.
Richard Evans	Community Pharmacy Lead, Aneurin Bevan UHB.
Jason Carroll	Pharmacist Team Leader, Community Services, Cwm Taf Morgannwg UHB.
Carys James	Community Pharmacy Facilitator, Cwm Taf Morgannwg UHB.
Emma Hinks	Deputy Chief Pharmaceutical Officer, Welsh Government.
Debra Roberts	Head of Programme Development, Associate Dean, HEIW.
Dianne Burnett	Director, Welsh Medicines Advice Service (WMAS), Cardiff and Vale UHB.
Anna Burgess	Digital Lead Pharmacist, WMAS, Cardiff and Vale UHB.
Alya Al-Afan	Resource Development Lead for CAS, WMAS, Cardiff and Vale UHB.
Nia Sainsbury	Publications Lead, WMAS, Cardiff and Vale UHB.

Date CPCAG approval of PGDs: 04 September 2025

Date All Wales PGD Advisory Board ratification: 09 September 2025

Acknowledgements:

This PGD has been developed in line with the Common Ailments Service (CAS) formulary monograph. We gratefully acknowledge members of the Clinician Reference Group and the Community Pharmacy User Group for their contribution to the clinical content of the CAS monograph and the associated PGDs.

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		
Chief Pharmacist for PTHB	Jonathan Boyd		
Clinical Governance Lead for PTHB	Amanda Edwards		
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard		

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.

Retention Statement

The final authorised copy of this PGD should be kept by the authorising organisation completing section 3 for 8 years after the PGD expires if the PGD relates to adults only, and for 25 years after the PGD expires if the PGD relates to children only or adults and children.

Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

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 Ailments component of the Clinical Community Pharmacy Service. ➢ have met the training requirements for the service as published by HEIW (Health Education and Improvement Wales). ➢ be familiar with the British National Formulary (BNF) and SmPC entries for omeprazole. ➢ have awareness of the adverse drug reactions associated with omeprazole. **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 dyspepsia in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	**Omeprazole 20 mg capsules can be given to:** Individuals aged 18 years and over, presenting with symptoms of dyspepsia which include upper abdominal pain or discomfort, heartburn, acid reflux, nausea and/or vomiting and: ➢ both lifestyle modifications and antacid and / or alginate have failed to reduce symptoms. ➢ informed consent has been given (individual or carer).
Criteria for exclusion[2] (continued over page)	**Omeprazole 20 mg capsules should not be supplied to individuals with features that put them at higher risk of a more serious underlying cause as follows**: ➢ pain on exertion, pain in the neck/ left shoulder, history of myocardial infarction. ➢ unintentional weight loss or loss of appetite. ➢ anaemia is suspected e.g. shortness of breath, tiredness, fatigue, headache, pale skin, feeling faint, palpitations. ➢ altered bowel habit. ➢ persistent nausea and or vomiting. ➢ jaundice. ➢ newly diagnosed diabetes and the individual is aged 60 years and over. ➢ difficulty swallowing that has not been investigated or diagnosed. ➢ signs of bleeding e.g. blood in stools / urine or vomit. ➢ history of Barrett's oesophagus. ➢ tender, swollen abdomen or a mass reported on self-examination. ➢ previous gastric / peptic ulceration or Zollinger Ellison syndrome. ➢ new onset, persistent or unexplained dyspepsia in individuals aged 55 years and over. ➢ symptoms that have not been relieved following 4 weeks of a PPI including if an individual has had Helicobacter pylori eradication previously. ➢ diagnostic uncertainty.

[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.

Criteria for exclusion (continued)	**Omeprazole 20 mg capsules should not be supplied:** ➢ to individuals with known liver disease. ➢ to individuals with a known or suspected pregnancy. ➢ to individuals at risk of hypomagnesaemia for example individuals prescribed drugs that can cause hypomagnesaemia such as digoxin and diuretics. ➢ to individuals with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. ➢ to individuals with known hypersensitivity to omeprazole or any of the excipients – see SmPC. ➢ to individuals with known hypersensitivity to other PPIs. ➢ to individuals with a history of subacute cutaneous lupus erythematosus (SCLE) after previous treatment with a PPI. ➢ to individuals taking a contraindicated medicine (see drug interactions section for further detail) including: o any drug(s) that the SmPC and BNF advises to avoid concomitant use including, for example: ▪ HIV protease inhibitors atazanavir, nelfinavir. ▪ individuals taking cilostazol, citalopram, clopidogrel, diazepam, erlotinib, escitalopram, itraconazole, ketoconazole, methotrexate, phenytoin, posaconazole, rifampicin, St John's wort (*Hypericum perforatum*), tacrolimus, voriconazole. ▪ oral vitamin B12 therapy. ➢ to individuals with a current infection caused by *Salmonella*, *Campylobacter* or *Clostridioides difficile.* ➢ if the pharmacist is unable to undertake an appropriate assessment, to determine the need for the medicine and that it would be appropriate for the individual to use it. ➢ to individuals who are unable to use the product effectively themselves or who do not have a carer to administer or apply the medication for them. See route / method of administration section. ➢ if the individual does not agree to share relevant clinical information.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for omeprazole for full details of special warnings and precautions for use. **Taking prescribed medication thought to be an exacerbating factor for example**: ➢ anticholinergics. ➢ benzodiazepines. ➢ beta blockers.

(continued over page)	➢ bisphosphonates.
Cautions (including relevant actions to be taken) (continued)	➢ calcium channel blockers. ➢ corticosteroids. ➢ nitrates. ➢ NSAIDs. ➢ theophyllines. ➢ tricyclic antidepressants. Treatment can be offered if appropriate and advise the individual to see the clinician responsible for the treatment prescribed. **Risk of *Clostridioides difficile* infection (CDI).** Concomitant use of a proton pump inhibitor or other acid suppressing drugs with antibiotics can increase the risk of CDI. **Breastfeeding** Omeprazole is the PPI of choice in breastfeeding. Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. **Interference with laboratory tests** Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, omeprazole should be stopped for at least 5 days before CgA measurements. See also drug interactions section below for additional cautions.
Action to be taken if the individual is excluded or declines treatment	➢ If the individual meets the exclusion criteria, refer to the most appropriate clinician. The urgency with which a referral needs to be made is based on the presenting symptoms. ➢ 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 (individual or carer) intended actions. ➢ If appropriate, individuals may be offered a suitable alternative to omeprazole from the All-Wales Common Ailments Service Formulary. Alternatively, refer the individual to their GP or a Community Pharmacist Independent Prescriber (PIP) if appropriate and/or provide them with information about further options.

Further advice	If there is any doubt about the supply of medication or the individual's fitness or suitability to receive the medication, a doctor or appropriate community pharmacist independent prescriber (PIP) should be consulted. ➢ 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	Omeprazole 20 mg gastro-resistant hard capsules
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	No
Route / method of administration	Oral. Swallowed whole with half a glass of water. **Swallowing difficulties:** Advise the individual to open the capsule and swallow the contents directly with half a glass of water or put the contents into a glass of still (non-fizzy) water, fruit juice (e.g. apple, orange or pineapple) or apple sauce. The mixture should be stirred before drinking it (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes. Rinse the glass well with half a glass of water and drink it. Alternatively, individuals can suck the capsule and swallow the pellets with half a glass of water. The enteric coated pellets must not be chewed. See individual or carer advice section.
Dose and frequency of administration	ONE (20 mg) capsule to be taken DAILY in the morning for 28 days.
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied	Appropriately labelled pack to provide treatment for 28 days. 1 x 28 capsule pack to provide 28 days treatment at a dose of ONE (20 mg) capsule DAILY.
Drug interactions (continued over page)	The following list is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF. **Contraindications** Any drug(s) that the SmPC and BNF advises to avoid concomitant use, including for example: ➢ HIV protease inhibitors atazanavir, nelfinavir. ➢ cilostazol, citalopram, clopidogrel, diazepam, erlotinib, escitalopram, itraconazole, ketoconazole, methotrexate, phenytoin, posaconazole, rifampicin and St John's wort (*Hypericum perforatum*), tacrolimus, voriconazole. ➢ oral vitamin B12 therapy.

Drug interactions (continued)	**Cautions** **Oral anticoagulants** Bleeding events (bruising, epistaxis, gastrointestinal bleeding, haematuria and melena) have been reported rarely, in association with increases in prothrombin time in individuals receiving PPIs concurrently with warfarin. INR and prothrombin times should be monitored while receiving omeprazole and oral anticoagulants concomitantly. **Advise the individual to contact the clinic responsible for their INR monitoring within 3-5 days of starting omeprazole treatment.** **Indigestion remedies** Separate administration by 2 hours.
Identification & management of adverse reactions (continued over page)	Advise the individual that if any of the following side effects occur to **discontinue treatment immediately and contact the emergency department or dial 999:** ➢ 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 with omeprazole: **Very common to common** (affecting less than 1 in 10 or between 1 in 10 and 1 in 100 patients): ➢ headache, abdominal pain, constipation, diarrhoea, flatulence, nausea and vomiting, fundic gland polyps (benign). **Uncommon** (affecting between 1 in 100 and 1 in 1000 patients): ➢ insomnia. ➢ dizziness, paraesthesia, somnolence. ➢ vertigo. ➢ increase liver enzymes. ➢ dermatitis, pruritis, rash, urticaria. ➢ fracture of the hip, wrist or spine. ➢ malaise, peripheral oedema. **Rare to very rare** (affecting up to or less than 1 in 10,000 patients): ➢ leukopenia, thrombocytopenia, agranulocytosis, pancytopenia.

	➢ hypersensitivity reactions e.g. fever, angioedema and anaphylactic shock.
Identification & management of adverse reactions (continued)	➢ hyponatraemia. ➢ agitation, confusion, depression, aggression, hallucinations. ➢ taste disturbances. ➢ blurred vision. ➢ bronchospasm. ➢ dry mouth, stomatitis, gastrointestinal candidiasis. ➢ hepatitis with or without jaundice, hepatic failure, encephalopathy in patients with pre-existing liver disease. ➢ alopecia, photosensitivity, acute generalised exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS) erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN). ➢ arthralgia, myalgia, muscular weakness. ➢ tubulointerstitial nephritis (with possible progression to renal failure). ➢ gynaecomastia. ➢ increased sweating. **Not known** (cannot be estimated from the available data): ➢ hypomagnesaemia: severe hypomagnesaemia may result in hypocalcaemia. Hypomagnesaemia may be associated with hypokalaemia. ➢ microscopic colitis. ➢ subacute cutaneous lupus erythematosus (SCLE). 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.
Individual or carer advice / follow up	Supply the marketing authorisation holder's patient information leaflet (PIL). Advise the individual or their carer: ➢ if they get any side effects, to talk to their doctor, 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 discontinue treatment and seek medical advice if they develop:

(continued over page)	○ severe and / or persistent diarrhoea. ○ skin lesions especially in sun exposed areas and arthralgia. ➢ to read the PIL before taking the medication.
Individual or carer advice / follow up (continued)	➢ to visit the NHS website on indigestion, gastritis and omeprazole for more information. ➢ to swallow the capsule whole; do not crush or chew. ➢ if they have difficulty swallowing the capsule, they can open the capsule and swallow the contents with half a glass of water or after mixing the contents in fruit juice or apple sauce or in non-carbonated water; advise that the dispersion should be taken immediately and stirred just before drinking and rinsed down with half a glass of water. Alternatively, individuals can suck the capsule and swallow the pellets with half a glass of water; the enteric coated pellets must not be chewed. ➢ that indigestion remedies (antacids or alginates) can continue to be taken for short term symptom control, but long-term continuous use is not recommended. ➢ to take the indigestion remedies (antacids or alginates) 2 hours before or after taking omeprazole. ➢ that omeprazole can cause side effects like dizziness and visual disturbances. If affected, they should not drive or operate machinery. ➢ that treatment is for 28 days. If symptoms persist / change or become more frequent they should see a GP. ➢ if symptoms resolve, to reduce the risk of rebound hypersecretion they can taper the dose of omeprazole towards the end of the treatment course and / or use an alginate if symptoms recur, e.g. they can take omeprazole every other day or on a when required basis.
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 individual 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*

- All Wales Medicines Strategy Group. All Wales Common Ailments Formulary. June 2025. Available from: https://awttc.nhs.wales [accessed 14 August 2025]
- British National Formulary (BNF) – current edition. Available from: https://bnf.nice.org.uk/ [accessed 14 August 2025]
- General Pharmaceutical Council. In Practice: Guidance on Confidentiality. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 14 August 2025]
- General Pharmaceutical Council. In Practice: Guidance on Consent. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 14 August 2025]
- National Institute for Health and Care Excellence (NICE). Patient group directions [MPG2]: Competency framework for health professionals using patient group directions. Updated March 2017. Available from: http://www.nice.org.uk/guidance/mpg2/resources [accessed 14 August 2025]
- National Institute for Health and Care Excellence. Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management.[CG184]. Updated 18 October 2019. Available from: https://www.nice.org.uk/guidance/cg184 [accessed 14 August 2025]
- National Institute for Health and Care Excellence. Suspected cancer: recognition and referral. [NG12]. Updated 01 May 2025. Available from: https://www.nice.org.uk/guidance/ng12 [accessed 14 August 2025]
- National Institute for Health and Care Excellence: Clinical Knowledge Summaries. Dyspepsia – unidentified cause. Last revised May 2024. Available from: https://cks.nice.org.uk [accessed 14 August 2025]
- NHS 111 Wales Health A-Z. Available from: https://111.wales.nhs.uk [accessed 14 August 2025]
- NHS Medicines A-Z. Available from: https://www.nhs.uk [accessed 14 August 2025]
- Specialist Pharmacy Service. Using Warfarin with Proton Pump Inhibitors (PPIs) alongside warfarin. Updated 19 April 2023. Available from: https://www.sps.nhs.uk [accessed 14 August 2025]
- Summary Product Characteristics (SmPC). Available from: https://www.medicines.org.uk/emc [accessed 14 August 2025]
- Yellow Card Reporting. Available from: https://yellowcard.mhra.gov.uk/ [accessed 14 August 2025]

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Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of: omeprazole 20 mg capsules by community pharmacists under the Clinical Community Pharmacy Service, Common Ailments Service for dyspepsia 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

This authorisation sheet should be kept to serve as a record of those practitioners authorised to work under this PGD in accordance with the retention statement in the organisational authorisation section.