

Patient Group Direction

For the supply of

Docusate sodium 100 mg capsules

By community pharmacists providing the

NHS Wales Clinical Community Pharmacy Service for

the treatment of constipation

in **[Powys Teaching Health Board]**

Operational from: 1st July 2023

Review Date: 31st March 2026

Version number: 1.0

*PGD for the supply of docusate sodium 100 mg capsules for constipation
as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026*

Reg No: PGD 0218
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PGD for the supply of docusate sodium 100 mg capsules for the treatment of constipation by pharmacists delivering the Common Ailment Service component of the Clinical Community Pharmacy Service

Reference: Docusate sodium 100 mg capsules 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	7 th March 2023

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

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1. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Advisory Group 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
Richard Evans	CPCAG reviewer	Community Pharmacy Advisor, Aneurin Bevan UHB
Emlyn Pritchard	CPCAG reviewer	Head of Primary Care Medicines Management, Powys Teaching Health Board
Dr. Nia Hughes	Medical Reviewer	GP and Cluster Lead/Interim area Medical Director (Community and Primary Care), Betsi Cadwaladr UHB
Dr. Nicky Davies	Medical Reviewer	GP and Assistant Medical Director (Community and Primary Care), Betsi Cadwaladr UHB

Date CPCAG approval of PGD: 7th June 2023

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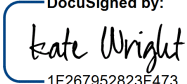
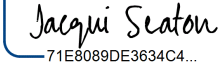


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2. Organisational authorisations

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:  1F267952823F473...	9/7/2023
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by:  71E8089DE3634C4...	9/12/2023
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by:  74A4E51A42E9473...	9/12/2023
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard	DocuSigned by:  EB776BA7283F49B...	9/7/2023

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.

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3. Characteristics of Staff

Qualifications and professional registration	<p>This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC).</p>
Additional requirements	<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 set out 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>
Ongoing training and competency	<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.

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	<ul style="list-style-type: none"> ➤ 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

Clinical condition or situation to which this PGD applies	For the treatment of constipation in accordance with the community pharmacy Common Ailment Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	<p>Docusate sodium 100 mg capsules can be given 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 ➤ where informed consent has been given (patient, parent/guardian, carer)
Criteria for exclusion²	<p>Docusate sodium 100 mg capsules should not be supplied if the pharmacist is unsure of the diagnosis and/or:</p> <ul style="list-style-type: none"> ➤ if symptoms involve new onset pain, tingling, weakness or numbness in one or both legs ➤ if there is blood or mucous present in the stools ➤ if rectal bleeding is present ➤ if unexplained weight loss or tiredness is present ➤ if severe abdominal pain is present ➤ if an abdominal mass/lump is suspected ➤ if intestinal obstruction or perforation is suspected ➤ if paralytic ileus is suspected ➤ in individuals with severe inflammatory conditions of the intestinal tract (e.g. ulcerative colitis, Crohn's disease and toxic megacolon) ➤ in the case of colonic atony, faecal loading or faecal

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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(continued over page)	<p>impaction</p> <ul style="list-style-type: none"> ➤ if there is persistent bloating ➤ if there is co-existing diarrhoea ➤ 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
Criteria for exclusion (continued)	<ul style="list-style-type: none"> ➤ if the individual mentions they have a sudden altered bowel habit ➤ if manual measures are being used to relieve constipation ➤ if fever, nausea or vomiting is present ➤ if symptoms persist after trying an altered diet and use of laxatives for at least 2 weeks ➤ if there is a history of prolonged use of laxatives ➤ if an individual is on a palliative care pathway ➤ if other laxatives in the formulary pathway have not yet been tried (provided there are no contraindications to them - for example if the individual is unable to increase fluid intake sufficiently to use osmotic/bulk-forming laxatives safely) ➤ if mineral oil is being taken by the individual (see further details in drug interactions section below) ➤ if baloxavir marboxil is being taken by the individual (see further details in drug interactions section below) ➤ if an individual is also taking clozapine (<u>requires urgent review</u>) ➤ if an individual has had constipation for > 3 months ➤ if there is progressive faecal retention, distension of the rectum, and/or loss of sensory and motor function ➤ if there are associated urinary symptoms, urinary incontinence or retention, or dyspareunia ➤ if there is a suspected anal fissure ➤ if the individual has a rare hereditary problem of fructose intolerance (the product contains sorbitol) ➤ in breastfeeding

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	<ul style="list-style-type: none"> ➤ to individuals with known hypersensitivity to docusate sodium 100 mg capsules or any of the excipients – see SmPC ➤ 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
Cautions (including relevant actions to be taken)	<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 prescribed medicine is suspected to be the cause of the constipation (provide treatment but refer). ➤ In pregnancy (docusate is not known to be harmful – the manufacturer advises caution). ➤ The medication contains sunset yellow (E110) which may cause allergic reactions. <p>See also drug interactions section below for additional cautions.</p>
Action to be taken if the individual is excluded or declines treatment	<ul style="list-style-type: none"> ➤ 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 docusate sodium 100 mg capsules 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	<p>Further information can be found in the SmPC, BNF and the All Wales Common Ailments Service Formulary.</p>

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5. Description of treatment

Name, strength & formulation of drug	Docusate sodium 100 mg capsules
Legal category	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/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product license.
Route / method of administration	Oral
Dose and frequency of administration	<u>Individuals aged 18 years and over:</u> 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	This PGD only allows for the duration stated in the dosage schedule below.
Quantity to be supplied/administered	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	Contraindications ➤ 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. The SmPC and the BNF should be referred to prior to supplying the medication.
Identification & management of adverse reactions	If the patient experiences any of the following they must discontinue treatment:

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(continued over page)	<ul style="list-style-type: none"> ➤ difficulty breathing or swallowing ➤ swelling of the mouth, face, lips, tongue or throat (severe allergic reaction symptoms)
Identification & management of adverse reactions (continued)	<ul style="list-style-type: none"> ➤ severe itching of the skin, with a rash or raised lumps, hives or blisters <p>The following side effects have been reported as:</p> <p><u>Rare to very rare</u> (affecting up to or less than 1 in 10,000 patients)</p> <ul style="list-style-type: none"> ➤ Diarrhoea, nausea, abdominal cramps <p><u>Not known</u> (cannot be estimated from the available data)</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>
Patient or carer advice/follow up	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>Laxative treatment</p> <ul style="list-style-type: none"> ➤ Ensure adequate fluid intake to avoid dehydration and obstruction. ➤ Docusate sodium 100 mg capsules can be taken with or without food but should be taken with a drink of water. ➤ If an effect is not seen within 48 hours, seek medical advice. <p>Lifestyle measures</p> <ul style="list-style-type: none"> ➤ Eat a healthy, balanced diet with regular meals. ➤ Your diet should contain whole grains, vegetables, fruits/ fruit juice high in sorbitol (e.g., apples, apricots, grapes, raisins, peaches, pears, plums, prunes, raspberries, and strawberries). ➤ Increase dietary fibre. Aim for 30 g of fibre a day (increase gradually, to minimise bloating and flatulence). Beneficial effects of this may take several weeks to be observed.

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(continued over page)	<ul style="list-style-type: none"> ➤ Avoid dehydration by drinking plenty of water (8–10 cups per day). ➤ Exercise regularly. ➤ Respond straight away to the sensation of needing to go to the toilet. Try not to hurry, make sure you have enough time to empty your bowel.
Patient or carer advice/follow up (continued)	<ul style="list-style-type: none"> ➤ Try resting feet on a low stool while going to the toilet, so that the knees are above the hips; this can make passing stools easier. ➤ Avoid codeine-containing products as these make constipation worse. Paracetamol is not known to cause constipation so can be taken for minor pain if no other exclusions apply. <p>Signposting</p> <p>Inform 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 if their condition deteriorates and/or they become systemically unwell. ➤ to read the PIL before taking the medication. ➤ to visit the NHS website on constipation for more information.
Records	<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. 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.</p>

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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. Constipation. Last revised January 2023. Available from: <https://cks.nice.org.uk> [accessed 02 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]

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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 Ailment Service (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

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