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National reference:
CYM-25028

Local reference:
PGD 0218A

Community Pharmacy Common Ailments Service Patient Group Direction

for the supply of

docusate sodium 100 mg capsules

in [Powys Teaching Health Board]

Operational from: 01 November 2025

Review Date: 31 July 2028

Expiry Date: 31 October 2028

Version number: 2.0



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PGD for the supply of docusate sodium 100 mg capsules for the treatment of constipation by pharmacists delivering the Common Ailments Service component of the Clinical Community Pharmacy Service

Reference: Docusate sodium 100 mg capsules PGD
Version no: 2.0
Valid from: 01 November 2025
Review date: 31 July 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	7 th March 2023
2.0	PGD reviewed and updated to align with other national templates. Exclusion criteria updated to reflect changes to referral criteria in monograph. Acknowledgement of contribution by clinician reference group and community pharmacy user group added.	17 June 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 healthcare 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 – Emlyn Pritchard	Head of Primary Care Medicines Management, Powys THB.	
Expert reviewer – Dr Nia Hughes	Arfon Cluster Lead, Primary Care Medical Director, West Betsi Cadwaladr 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	Principal Pharmacist, 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-Affan	Resource Development Lead for CAS, WMAS, Cardiff and Vale UHB.
Nia Sainsbury	Publications Lead, WMAS, Cardiff and Vale UHB.

Date CPCAG approval of PGD: 29 August 2025

Date All Wales PGD Advisory Board ratification: 04 September 2025



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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.

IPowys 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...	9/24/2025
Chief Pharmacist for PTHB	Jonathan Boyd	 Signed by: Jon Boyd 6D8ECFE8C9EB423...	9/29/2025
Clinical Governance Lead for PTHB	Amanda Edwards	 DocuSigned by: Amanda Edwards 74A4E51A42E9473...	10/7/2025
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard	 DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	10/1/2025

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.



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3. Characteristics of Staff

<p>Qualifications and professional registration</p>	<p>This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC).</p>
<p>Additional requirements</p>	<p>Pharmacists must:</p> <ul style="list-style-type: none"> ➤ 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 published by HEIW (Health Education and Improvement Wales). ➤ be familiar with the British National Formulary (BNF) and SmPC entries for docusate sodium 100 mg capsules. ➤ have awareness of the adverse drug reactions associated with docusate sodium 100 mg capsules. <p>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.</p>
<p>Ongoing training and competency</p>	<p>Pharmacists must:</p> <ul style="list-style-type: none"> ➤ 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. <p>A record of any training and competency assessments undertaken must be maintained.</p>



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4. Clinical condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>For the treatment of constipation in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).</p>
<p>Inclusion criteria</p>	<p>Docusate sodium 100 mg capsules can be supplied to individuals aged 18 years and over, presenting with symptoms of short-term constipation (less than 3 months) if lifestyle changes have been ineffective and:</p> <ul style="list-style-type: none"> ➤ they have no contraindications to docusate sodium 100 mg capsules – see SmPC. ➤ informed consent has been given (individual or carer).
<p>Exclusion criteria²</p> <p>(continued over page)</p>	<p>Docusate sodium 100 mg capsules should not be supplied:</p> <ul style="list-style-type: none"> ➤ if the pharmacist is unsure of the diagnosis. ➤ if intestinal obstruction or perforation is suspected. Symptoms include frequent and forceful vomiting sometimes with presence of bile, difficulty passing gas, feeling of fullness even without eating much, sometimes diarrhoea occurs (requires urgent review). ➤ if paralytic ileus is suspected. Symptoms include nausea, abdominal distension or tenderness, recent abdominal or non-abdominal surgery, acute conditions e.g. pneumonia, trauma and systemic conditions e.g. sepsis (requires urgent review). ➤ if an individual is taking clozapine (requires urgent review). ➤ to individuals with symptoms of toxic megacolon. Symptoms include abdominal pain, tenderness and distension, fever, chills, changes in mental state (requires urgent review). ➤ if there are symptoms of spinal cord injury e.g. new onset pain, tingling, weakness or numbness in one or both legs (requires urgent review). ➤ if there is blood or mucous present in the stools not believed to be due to haemorrhoids. ➤ if rectal bleeding and or anal pain is present and not believed to be due to haemorrhoids. ➤ if unexplained weight loss, appetite loss, tiredness is present. ➤ if severe abdominal pain is present. ➤ if an abdominal or very painful rectal mass / lump is suspected. ➤ if there is co-existing diarrhoea. ➤ in the case of colonic atony, faecal loading or faecal impaction. ➤ in severe inflammatory conditions of the intestinal tract (e.g. ulcerative colitis, Crohn’s disease). ➤ if faecal urgency is present.

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.



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<p>Exclusion criteria (continued)</p>	<ul style="list-style-type: none"> ➤ if tenesmus (continuously feeling the need to defecate without producing significant amounts of faeces, or after passing a normal amount of stool) is described by the individual. ➤ if the individual is pregnant. ➤ if the individual is breastfeeding AND presents with suspected opioid induced constipation. ➤ if the individual is aged over 60 years and mentions they have a sudden altered bowel habit, particularly if lasting more than 3 weeks. ➤ if manual measures are being used to relieve constipation. ➤ if symptoms persist after trying an altered diet and laxative treatment. ➤ if there is a history of prolonged use of laxatives. ➤ if an individual is on a palliative care pathway. ➤ if fever, nausea or vomiting is present. ➤ if there are associated urinary symptoms, urinary incontinence or retention or dyspareunia. ➤ if concomitant iron deficiency anaemia is present at any age. ➤ if non-iron deficiency anaemia is present and the individual is 60 years old or more. ➤ in the presence of confusion, delirium, functional decline. ➤ in the presence of neurological conditions e.g. history of cerebrovascular disease, Parkinson’s disease, tumours. ➤ if a bulk-forming laxative has not been tried first (provided there are no contraindications to it and symptoms are not opioid-induced). ➤ if there is progressive faecal retention, distension of the rectum, and/or loss of sensory and motor function. ➤ if the individual has fructose intolerance. ➤ to individuals with known hypersensitivity to docusate sodium 100mg capsules containing products or any of the excipients – see SmPC. ➤ 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 administer or use the product effectively themselves or who do not have a carer to administer the medication for them. ➤ if individual does not agree to share necessary clinical information.
<p>Cautions (including relevant actions to be taken) (continued over page)</p>	<p>Please refer to the SmPC for docusate sodium 100 mg capsules for full details of special warnings and precautions for use.</p> <ul style="list-style-type: none"> ➤ If an individual has persistent bloating (over 3 weeks) and/or are taking prescribed medicines that are suspected to be the cause of the constipation - provide treatment AND refer. See patient advice section.



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<p>Cautions (including relevant actions to be taken) (continued)</p>	<ul style="list-style-type: none"> ➤ The medication contains sunset yellow (E110) which may cause allergic reactions. <p>See also drug interactions section below for additional cautions.</p>
<p>Action to be taken if the individual is excluded or declines treatment</p>	<ul style="list-style-type: none"> ➤ 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 referrals made and their (individual or carer) intended actions. ➤ If appropriate, individuals may be offered a suitable alternative to docusate sodium 100 mg capsules from the All-Wales Common Ailments Service Formulary. Alternatively, refer the individual to their GP or a Community Pharmacist Independent Prescriber (PIP) if appropriate.
<p>Further advice</p>	<p>If there is any doubt about the supply of the medication or individual's fitness or suitability to receive the medication, a doctor or appropriate Community Pharmacist Independent Prescriber (PIP) should be consulted.</p> <ul style="list-style-type: none"> ➤ Further information can be found in the SmPC, BNF and the All Wales Common Ailments Service.



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5. Description of treatment

Name, strength & formulation of drug	Docusate sodium 100 mg capsules
Legal category	Pharmacy only (P)
Black triangle ▼	No
Off-label use	Yes (licensed use is for chronic constipation). Where a drug is recommended off-label, consider as part of the consent process, informing the individual / carer, that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration	Oral.
Dose and frequency of administration	Individuals aged 18 years and over: Starting dose: ONE capsule TWO to THREE times daily. If required, the dose can be increased up to FIVE capsules daily. Individuals should be advised not to take more than 5 capsules in a 24-hour period.
Duration of treatment	If treatment provides adequate symptom control, advise the individual to gradually reduce the number of capsules and stop once the stool becomes soft and passes easily without straining, at least 3 times a week. Advise the individual to return if symptoms are persistent or treatment is ineffective, and treatment options have not been exhausted.
Quantity to be supplied	Appropriately labelled pack to provide treatment for SEVEN days. 1 x 30 capsule pack to provide 7 days treatment at a dose of up to 5 times daily.
Drug interactions	The following list is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF . Contraindications <ul style="list-style-type: none"> ➤ Baloxavir marboxil: docusate may decrease the concentration of the active metabolite baloxavir. ➤ Mineral oil: absorption of mineral oil can be increased if taken concurrently with docusate.



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<p>Identification & management of adverse reactions</p>	<p>Advise the individual that if any of the following side effects occur to discontinue treatment immediately and contact the emergency department or dial 999:</p> <ul style="list-style-type: none"> ➤ Allergic reactions such as sudden wheeziness, difficulty with breathing, speaking and swallowing. ➤ Swelling of the eyelids, face or lips. ➤ Rash or itching (especially affecting the whole body). <p>The following side effects have been reported by individuals taking docusate capsules:</p> <p>Rare (affecting between 1 in 1000 and 1 in 10,000 patients):</p> <ul style="list-style-type: none"> ➤ diarrhoea. ➤ nausea. ➤ abdominal cramps. <p>Unknown incidence:</p> <ul style="list-style-type: none"> ➤ skin rash. ➤ pruritus. <p>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.</p>
<p>Individual or carer advice / follow up</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>Advise the individual or their carer:</p> <ul style="list-style-type: none"> ➤ 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 from an appropriate practitioner if their condition deteriorates and/or they become systemically unwell. ➤ if they have persistent bloating (over 3 weeks) to see a GP for routine assessment. ➤ if they take a prescribed medicine thought to be the cause of the constipation to see a GP for routine assessment. ➤ to read the PIL before taking the medication. ➤ to visit the NHS website on constipation for more information.



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	<p>➤ if symptoms do not improve after initial treatment, to return to the pharmacy to discuss other options within CAS that may be suitable to try.</p>
<p>Records</p>	<p>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.</p> <p>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.</p>



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Appendices

Appendix A: Key references

- All Wales Medicines Strategy Group. All Wales Common Ailments Formulary. August 2023. Updated June 2025. Available from: <https://awttc.nhs.wales> [accessed 05 June 2025]
- British National Formulary (BNF) – current edition. Available from: <https://bnf.nice.org.uk/> [accessed 05 June 2025]
- General Pharmaceutical Council. In Practice: Guidance on Confidentiality. Revised June 2018. Available from: <https://www.pharmacyregulation.org> [accessed 05 June 2025]
- General Pharmaceutical Council. In Practice: Guidance on Consent. Revised June 2018. Available from: <https://www.pharmacyregulation.org> [accessed 05 June 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 05 June 2025]
- National Institute for Health and Care Excellence: Clinical Knowledge Summaries. Constipation. Last revised June 2025. Available from: <https://cks.nice.org.uk> [accessed 05 June 2025]
- NHS 111 Wales. Health A-Z. Available from: <https://111.wales.nhs.uk> [accessed 05 June 2025]
- NHS Medicines A-Z. Available from: <https://www.nhs.uk> [accessed 06 June 2025]
- NHS Wales. Welsh Health Technical Memorandum 07-01 – Safe management of healthcare waste. Published 2013. Available from: <https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/> [accessed 05 June 2024]
- Summary Product Characteristics (SmPC). Available from: <https://www.medicines.org.uk/emc/> [accessed 05 June 2025]
- Yellow Card Reporting. Available from: <https://yellowcard.mhra.gov.uk/> [accessed 05 June 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:
docusate sodium 100 mg capsules by community pharmacists under the Clinical Community
Pharmacy Service, Common Ailments Service for constipation 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, serving as a record of those practitioners authorised to work under this PGD in accordance with the retention statement in the [organisational authorisation section](#).