



**National reference:**  
CYM-24005

**Local reference:**  
PGD 0241

# Community Pharmacy Urinary Tract Infection Service

Patient Group Directions for the supply of nitrofurantoin or trimethoprim

in [Powys Teaching Health Board]

Operational from: 03 June 2024

Review date: 08 February 2027

Expiry date: 02 June 2027

Version number: v1.0



**PGDs for the supply of antibiotics for acute, uncomplicated lower urinary tract infection in non-pregnant females or transgender males who have not undergone sex reassignment surgery between 16 and 64 years of age by pharmacists delivering the Urinary Tract Infection Service component of the Clinical Community Pharmacy Service**

Reference: Nitrofurantoin and trimethoprim PGDs  
Version no: 1.0  
Valid from: 03 June 2024  
Review date: 08 February 2027  
Expiry date: 02 June 2027

**Welsh Medicines Advice Service has developed these PGDs for local authorisation**

Those using these PGDs 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)<sup>1</sup>. **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 these PGDs is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGDs.

**INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THESE PGDs BEFORE WORKING ACCORDING TO IT.**

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

Any queries regarding the clinical content of a PGD should be addressed to: [welshmedicines.information@wales.nhs.uk](mailto:welshmedicines.information@wales.nhs.uk)

**Change history:**

Version number	Change details	Date
1.0	Original PGD developed	22 December 2023

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



## 1. PGD development

These PGDs have been developed by the following health care professionals on behalf of NHS Wales.

**This section MUST REMAIN when these PGDs are adopted by an organisation**

### PGD Development

Name	Designation	Signature
Main author – Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB	
Expert reviewer – Louise Allen Nitrofurantoin	Head of Community Pharmacy, PCIC, Cardiff and Vale UHB	
Expert reviewer – Emlyn Pritchard Trimethoprim tablets	Head of Primary Care Medicines Management, Powys THB	
Expert reviewer – Adam Mackridge Trimethoprim liquid	Strategic Lead Pharmacist for Community Pharmacy, Betsi Cadwaladr UHB	
Expert reviewer – Richard Coulthard	Consultant Urologist. Cardiff and Vale UHB	

These PGDs have 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, PCIC, Cardiff and Vale UHB
Amy David	Primary Care Pharmacist, Swansea Bay UHB
Avril Tucker	Antimicrobial Pharmacist/Locality Team Leader, Cwm Taf Morgannwg 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
Anna Burgess	Digital Lead Pharmacist, Welsh Medicines Advice Service, Cardiff and Vale UHB
Jason Carroll	Pharmacist Team Leader, Cwm Taf Morgannwg UHB



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Samuel MacDonald	Clinical Fellow, Welsh Government
Debra Roberts	Head of Programme Development, Associate Dean, HEIW
Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB

**Date CPCAG approval of PGDs:** 22 April 2024

**Date All Wales PGD Advisory Board ratification:** 09 May 2024



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### 3. Organisational Authorisations

These PGDs are not legally valid until they have 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 these PGDs.

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

Local Health Board approval (legal requirement) as per health board policy			
Role	Name	Sign	Date
Lead Doctor for PTHB	Kate Wright	DocuSigned by: <i>Kate Wright</i> 1F267952823F473...	5/31/2024
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by: <i>Jacqui Seaton</i> 71E8089DE3634C4...	5/15/2024
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by: <i>Amanda Edwards</i> 74A4E51A42E9473...	6/4/2024
Senior Pharmacist Lead for Community Pharmacies PTHB	Emlyn Pritchard	DocuSigned by: <i>Emlyn Pritchard</i> EB776BA7283F49B...	5/16/2024

Local enquiries regarding the use of these PGDs may be directed to:

[welshmedicines.information@wales.nhs.uk](mailto:welshmedicines.information@wales.nhs.uk)

[Appendix B](#) provides a practitioner listing sheet. Individual practitioners must be listed by name to work to these PGDs. 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 these PGDs.

#### 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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#### 4. Characteristics of Staff

<p><b>Qualifications and professional registration</b></p>	<p>This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC).</p>
<p><b>Additional requirements</b></p>	<p>Pharmacists must:</p> <ul style="list-style-type: none"> <li>➤ be employed by, or providing services on behalf of a pharmacy listed in the All Wales Pharmacy Database (AWPD) for the Urinary Tract Infection service.</li> <li>➤ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it by completing <a href="#">Appendix B</a>.</li> <li>➤ be familiar with the medicine and alert to changes in the <a href="#">Summary of Product Characteristics (SmPC)</a>.</li> <li>➤ 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 <a href="#">NICE Competency framework</a> for health professionals using PGDs).</li> <li>➤ be named in the All Wales Pharmacy Database for the Urinary Tract Infection service.</li> <li>➤ have met the training requirements for the service as published by HEIW (Health Education and Improvement Wales).</li> <li>➤ be familiar with the <a href="#">British National Formulary (BNF)</a> and <a href="#">SmPC</a> entries for nitrofurantoin and trimethoprim.</li> <li>➤ have awareness of the adverse drug reactions associated with nitrofurantoin and trimethoprim.</li> </ul> <p><b>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.</b></p>
<p><b>Ongoing training and competency</b></p>	<p>Pharmacists must:</p> <ul style="list-style-type: none"> <li>➤ undertake regular CPD and maintain own level of competence and knowledge in this clinical area to provide the service.</li> <li>➤ be aware of any updates made to the products in <a href="#">SmPC</a> and <a href="#">BNF</a>.</li> <li>➤ be aware of any updates to relevant national and local guidelines.</li> <li>➤ as registered professionals, be professionally accountable and must work within their competence.</li> </ul> <p>A record of any training and competency assessments undertaken must be maintained.</p>

## PGD for the supply of nitrofurantoin 100 mg modified release capsules

### 1. Clinical Condition

<b>Clinical condition or situation to which this PGD applies</b>	Treatment for acute, uncomplicated lower urinary tract infection (UTI), in accordance with the community pharmacy Urinary Tract Infection component of the Clinical Community Pharmacy Service.																		
<b>Inclusion criteria</b>	<p>Nitrofurantoin 100 mg modified-release capsules can be given to:</p> <p>Non-pregnant females or transgender males who have not undergone sex reassignment surgery between 16 and 64 years old with:</p> <table border="1" data-bbox="464 651 1465 1680"> <tr> <td colspan="2" style="background-color: #cccccc;"><b>Scenario 1</b></td> </tr> <tr> <td colspan="2"><b>2 or 3 of the following symptoms</b></td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> <li>○ dysuria</li> <li>○ new nocturia</li> <li>○ cloudy urine</li> </ul> </td> </tr> <tr> <td colspan="2" style="background-color: #cccccc;"><b>OR Scenario 2</b></td> </tr> <tr> <td colspan="2"><b>Only 1 of the following symptoms AND a positive urine dipstick</b></td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> <li>○ dysuria</li> <li>○ new nocturia</li> <li>○ cloudy urine</li> </ul> </td> </tr> <tr> <td colspan="2" style="background-color: #cccccc;"><b>OR Scenario 3</b></td> </tr> <tr> <td colspan="2"><b>One or more of the following other urinary symptoms AND a positive urine dipstick</b></td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> <li>○ visible haematuria</li> <li>○ frequency</li> <li>○ suprapubic tenderness</li> <li>○ urgency</li> </ul> </td> </tr> </table> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>➤ they have no contraindications to nitrofurantoin.</li> <li>➤ informed consent has been given.</li> <li>➤ individuals assigned female at birth.</li> </ul> <p>For signs, symptoms and diagnosis of UTI see the UTI algorithm available here <a href="https://www.wmic.wales.nhs.uk/cas-uti-summary">https://www.wmic.wales.nhs.uk/cas-uti-summary</a> and the <a href="#">All Wales Common Ailments Service Formulary</a>.</p>	<b>Scenario 1</b>		<b>2 or 3 of the following symptoms</b>		<ul style="list-style-type: none"> <li>○ dysuria</li> <li>○ new nocturia</li> <li>○ cloudy urine</li> </ul>		<b>OR Scenario 2</b>		<b>Only 1 of the following symptoms AND a positive urine dipstick</b>		<ul style="list-style-type: none"> <li>○ dysuria</li> <li>○ new nocturia</li> <li>○ cloudy urine</li> </ul>		<b>OR Scenario 3</b>		<b>One or more of the following other urinary symptoms AND a positive urine dipstick</b>		<ul style="list-style-type: none"> <li>○ visible haematuria</li> <li>○ frequency</li> <li>○ suprapubic tenderness</li> <li>○ urgency</li> </ul>	
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## Exclusion criteria<sup>2</sup>

Nitrofurantoin 100 mg modified release capsules should not be given to individuals:

- **who have one or more of the following – refer to Emergency Department (ED):**
  - difficulty breathing.
  - severe symptoms, getting worse quickly, signs of sepsis or systemically very unwell / severe pain.
  - confusion, drowsiness or slurred speech.
  - systemically unwell and at risk of immunosuppression.
  - skin changes, e.g. very cold, or a strange colour or rash develops.
  - presence of blood clots in urine along with struggling to pass urine.
  - not passing urine all day.
- individuals assigned male at birth.
- who are pregnant, or suspected of being pregnant or they have recently given birth, terminated a pregnancy or had a miscarriage in the last 6 weeks.
- if they are currently breastfeeding.
- with haematuria (visible or non-visible) without any other UTI symptoms, urinary retention or unexplained by menstruation.
- with haematuria (visible or non-visible) and they are taking an anticoagulant.
- with the presence of symptoms for more than 7 days.
- if they describe the presence of a pelvic or abdominal mass.
- known to be immunosuppressed (accompanied by other clinical symptoms of blood disorders), including for example:
  - a patient who is on chemotherapy, radiotherapy, has known or suspected leukaemia, asplenia, aplastic anaemia or HIV/AIDS, or is taking an immunosuppressive drug following a transplant.
  - a patient who is taking a disease-modifying anti-rheumatic drug (DMARD), e.g. sulfasalazine, methotrexate.
  - a patient who is taking a medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection including cytotoxic drugs, carbimazole, clozapine and sulfasalazine.
- any previous UTIs in the last 6 months or 2 or more UTIs in the last 12 months.
- who have recently travelled to a country with increased antimicrobial resistance (outside northern Europe and Australasia).

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<sup>2</sup> 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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## Exclusion criteria

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- with known previous resistance to nitrofurantoin.
- taking prophylactic antibiotics for recurrent UTI.
- if they have been in hospital for more than 7 days in the past 6 months.
- if they are resident in a long-term care facility.
- if they are currently using urinary catheter devices including indwelling or suprapubic urethral catheters, and intermittent self-catheterisation.
- if they have symptoms suggestive of upper UTI/ pyelonephritis, e.g.
  - myalgia.
  - rigors or raised temperature (37.9°C or above).
  - nausea and vomiting.
  - flank / loin pain (typically unilateral) with or without abdominal pain / tenderness.
- with suspected sexually transmitted infection.
- with vaginal or urethral discharge, irritation, itch or skin rash not associated with vulvovaginal candidiasis.
- with urinary symptoms thought to be caused by genitourinary syndrome of menopause:
  - dryness, burning or irritation of the vulva or vagina, vulvovaginal atrophy.
  - sexual symptoms, e.g. lack of lubrication, discomfort, pain, post coital bleeding, impaired sexual function.
- with known structural or neurological abnormalities of the urinary tract, or stent in tract
- with known kidney stones or history of kidney stones.
- with known or suspected severe hepatic impairment.
- with known Chronic Kidney Disease (CKD) stages 3b, 4 or 5 or suspected renal impairment (eGFR less than 45 mL/min/1.73m<sup>2</sup>).
- with known acute porphyria.
- with known glucose-6-phosphate dehydrogenase deficiency (G6PD) deficiency.
- with known anaemia.
- with known diabetes mellitus (type 1 or 2), and in the opinion of the pharmacist:
  - there are concerns regarding their individual diabetic control.
  - the individual is at increased risk of detrimental symptoms associated with poorly controlled diabetes; symptoms can include thirst, blurred vision, fatigue, increased frequency of urination.
  - the individual is unsure how to manage their diabetes.
- with known folate deficiency.
- with known vitamin B deficiency.

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<p><b>Exclusion criteria</b> (continued)</p>	<ul style="list-style-type: none"> <li>➤ with known peripheral neuropathy.</li> <li>➤ with known electrolyte imbalance.</li> <li>➤ with known rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption.</li> <li>➤ with known rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency.</li> <li>➤ who are taking contraindicated medicines (see <a href="#">drug interactions</a> section for further detail) including: <ul style="list-style-type: none"> <li>○ probenecid.</li> <li>○ sulfipyrazone.</li> <li>○ recent typhoid vaccination (oral).</li> <li>○ acetazolamide.</li> </ul> </li> <li>➤ with a known hypersensitivity to nitrofurantoin– see <a href="#">SmPC</a>.</li> <li>➤ with known hypersensitivity to any of the excipients – see <a href="#">SmPC</a>.</li> <li>➤ if they cannot swallow the capsules</li> <li>➤ if informed consent has not been given; where patients do not agree to share relevant clinical information or there is no valid consent.</li> <li>➤ who the pharmacist has assessed as not having capacity to understand the nature and purpose of treatment.</li> <li>➤ where a request has been made by a third party on behalf of a patient.</li> </ul>
<p><b>Cautions (including relevant actions to be taken)</b></p> <p>(continued over page)</p>	<p>Please refer to the <a href="#">SmPC</a> for nitrofurantoin for full details of special warnings and precautions for use.</p> <p><b>Concurrent medication and urinary tract symptoms</b></p> <ul style="list-style-type: none"> <li>➤ medications that can cause overactive bladder that can lead to urgency and frequency: <ul style="list-style-type: none"> <li>○ parasympathomimetic drugs.</li> <li>○ antidepressants.</li> <li>○ HRT.</li> <li>○ diuretics.</li> </ul> </li> <li>➤ medications that can decrease bladder contractility leading to retention and overflow incontinence: <ul style="list-style-type: none"> <li>○ antimuscarinic drugs.</li> <li>○ sympathomimetics.</li> <li>○ antidepressants.</li> <li>○ antihistamines.</li> <li>○ antipsychotics.</li> <li>○ ACE inhibitors.</li> </ul> </li> </ul>



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## Cautions (including relevant actions to be taken)

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- beta agonists.
- alpha blockers.
- anti-parkinsonian drugs.
- sedatives and hypnotics.
- diuretics.
- HRT.
- opioids.
- calcium channel blockers.

Supply antibiotics if applicable and safe, but refer the individual to their GP for review of medication where necessary.

### Haematuria (visible and non-visible)

**Visible haematuria** – consider treatment for UTI and inform individual if after completing their course of antibiotics:

- visible haematuria still persists, even if they feel better, to see their GP or seek medical attention as soon as possible.
- they are completely symptom free and feel better, to return in 6 weeks' time for a follow up assessment

**Non-visible haematuria** – consider treatment for UTI and inform individual to return in 6 weeks' time for a follow up assessment.

### Concomitant illness

Pre-existing conditions may mask hepatic or pulmonary adverse reactions, nitrofurantoin should be used with caution in individuals with pulmonary disease, any degree of hepatic dysfunction, neurological disorders, and allergic conditions (e.g. hay fever, allergic rhinitis, bronchial asthma atopic dermatitis). Advise the individual to seek medical advice if:

- they experience trouble breathing, shortness of breath, a lingering cough, coughing up blood or mucus, or pain or discomfort when breathing.
- if they develop yellowing of the skin or eyes, upper right abdominal pain, dark urine and pale or grey coloured stools, itching or joint pain and swelling.
- if they develop numbness and tingling in the feet or hands, burning, stabbing or shooting pains, loss of balance and co-ordination, muscle weakness, especially in the feet.

### Colitis

Caution should be used when treating patients with a history of antibiotic-associated colitis and other risk factors for *Clostridioides difficile* infection (CDI) (see [Risk factors | Background information | Diarrhoea - antibiotic associated | CKS | NICE](#)).

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<p><b>Cautions (including relevant actions to be taken)</b></p> <p>(continued)</p>	<p>Sustained severe diarrhoea should prompt suspicion of pseudomembranous colitis. As this condition may be life threatening, nitrofurantoin should be withdrawn immediately.</p> <p>Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening.</p> <p><i>Clostridioides difficile</i>-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhoea to fatal colitis.</p> <p><b>Diabetes</b></p> <p>Individuals with diabetes can be supplied with treatment and if, in the opinion of the pharmacist, there are no concerns or symptoms suggestive of poor control; for example, thirst, blurred vision, fatigue etc, treatment can be supplied. Individuals should be reminded of the diabetes sick day rules (see <a href="#">patient or carer advice</a>).</p> <p><b>Oral hypoglycaemic agents/insulin</b> – careful monitoring of glucose is recommended.</p> <p><b>Oral anticoagulants</b></p> <p>There is a risk of serious haemorrhage and significant elevations in International Normalized Ratio (INR) and prothrombin time when antibacterial agents are co-administered with warfarin. INR and prothrombin times should be frequently monitored while patients are receiving nitrofurantoin and oral anticoagulants concurrently.</p> <p><b>Advise the individual to contact their clinic responsible for INR monitoring within 3 days of starting nitrofurantoin treatment.</b></p> <p>Caution should be exercised when nitrofurantoin is co-administered with direct acting oral anticoagulants such as dabigatran, rivaroxaban and apixaban, particularly to patients at high risk of bleeding.</p> <p><b>Effect on laboratory tests</b></p> <p>During treatment with nitrofurantoin urine may be coloured yellow or brown. Individuals on nitrofurantoin are susceptible to false positive urinary glucose (if tested for reducing substances).</p>
<p><b>Action to be taken if the individual is excluded or declines treatment</b></p> <p>(continued over page)</p>	<ul style="list-style-type: none"> <li>➤ If patient meets the exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination.</li> <li>➤ Explain the reasons for exclusion to the individual and document in the consultation record.</li> <li>➤ If the individual declines advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent/carer or guardian) intended actions.</li> </ul>



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<p><b>Action to be taken if the individual is excluded or declines treatment</b></p> <p>(continued)</p>	<ul style="list-style-type: none"> <li>➤ If appropriate, patients may be offered a suitable alternative antibiotic or provided with advice and symptomatic treatment from the <a href="#">All Wales Common Ailments Service Formulary</a>. Alternatively, refer the individual to their GP if appropriate.</li> </ul>
<p><b>Further advice</b></p>	<p>If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a Doctor or appropriate Independent Prescriber should be consulted.</p> <ul style="list-style-type: none"> <li>➤ Refer to <a href="#">SmPC</a>, <a href="#">BNF</a> and the <a href="#">All Wales Common Ailments Service</a>.</li> </ul>

## 2. Description of Treatment

<b>Name, strength &amp; formulation of drug</b>	Nitrofurantoin 100 mg modified-release capsules.
<b>Legal category</b>	POM – Prescription Only Medicine.
<b>Black triangle ▼</b>	No.
<b>Off-label use</b>	<p>Yes.</p> <p>The <a href="#">SmPC</a> states nitrofurantoin 100 mg MR caps is indicated for acute uncomplicated UTI and treatment is 7 days.</p> <p>The <a href="#">All Wales Primary Care antimicrobial guidelines</a> state that for uncomplicated UTI, treatment is recommended for 3 days.</p> <p>Medicines should be stored according to the conditions detailed in the Storage section in this document. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by Pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with Pharmacy/Medicines Management.</p> <p>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.</p>
<b>Route / method of administration</b>	<p>Oral.</p> <p>Take with or just after food, or a meal.</p> <p>Swallow this medicine whole. Do not chew or crush.</p> <p>This medicine may colour your urine.</p>
<b>Dose and frequency of administration</b>	100 mg (ONE) modified release (MR) capsule to be taken TWICE daily (every 12 hours) for THREE days.
<b>Duration of treatment</b>	<p>THREE days.</p> <p>This PGD only allows for the duration stated in the <a href="#">dosage schedule</a> above.</p>
<b>Quantity to be supplied</b>	<p>Appropriately labelled pack to provide treatment for THREE days:</p> <p><b>6 x 100 mg</b> modified-release capsules to provide THREE days treatment at a dose of 100 mg (ONE) capsule TWICE daily.</p>
<b>Storage</b>	Medicines must be stored securely and in accordance with product <a href="#">SmPC</a> .
<b>Disposal</b>	No special requirements.



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<p><b>Drug interactions</b></p>	<p>The following list is not exhaustive. A detailed list of drug interactions can be found in the <a href="#">SmPC</a> and the <a href="#">BNF</a>.</p> <p><b>Contraindicated</b></p> <ul style="list-style-type: none"> <li>➤ typhoid vaccine (oral) – antibacterial agents may inactivate oral typhoid vaccine if ingested concomitantly; avoid where recent vaccination or vaccination due. The Green Book advises that the vaccine should not be commenced within three days of completing any antibacterial agent.</li> <li>➤ probenecid and sulfapyridine.</li> <li>➤ acetazolamide.</li> </ul> <p><b>Caution</b></p> <ul style="list-style-type: none"> <li>➤ antacids like magnesium trisilicate may reduce the absorption of nitrofurantoin. Avoid concomitant use.</li> <li>➤ medicines that affect the urinary pH, e.g. sodium bicarbonate, potassium citrate or sodium citrate, may reduce the urinary antibacterial efficacy of nitrofurantoin.</li> <li>➤ medicines that increase the risk of peripheral neuropathy including but not limited to:             <ul style="list-style-type: none"> <li>○ some types of chemotherapy for cancer, especially for bowel cancer, lymphoma or myeloma</li> <li>○ amiodarone, isoniazid, lamivudine, metronidazole, phenytoin, stavudine, thalidomide</li> </ul> </li> <li>➤ oral contraceptives – nitrofurantoin does not reduce their efficacy but if it makes them sick or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from <a href="#">What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk)</a>.</li> </ul>
<p><b>Identification &amp; management of adverse reactions</b></p> <p>(continued over page)</p>	<p>Advise the patient that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999:</p> <ul style="list-style-type: none"> <li>➤ allergic reactions such as sudden wheeziness, difficulty with breathing, speaking and swallowing.</li> <li>➤ swelling of the eyelids, face or lips.</li> <li>➤ rash or itching (especially affecting your whole body).</li> </ul> <p>The following side effects have been reported by patients taking nitrofurantoin:</p> <p><b>Very common to common</b> (affecting between 1 in 10 and 1 in 100 patients):</p> <ul style="list-style-type: none"> <li>➤ nausea and vomiting.</li> <li>➤ diarrhoea.</li> <li>➤ loss of appetite.</li> </ul>



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<p><b>Identification &amp; management of adverse reactions</b></p> <p>(continued)</p>	<ul style="list-style-type: none"> <li>➤ headaches.</li> <li>➤ dizziness.</li> <li>➤ drowsiness.</li> <li>➤ discoloured dark yellow or brown urine.</li> </ul> <p><b>Pulmonary reactions</b></p> <p>Acute pulmonary reactions usually occur within the first week of treatment and are reversible with cessation of therapy. Increased vigilance for respiratory symptoms in patients who have just started therapy is warranted (especially in elderly). Commonly manifested by fever, chills, cough, chest pain, dyspnoea, pulmonary infiltration with consolidation or pleural effusion on chest x-ray, and eosinophilia.</p> <p>Chronic pulmonary reactions (including pulmonary fibrosis and diffuse interstitial pneumonitis) can develop insidiously and can often occur in elderly patients. These occur rarely in patients who have received continuous therapy for six months or longer.</p> <p>Discontinue treatment immediately if pulmonary reactions occur.</p> <p>Signs of pulmonary damage include difficulty and or pain when breathing, shortness of breath and coughing up blood or mucous.</p> <p><b>Hepatic reactions</b></p> <p>Hepatic reactions, including fatal cases, have been reported. Discontinue immediately if hepatitis occurs.</p> <p>Hepatic reactions have included hepatitis, autoimmune hepatitis, cholestatic jaundice, chronic active hepatitis, and hepatic necrosis, occur rarely.</p> <p><b>Neurological disorders</b></p> <p>Advise to seek urgent medical advice if peripheral neuropathy develops.</p> <p>N.B. detailed lists of adverse reactions are available in the <a href="#">SmPC</a>, and the <a href="#">BNF</a>. 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><b>Patient or carer advice/follow up</b></p> <p>(continued over page)</p>	<p>Supply the marketing authorisation holder's patient information leaflet (<a href="#">PIL</a>).</p> <p>Use <a href="#">TARGET antibiotic checklist</a> for counselling.</p> <p>Inform the individual or their carer:</p> <ul style="list-style-type: none"> <li>➤ the medication should be taken at regular intervals with food or milk.</li> <li>➤ the tablets may discolour their urine (dark yellow or brown colour).</li> <li>➤ to take plenty of rest.</li> <li>➤ they should drink enough fluids so they pass pale urine regularly during the day. Cranberry products or urine alkalinising agents are not currently recommended. Avoid alcoholic or caffeinated drinks which may irritate the bladder.</li> </ul>



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**Patient or carer  
advice/follow up**

(continued)

- medicines that make the urine less acidic like over the counter cystitis preparations (containing potassium citrate, sodium citrate or sodium bicarbonate) can reduce the antibacterial action of nitrofurantoin and should not be taken during the course of nitrofurantoin.
- antacids such as magnesium trisilicate can decrease the absorption of nitrofurantoin and should not be taken during the course of nitrofurantoin.
- they should avoid having sexual intercourse until the UTI has cleared as this may aggravate symptoms.
- that taking simple analgesia such as ibuprofen or paracetamol at regular intervals will help with discomfort.
- if on assessment they had:
  - visible haematuria, they should seek medical attention if they still have blood in their urine after the 3-day course of antibiotics.
  - visible or non-visible haematuria they should return in six weeks' time for follow up assessment which may or may not include a second urine dipstick.
  - when considering management options, pharmacists should interpret information derived from urinalysis in conjunction with other clinically relevant information.
- symptoms should start to improve within 48 hours of taking nitrofurantoin – advise individual to seek medical advice if no improvement or symptoms worsen within this time.
- that if they have diabetes, their blood sugars may be higher or lower than usual whilst they are unwell. They should follow their diabetes sick day rules; see [Diabetes and being ill | Managing when you're sick | Diabetes UK](#).
- that 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](#).
- nitrofurantoin can sometimes cause dizziness or drowsiness. Advise that if they are affected, not to drive or operate machinery.
- to seek medical attention:
  - if they experience trouble breathing, shortness of breath, a lingering cough, coughing up blood or mucus, or pain or discomfort when breathing.
  - if they develop yellowing of the skin or eyes, upper right abdominal pain, dark urine and pale or grey coloured stools, itching or joint pain and swelling, loss of appetite, fever, nausea and vomiting.
  - if they develop numbness and tingling in the feet or hands, burning, stabbing or shooting pains, loss of balance and co-ordination, muscle weakness, especially in the feet.

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<p><b>Patient or carer advice/follow up</b> (continued)</p>	<ul style="list-style-type: none"> <li>➤ that in the event of a severe adverse reaction to discontinue treatment immediately and to seek medical advice if their condition deteriorates and/or they become systemically unwell.</li> <li>➤ to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet.</li> <li>➤ to read the <a href="#">PIL</a> before taking the medication.</li> <li>➤ provide the <a href="#">TARGET Treating your infection – urinary tract infection (UTI) leaflet</a>.</li> <li>➤ to visit the <a href="#">NHS website</a> on nitrofurantoin for more information.</li> <li>➤ to visit the <a href="#">NHS 111 Wales</a> site for further information on kidney infection.</li> </ul> <p>Lifestyle measures such as:</p> <ul style="list-style-type: none"> <li>➤ avoid lots of sugary foods and or drinks.</li> <li>➤ avoid spermicides.</li> <li>➤ wash the genital area with warm water (including before and after sex) and avoid using scented, perfumed soap and shower gel.</li> <li>➤ avoid vaginal douching.</li> <li>➤ urinate as soon as possible after sex.</li> <li>➤ wear cotton or breathable underwear instead of tight, synthetic underwear such as nylon.</li> <li>➤ promptly change sanitary or incontinence pads if they're soiled.</li> </ul> <p>Some hygiene behaviours which may help prevent UTIs include:</p> <ul style="list-style-type: none"> <li>➤ do not hold urine in if you feel the urge to go; when you do go, ensure you empty your bladder fully.</li> <li>➤ wipe from front to back when you go to the toilet.</li> <li>➤ keep the genital area clean and dry.</li> </ul>
<p><b>Records</b></p>	<p>The consultation details including any medication supplied under the 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 onto the Choose Pharmacy Urinary Tract Infection module as soon as practically possible following the consultation.</p> <p>If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes.</p>



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## PGD for the supply of trimethoprim 200 mg tablets

### 1. Clinical Condition

<b>Clinical condition or situation to which this PGD applies</b>	Treatment for acute, uncomplicated lower urinary tract infection (UTI), in accordance with the community pharmacy Urinary Tract Infection component of the Clinical Community Pharmacy Service.																																
<b>Inclusion criteria</b>	<p>Trimethoprim 200 mg tablets can be given to:</p> <p>Non-pregnant females or transgender males who have not undergone sex reassignment surgery between 16 and 64 years old and with:</p> <table border="1" data-bbox="464 651 1465 1682"> <tr> <td colspan="2" style="background-color: #cccccc;"><b>Scenario 1</b></td> </tr> <tr> <td colspan="2"><b>2 or 3 of the following symptoms</b></td> </tr> <tr> <td><input type="radio"/></td> <td>dysuria</td> </tr> <tr> <td><input type="radio"/></td> <td>new nocturia</td> </tr> <tr> <td><input type="radio"/></td> <td>cloudy urine</td> </tr> <tr> <td colspan="2" style="background-color: #cccccc;"><b>OR Scenario 2</b></td> </tr> <tr> <td colspan="2"><b>Only 1 of the following symptoms AND a positive urine dipstick</b></td> </tr> <tr> <td><input type="radio"/></td> <td>dysuria</td> </tr> <tr> <td><input type="radio"/></td> <td>new nocturia</td> </tr> <tr> <td><input type="radio"/></td> <td>cloudy urine</td> </tr> <tr> <td colspan="2" style="background-color: #cccccc;"><b>OR Scenario 3</b></td> </tr> <tr> <td colspan="2"><b>One or more of the following other urinary symptoms AND a positive urine dipstick</b></td> </tr> <tr> <td><input type="radio"/></td> <td>visible haematuria</td> </tr> <tr> <td><input type="radio"/></td> <td>frequency</td> </tr> <tr> <td><input type="radio"/></td> <td>suprapubic tenderness</td> </tr> <tr> <td><input type="radio"/></td> <td>urgency</td> </tr> </table> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>➤ they have no contraindications to trimethoprim.</li> <li>➤ nitrofurantoin is not suitable.</li> <li>➤ informed consent has been given.</li> <li>➤ individuals assigned female at birth.</li> </ul> <p>For signs, symptoms and diagnosis of UTI see the UTI algorithm available here <a href="https://www.wmic.wales.nhs.uk/cas-uti-summary">https://www.wmic.wales.nhs.uk/cas-uti-summary</a> and the <a href="#">All Wales Common Ailments Service Formulary</a>.</p>	<b>Scenario 1</b>		<b>2 or 3 of the following symptoms</b>		<input type="radio"/>	dysuria	<input type="radio"/>	new nocturia	<input type="radio"/>	cloudy urine	<b>OR Scenario 2</b>		<b>Only 1 of the following symptoms AND a positive urine dipstick</b>		<input type="radio"/>	dysuria	<input type="radio"/>	new nocturia	<input type="radio"/>	cloudy urine	<b>OR Scenario 3</b>		<b>One or more of the following other urinary symptoms AND a positive urine dipstick</b>		<input type="radio"/>	visible haematuria	<input type="radio"/>	frequency	<input type="radio"/>	suprapubic tenderness	<input type="radio"/>	urgency
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### Exclusion criteria<sup>3</sup>

Trimethoprim 200 mg tablets should not be given to individuals:

- **who have one or more of the following – refer to Emergency Department (ED):**
  - difficulty breathing.
  - severe symptoms, getting worse quickly, signs of sepsis or systemically very unwell / severe pain.
  - confusion, drowsiness, slurred speech.
  - systemically unwell and at risk of immunosuppression.
  - skin changes, e.g. very cold, or a strange colour or rash develops.
  - presence of blood clots in urine along with struggling to pass urine.
  - not passing urine all day.
- individuals assigned male at birth.
- who are pregnant, or suspected of being pregnant or they have recently given birth, terminated a pregnancy or had a miscarriage in the last 6 weeks.
- with haematuria (visible or non-visible) without any other UTI symptoms, urinary retention or unexplained by menstruation.
- with haematuria (visible or non-visible) and they are taking an anticoagulant.
- with the presence of symptoms for more than 7 days.
- if they describe the presence of a pelvic or abdominal mass.
- known to be immunosuppressed (accompanied by other clinical symptoms of blood disorders), including for example:
  - a patient who is on chemotherapy, radiotherapy, has known or suspected leukaemia, asplenia, aplastic anaemia or HIV/AIDS, or is taking an immunosuppressive drug following a transplant.
  - a patient who is taking a disease-modifying anti-rheumatic drug (DMARD), e.g. sulfasalazine, methotrexate.
  - a patient who is taking a medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection including cytotoxic drugs, carbimazole, clozapine and sulfasalazine.
- any previous UTIs in the last 6 months or 2 or more UTIs in the last 12 months.
- who have recently travelled to a country with increased antimicrobial resistance (outside northern Europe and Australasia).
- with known previous resistance to trimethoprim.
- taking prophylactic antibiotics for recurrent UTI.

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<sup>3</sup> 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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## Exclusion criteria

(continued)

- if they have been in hospital for more than 7 days in the past 6 months.
- if they are resident in a long-term care facility.
- if they are currently using urinary catheter devices including indwelling or suprapubic urethral catheters, and intermittent self-catheterisation.
- if they have symptoms suggestive of upper UTI/pyelonephritis, e.g.
  - myalgia.
  - rigors or raised temperature (37.9°C or above).
  - nausea and vomiting.
- flank / loin pain (typically unilateral) with or without abdominal pain / tenderness.
- with suspected sexually transmitted infection.
- with vaginal or urethral discharge, irritation, itch or skin rash not associated with vulvovaginal candidiasis.
- with urinary symptoms thought to be caused by genitourinary syndrome of menopause:
  - dryness, burning or irritation of the vulva or vagina, vulvovaginal atrophy.
  - sexual symptoms, e.g. lack of lubrication, discomfort, pain, post coital bleeding, impaired sexual function.
- with known structural or neurological abnormalities of the urinary tract, or stent in tract.
- with known kidney stones or history of kidney stones.
- with known or suspected severe hepatic impairment.
- with known megaloblastic anaemia and other blood dyscrasias.
- with known renal impairment eGFR less than 30 mL/min.
- with known acute porphyria.
- with known diabetes mellitus (type 1 or 2), and in the opinion of the pharmacist:
  - there are concerns regarding their individual diabetic control.
  - the individual is at increased risk of detrimental symptoms associated with poorly controlled diabetes; symptoms can include thirst, blurred vision, fatigue, increased frequency of urination.
  - the individual is unsure how to manage their diabetes.
- with known folate deficiency.
- with known rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption.
- who are taking contraindicated medicines (see [drug interactions](#) section for further detail) including:
  - azathioprine.
  - mercaptopurine.

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**Cautions (including relevant actions to be taken)**

(continued)

- opioids.
- calcium channel blockers.

Supply antibiotics if applicable and safe but refer the individual to their GP for review of medication where necessary.

**Haematuria (visible and non-visible)**

**Visible haematuria** –consider treatment for UTI and inform individual if after completing their course of antibiotics:

- visible haematuria still persists, even if they feel better, to see their GP or seek medical attention as soon as possible.
- they are completely symptom free and feel better, to return in 6 weeks' time for a follow up assessment.

**Non-visible haematuria** – consider treatment for UTI and inform individual to return in 6 weeks' time for a follow up assessment.

**Colitis**

Caution should be used when treating patients with a history of antibiotic-associated colitis and other risk factors for *Clostridioides difficile* infection (CDI) (see [Risk factors | Background information | Diarrhoea - antibiotic associated | CKS | NICE](#)).

Sustained severe diarrhoea should prompt suspicion of pseudomembranous colitis. As this condition may be life threatening, trimethoprim should be withdrawn immediately.

Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening.

*Clostridioides difficile*-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhoea to fatal colitis.

**Diabetes**

Individuals with diabetes can be supplied with treatment and if, in the opinion of the pharmacist, there are no concerns or symptoms suggestive of poor control; for example, thirst, blurred vision, fatigue etc, treatment can be supplied. Individuals should be reminded of the diabetes sick day rules (see [patient or carer advice](#)).

**Oral hypoglycaemic agents/insulin** – The concomitant use of trimethoprim and oral hypoglycaemic agents (such as sulphonylureas) and/or insulin can result in significant hypoglycaemia.

**Careful monitoring of glucose is recommended.**

**Oral anticoagulants**

There is a risk of serious haemorrhage and significant elevations in International Normalized Ratio (INR) and prothrombin time when antibacterial agents are co-administered with warfarin. INR and prothrombin

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<p><b>Cautions (including relevant actions to be taken)</b> (continued)</p>	<p>times should be frequently monitored while patients are receiving trimethoprim and oral anticoagulants concurrently.</p> <p><b>Advise the individual to contact their clinic responsible for INR monitoring within 3 days of starting trimethoprim treatment.</b></p> <p>Caution should be exercised when trimethoprim is co-administered with direct acting oral anticoagulants such as dabigatran, rivaroxaban and apixaban, particularly to patients at high risk of bleeding.</p> <p><b>Breastfeeding</b></p> <p>Trimethoprim passes into breast milk in very small amounts and is unlikely to be harmful. It may cause some babies to have mild stomach upsets. They should contact their health visitor, midwife or general practitioner if:</p> <ul style="list-style-type: none"> <li>➤ their baby is not feeding as well as usual.</li> <li>➤ they are unsettled after feeding.</li> <li>➤ they develop diarrhoea and or vomiting.</li> <li>➤ they develop a rash.</li> <li>➤ they are unusually sleepy.</li> <li>➤ if they have oral thrush.</li> </ul>
<p><b>Action to be taken if the individual is excluded or declines treatment</b></p>	<ul style="list-style-type: none"> <li>➤ If patient meets the exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination.</li> <li>➤ Explain the reasons for exclusion to the individual and document in the consultation record.</li> <li>➤ If the individual declines advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent/carer or guardian) intended actions.</li> <li>➤ If appropriate, patients may be offered a suitable alternative antibiotic or provided with advice and symptomatic treatment from the <a href="#">All Wales Common Ailments Service Formulary</a>. Alternatively, refer the individual to their GP if appropriate.</li> </ul>
<p><b>Further advice</b></p>	<p>If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a Doctor or appropriate Independent Prescriber should be consulted.</p> <ul style="list-style-type: none"> <li>➤ Refer to the SmPC (<a href="#">MHRA products</a>), <a href="#">BNF</a> and the <a href="#">All Wales Common Ailments Service</a>.</li> </ul>

## 2. Description of Treatment

<b>Name, strength &amp; formulation of drug</b>	Trimethoprim 200 mg tablets.
<b>Legal category</b>	POM – Prescription Only Medicine.
<b>Black triangle▼</b>	No.
<b>Off-label use</b>	<p>No.</p> <p>Medicines should be stored according to the conditions detailed in the Storage section in this document. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by Pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with Pharmacy/Medicines Management.</p> <p>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.</p>
<b>Route / method of administration</b>	Oral.
<b>Dose and frequency of administration</b>	200 mg (ONE) tablet to be taken TWICE daily (every 12 hours) for THREE days.
<b>Duration of treatment</b>	<p>THREE days.</p> <p>This PGD only allows for the duration stated in the <a href="#">dosage schedule</a> above.</p>
<b>Quantity to be supplied</b>	<p>Appropriately labelled pack to provide treatment for THREE days:</p> <p><b>6 x 200 mg</b> tablets to provide THREE days treatment at a dose of 200 mg (ONE) tablet TWICE daily.</p>
<b>Storage</b>	Medicines must be stored securely and in accordance with product SmPC available at <a href="#">MHRA products</a> .
<b>Disposal</b>	No special requirements.
<b>Drug interactions</b>	<p>The following list of interactions is not exhaustive. A detailed list of drug interactions can be found in the SmPC (<a href="#">MHRA products</a>) and the <a href="#">BNF</a>.</p> <p><b>Contraindicated</b></p> <ul style="list-style-type: none"> <li>➤ typhoid vaccine (oral) – antibacterial agents may inactivate oral typhoid vaccine if ingested concomitantly; avoid where recent vaccination or vaccination due. The Green Book advises that the vaccine should not be commenced within three days of completing any antibacterial agent.</li> </ul>
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<p><b>Identification &amp; management of adverse reactions</b> (continued)</p>	<p>N.B. detailed lists of adverse reactions are available in the SmPC (<a href="#">MHRA products</a>), and the <a href="#">BNF</a>. 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><b>Patient or carer advice/follow up</b></p> <p>(continued over page)</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL) available at <a href="#">MHRA products</a>.</p> <p>Use <a href="#">TARGET antibiotic checklist</a> for counselling.</p> <p>Inform the individual or their carer:</p> <ul style="list-style-type: none"> <li>➤ the tablets should be swallowed whole with water.</li> <li>➤ to take plenty of rest.</li> <li>➤ they should drink enough fluids so they pass pale urine regularly during the day. Cranberry products or urine alkalinising agents are not currently recommended as there is no evidence for their use. Avoid alcoholic or caffeinated drinks which may irritate the bladder.</li> <li>➤ they should avoid having sexual intercourse until the UTI has cleared as this may aggravate symptoms.</li> <li>➤ taking simple analgesia such as ibuprofen or paracetamol at regular intervals will help with discomfort.</li> <li>➤ if on assessment they had:             <ul style="list-style-type: none"> <li>○ visible haematuria, they should seek medical attention if they still have blood in their urine after the 3-day course of antibiotics.</li> <li>○ visible or non-visible haematuria they should return in six weeks' time for follow up assessment which may or may not include a second urine dipstick.</li> <li>○ when considering management options, pharmacists should interpret information derived from urinalysis in conjunction with other clinically relevant information.</li> </ul> </li> <li>➤ symptoms should start to improve within 48 hours of taking trimethoprim – advise individual to seek medical advice if no improvement or symptoms worsen within this time.</li> <li>➤ if they are breastfeeding they can continue; trimethoprim can cause some babies to have mild stomach upsets. If their baby is not feeding as well as usual or they are unsettled after feeding, if they have diarrhoea and or vomiting, if they develop a rash or are unusually sleepy, if they have oral thrush, or any concerns, they should contact their health visitor, midwife or general practitioner. <a href="#">Trimethoprim: antibiotic to treat bacterial infections - NHS (www.nhs.uk)</a>.</li> <li>➤ that if they have diabetes, their blood sugars may be higher or lower than usual whilst they are unwell. They should follow their diabetes sick day rules; see <a href="#">Diabetes and being ill   Managing when you're sick   Diabetes UK</a>.</li> <li>➤ that 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</li> </ul>

<p><b>Patient or carer advice/follow up</b></p> <p>(continued)</p>	<p><a href="#">Yellow Card</a> reporting scheme. This includes any possible side effects not listed in the <a href="#">PIL</a>.</p> <ul style="list-style-type: none"> <li>➤ to seek medical attention immediately if they develop unexplained bruising or bleeding including nose bleeds, a sore throat, mouth ulcers, a high temperature or they feel tired or generally unwell. These can be signs of a problem with the blood.</li> <li>➤ that in the event of a severe adverse reaction to discontinue treatment immediately and to seek medical advice if their condition deteriorates and/or they become systemically unwell.</li> <li>➤ to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet.</li> <li>➤ to read the <a href="#">PIL</a> before taking the medication.</li> <li>➤ provide the <a href="#">TARGET Treating your infection – urinary tract infection (UTI) leaflet</a>.</li> <li>➤ to visit the <a href="#">NHS website</a> on trimethoprim for more information.</li> <li>➤ to visit the <a href="#">NHS 111 Wales</a> site for further information on kidney infection.</li> </ul> <p>Lifestyle measures such as:</p> <ul style="list-style-type: none"> <li>➤ avoid lots of sugary foods and or drinks.</li> <li>➤ avoid spermicides.</li> <li>➤ wash the genital area with warm water (including before and after sex) and avoid using scented or perfumed soap and shower gel.</li> <li>➤ avoid vaginal douching.</li> <li>➤ urinate as soon as possible after sex.</li> <li>➤ wear cotton or breathable underwear instead of tight, synthetic underwear such as nylon.</li> <li>➤ promptly change sanitary or incontinence pads if they're soiled.</li> </ul> <p>Some hygiene behaviours which may help prevent UTIs include:</p> <ul style="list-style-type: none"> <li>➤ do not hold urine in if you feel the urge to go; when you do go, ensure you empty your bladder fully.</li> <li>➤ wipe from front to back when you go to the toilet.</li> <li>➤ keep the genital area clean and dry.</li> </ul>
<p><b>Records</b></p>	<p>The consultation details including any medication supplied under the 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 onto the Choose Pharmacy Urinary Tract Infection module as soon as practically possible following the consultation.</p> <p>If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes.</p>

## PGD for the supply of trimethoprim 50 mg / 5 mL suspension

### 1. Clinical Condition

<b>Clinical condition or situation to which this PGD applies</b>	Treatment for acute, uncomplicated lower urinary tract infection (UTI), in accordance with the community pharmacy Urinary Tract Infection component of the Clinical Community Pharmacy Service.									
<b>Inclusion criteria</b>	<p>Trimethoprim 50 mg / 5 mL suspension can be given to:</p> <p>Non-pregnant females or transgender males who have not undergone sex reassignment surgery between 16 and 64 years old and with:</p> <table border="1" data-bbox="464 647 1465 1641"> <tr> <td data-bbox="464 647 1465 719"> <b>Scenario 1</b> </td> </tr> <tr> <td data-bbox="464 719 1465 790"> <b>2 or 3 of the following symptoms</b> </td> </tr> <tr> <td data-bbox="464 790 1465 954"> <ul style="list-style-type: none"> <li>○ dysuria</li> <li>○ new nocturia</li> <li>○ cloudy urine</li> </ul> </td> </tr> <tr> <td data-bbox="464 954 1465 1025"> <b>OR Scenario 2</b> </td> </tr> <tr> <td data-bbox="464 1025 1465 1097"> <b>Only 1 of the following symptoms AND a positive urine dipstick</b> </td> </tr> <tr> <td data-bbox="464 1097 1465 1261"> <ul style="list-style-type: none"> <li>○ dysuria</li> <li>○ new nocturia</li> <li>○ cloudy urine</li> </ul> </td> </tr> <tr> <td data-bbox="464 1261 1465 1332"> <b>OR Scenario 3</b> </td> </tr> <tr> <td data-bbox="464 1332 1465 1429"> <b>One or more of the following other urinary symptoms AND a positive urine dipstick</b> </td> </tr> <tr> <td data-bbox="464 1429 1465 1641"> <ul style="list-style-type: none"> <li>○ visible haematuria</li> <li>○ frequency</li> <li>○ suprapubic tenderness</li> <li>○ urgency</li> </ul> </td> </tr> </table> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>➤ they have no contraindications to trimethoprim.</li> <li>➤ nitrofurantoin is not suitable.</li> <li>➤ trimethoprim tablets are not suitable or unavailable.</li> <li>➤ informed consent has been given.</li> <li>➤ individuals assigned female at birth.</li> </ul> <p>For signs, symptoms and diagnosis of UTI see the UTI algorithm available here <a href="https://www.wmic.wales.nhs.uk/cas-uti-summary">https://www.wmic.wales.nhs.uk/cas-uti-summary</a> and the <a href="#">All Wales Common Ailments Service Formulary</a>.</p>	<b>Scenario 1</b>	<b>2 or 3 of the following symptoms</b>	<ul style="list-style-type: none"> <li>○ dysuria</li> <li>○ new nocturia</li> <li>○ cloudy urine</li> </ul>	<b>OR Scenario 2</b>	<b>Only 1 of the following symptoms AND a positive urine dipstick</b>	<ul style="list-style-type: none"> <li>○ dysuria</li> <li>○ new nocturia</li> <li>○ cloudy urine</li> </ul>	<b>OR Scenario 3</b>	<b>One or more of the following other urinary symptoms AND a positive urine dipstick</b>	<ul style="list-style-type: none"> <li>○ visible haematuria</li> <li>○ frequency</li> <li>○ suprapubic tenderness</li> <li>○ urgency</li> </ul>
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#### Exclusion criteria<sup>4</sup>

Trimethoprim 50 mg / 5 mL suspension should not be given to individuals:

- **who have one or more of the following – refer to the Emergency Department (ED):**
  - difficulty breathing.
  - severe symptoms, getting worse quickly, signs of sepsis or systemically very unwell / severe pain.
  - confusion, drowsiness, slurred speech.
  - systemically unwell and at risk of immunosuppression.
  - skin changes, e.g. very cold, or a strange colour or rash develops.
  - presence of blood clots in urine along with struggling to pass urine.
  - not passing urine all day.
- individuals assigned male at birth.
- who are pregnant, or suspected of being pregnant or they have recently given birth, terminated a pregnancy or had a miscarriage in the last 6 weeks.
- with haematuria (visible or non-visible) without any other UTI symptoms, urinary retention or unexplained by menstruation.
- with haematuria (visible or non-visible) and they are taking an anticoagulant.
- with the presence of symptoms for more than 7 days.
- if they describe the presence of a pelvic or abdominal mass.
- known to be immunosuppressed (accompanied by other clinical symptoms of blood disorders), including for example:
  - a patient who is on chemotherapy, radiotherapy, has known or suspected leukaemia, asplenia, aplastic anaemia or HIV/AIDS, or is taking an immunosuppressive drug following a transplant.
  - a patient who is taking a disease-modifying anti-rheumatic drug (DMARD), e.g. sulfasalazine, methotrexate.
  - a patient who is taking a medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection including cytotoxic drugs, carbimazole, clozapine and sulfasalazine.
- any previous UTIs in the last 6 months or 2 or more UTIs in the last 12 months.
- who have recently travelled to a country with increased antimicrobial resistance (outside northern Europe and Australasia).
- with known previous resistance to trimethoprim.

<sup>4</sup> 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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## Exclusion criteria

(continued)

- taking prophylactic antibiotics for recurrent UTI.
- if they have been in hospital for more than 7 days in the past 6 months.
- if they are resident in a long-term care facility.
- if they are currently using urinary catheter devices including indwelling or suprapubic urethral catheters, and intermittent self-catheterisation.
- if they have symptoms suggestive of upper UTI/ pyelonephritis, e.g.
  - myalgia.
  - rigors or raised temperature (37.9°C or above).
  - nausea and vomiting.
  - flank / loin pain (typically unilateral) with or without abdominal pain / tenderness.
- with suspected sexually transmitted infection.
- with vaginal or urethral discharge, irritation, itch or skin rash not associated with vulvovaginal candidiasis.
- with urinary symptoms thought to be caused by genitourinary syndrome of menopause:
  - dryness, burning or irritation of the vulva or vagina, vulvovaginal atrophy.
  - sexual symptoms, e.g. lack of lubrication, discomfort, pain, post coital bleeding, impaired sexual function.
- with known structural or neurological abnormalities of the urinary tract, or stent in tract.
- with known kidney stones or history of kidney stones.
- with known or suspected severe hepatic impairment.
- with known megaloblastic anaemia and other blood dyscrasias.
- with known renal impairment eGFR less than 30 mL/min.
- with known acute porphyria.
- with known diabetes mellitus (type 1 or 2), and in the opinion of the pharmacist:
  - there are concerns regarding their individual diabetic control.
  - the individual is at increased risk of detrimental symptoms associated with poorly controlled diabetes; symptoms can include thirst, blurred vision, fatigue, increased frequency of urination.
  - the individual is unsure how to manage their diabetes.
- with known folate deficiency.
- with known rare hereditary problems of fructose intolerance.
- who are taking contraindicated medicines (see [drug interactions](#) section for further detail) including:
  - azathioprine.

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<p><b>Exclusion criteria</b> (continued)</p>	<ul style="list-style-type: none"> <li>○ mercaptopurine.</li> <li>○ methotrexate.</li> <li>○ pyrimethamine.</li> <li>○ phenytoin.</li> <li>○ digoxin.</li> </ul> <ul style="list-style-type: none"> <li>➤ with a known hypersensitivity to trimethoprim – see <a href="#">SmPC</a>.</li> <li>➤ with known hypersensitivity to any of the excipients – see <a href="#">SmPC</a>.</li> <li>➤ if informed consent has not been given; where patients do not agree to share relevant clinical information or there is no valid consent.</li> <li>➤ who the pharmacist has assessed as not having capacity to understand the nature and purpose of treatment.</li> <li>➤ where a request has been made by a third party on behalf of a patient.</li> </ul>
<p><b>Cautions (including relevant actions to be taken)</b></p> <p>(continued over page)</p>	<p>Please refer to the <a href="#">SmPC</a> for trimethoprim for full details of special warnings and precautions for use.</p> <p><b>Medication and urinary tract symptoms</b></p> <ul style="list-style-type: none"> <li>➤ medications that can cause overactive bladder that can lead to urgency and frequency: <ul style="list-style-type: none"> <li>○ parasympathomimetic drugs.</li> <li>○ antidepressants.</li> <li>○ HRT.</li> <li>○ diuretics.</li> </ul> </li> <li>➤ medications that can decrease bladder contractility leading to retention and overflow incontinence: <ul style="list-style-type: none"> <li>○ antimuscarinic drugs.</li> <li>○ sympathomimetics.</li> <li>○ antidepressants.</li> <li>○ antihistamines.</li> <li>○ antipsychotics.</li> <li>○ ACE inhibitors.</li> <li>○ beta agonists.</li> <li>○ alpha blockers.</li> <li>○ anti-parkinsonian drugs.</li> <li>○ sedatives and hypnotics.</li> <li>○ diuretics.</li> <li>○ HRT.</li> <li>○ opioids.</li> <li>○ calcium channel blockers.</li> </ul> </li> </ul>



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**Cautions (including relevant actions to be taken)**

(continued)

Supply antibiotics if applicable and safe, but refer the individual to their GP for review of medication where necessary.

**Haematuria (visible and non-visible)**

**Visible haematuria** – consider treatment for UTI and inform individual if after completing their course of antibiotics:

- visible haematuria still persists, even if they feel better, to see their GP or seek medical attention as soon as possible.
- they are completely symptom free and feel better, to return in 6 weeks' time for a follow up assessment.

**Non-visible haematuria** – consider treatment for UTI and inform individual to return in 6 weeks' time for a follow up assessment.

**Colitis**

Caution should be used when treating patients with a history of antibiotic-associated colitis and other risk factors for *Clostridioides difficile* infection (CDI) (see [Risk factors | Background information | Diarrhoea - antibiotic associated | CKS | NICE](#)).

Sustained severe diarrhoea should prompt suspicion of pseudomembranous colitis. As this condition may be life threatening, amoxicillin should be withdrawn immediately.

Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening.

*Clostridioides difficile*-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhoea to fatal colitis.

**Diabetes**

Individuals with diabetes can be supplied with treatment and if, in the opinion of the pharmacist, there are no concerns or symptoms suggestive of poor control; for example, thirst, blurred vision, fatigue etc, treatment can be supplied. Individuals should be reminded of the diabetes sick day rules (see [patient or carer advice](#)).

**Oral hypoglycaemic agents/insulin** – The concomitant use of trimethoprim and oral hypoglycaemic agents (such as sulphonylureas) and/or insulin can result in significant hypoglycaemia.

**Careful monitoring of glucose is recommended.**

**Oral anticoagulants**

There is a risk of serious haemorrhage and significant elevations in International Normalized Ratio (INR) and prothrombin time when antibacterial agents are co-administered with warfarin. INR and prothrombin times should be frequently monitored while patients are receiving trimethoprim and oral anticoagulants concurrently.

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<p><b>Cautions (including relevant actions to be taken)</b> (continued)</p>	<p><b>Advise the individual to contact their clinic responsible for INR monitoring within 3 days of starting trimethoprim treatment.</b></p> <p>Caution should be exercised when trimethoprim is co-administered with direct acting oral anticoagulants such as dabigatran, rivaroxaban and apixaban, particularly to patients at high risk of bleeding.</p> <p><b>Breastfeeding</b></p> <p>Trimethoprim passes into breast milk in very small amounts and is unlikely to be harmful. It may cause some babies to have mild stomach upsets. They should contact their health visitor, midwife or general practitioner if:</p> <ul style="list-style-type: none"> <li>➤ their baby is not feeding as well as usual.</li> <li>➤ they are unsettled after feeding.</li> <li>➤ they develop diarrhoea and or vomiting.</li> <li>➤ they develop a rash.</li> <li>➤ they are unusually sleepy.</li> <li>➤ if they have oral thrush.</li> </ul>
<p><b>Action to be taken if the individual is excluded or declines treatment</b></p>	<ul style="list-style-type: none"> <li>➤ If patient meets the exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination.</li> <li>➤ Explain the reasons for exclusion to the individual and document in the consultation record.</li> <li>➤ If the individual declines advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent/carer or guardian) intended actions.</li> <li>➤ If appropriate, patients may be offered a suitable alternative antibiotic or provided with advice and symptomatic treatment from the <a href="#">All Wales Common Ailments Service Formulary</a>. Alternatively, refer the individual to their GP if appropriate.</li> </ul>
<p><b>Further advice</b></p>	<p>If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a Doctor or appropriate Independent Prescriber should be consulted.</p> <ul style="list-style-type: none"> <li>➤ Refer to <a href="#">SmPC</a>, <a href="#">BNF</a> and the <a href="#">All Wales Common Ailments Service</a>.</li> </ul>

## 2. Description of Treatment

<b>Name, strength &amp; formulation of drug</b>	Trimethoprim 50 mg / 5 mL suspension.
<b>Legal category</b>	POM – Prescription Only Medicine.
<b>Black triangle ▼</b>	No.
<b>Off-label use</b>	<p>No.</p> <p>The <a href="#">SmPC</a> for trimethoprim liquid states that it is contraindicated in breastfeeding if the breastfed infant is less than 4 months of age.</p> <p>Medicines should be stored according to the conditions detailed in the Storage section in this document. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by Pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with Pharmacy/Medicines Management.</p> <p>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.</p>
<b>Route / method of administration</b>	Oral.
<b>Dose and frequency of administration</b>	200 mg (FOUR 5 mL spoonfuls) to be taken TWICE daily (every 12 hours) for THREE days.
<b>Duration of treatment</b>	<p>THREE days.</p> <p>This PGD only allows for the duration stated in the <a href="#">dosage schedule</a> above</p>
<b>Quantity to be supplied</b>	<p>Appropriately labelled packs to provide treatment for THREE days:</p> <p>2 original packs trimethoprim 50 mg / 5 mL suspension to provide THREE days treatment at a dose of 200 mg (FOUR 5 mL spoonfuls) TWICE daily.</p>
<b>Storage</b>	Medicines must be stored securely and in accordance with product <a href="#">SmPC</a> .
<b>Disposal</b>	No special requirements.
<b>Drug interactions</b>	<p>The following list of interactions is not exhaustive. A detailed list of drug interactions can be found in the <a href="#">SmPC</a> and the <a href="#">BNF</a>.</p> <p><b>Contraindicated</b></p> <ul style="list-style-type: none"> <li>➤ typhoid vaccine (oral) – antibacterial agents may inactivate oral typhoid vaccine if ingested concomitantly; avoid where recent vaccination or</li> </ul>
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<p><b>Identification &amp; management of adverse reactions</b></p> <p>(continued)</p>	<p>N.B. detailed lists of adverse reactions are available in the <a href="#">SmPC</a>, and the <a href="#">BNF</a>. 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><b>Patient or carer advice/follow up</b></p> <p>(continued over page)</p>	<p>Supply the marketing authorisation holder's patient information leaflet (<a href="#">PIL</a>).</p> <p>Use <a href="#">TARGET antibiotic checklist</a> for counselling.</p> <p>Inform the individual or their carer:</p> <ul style="list-style-type: none"> <li>➤ the suspension should be shaken well before each use.</li> <li>➤ to take plenty of rest.</li> <li>➤ that they should drink enough fluids so they pass pale urine regularly during the day. Cranberry products or urine alkalinising agents are not currently recommended as there is no evidence for their use. Avoid alcoholic or caffeinated drinks which may irritate the bladder.</li> <li>➤ that they should avoid having sexual intercourse until the UTI has cleared as this may aggravate symptoms.</li> <li>➤ that taking simple analgesia such as ibuprofen or paracetamol at regular intervals will help with discomfort.</li> <li>➤ if on assessment they had:             <ul style="list-style-type: none"> <li>○ visible haematuria, they should seek medical attention if they still have blood in their urine after the 3-day course of antibiotics.</li> <li>○ visible or non-visible haematuria they should return in six weeks' time for follow up assessment which may or may not include a second urine dipstick.</li> <li>○ when considering management options, pharmacists should interpret information derived from urinalysis in conjunction with other clinically relevant information.</li> </ul> </li> <li>➤ symptoms should start to improve within 48 hours of taking trimethoprim – advise individual to seek medical advice if no improvement or symptoms worsen within this time.</li> <li>➤ if they are breastfeeding they can continue; trimethoprim can cause some babies to have mild stomach upsets. If their baby is not feeding as well as usual or they are unsettled after feeding, if they have diarrhoea and or vomiting, if they develop a rash or are unusually sleepy, if they have oral thrush, or any concerns, they should contact their health visitor, midwife or general practitioner. <a href="#">Trimethoprim: antibiotic to treat bacterial infections - NHS (www.nhs.uk)</a>.</li> <li>➤ that if they have diabetes, their blood sugars may be higher or lower than usual whilst they are unwell. They should follow their diabetes sick day rules; see <a href="#">Diabetes and being ill   Managing when you're sick   Diabetes UK</a>.</li> <li>➤ that 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 <a href="#">Yellow Card</a> reporting scheme. This includes any possible side effects not listed in the <a href="#">PIL</a>.</li> </ul>



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<p><b>Patient or carer advice/follow up</b> (continued)</p>	<ul style="list-style-type: none"> <li>➤ that in the event of a severe adverse reaction to discontinue treatment immediately and to seek medical advice if their condition deteriorates and/or they become systemically unwell.</li> <li>➤ to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet</li> <li>➤ to read the <a href="#">PIL</a> before taking the medication.</li> <li>➤ provide the <a href="#">TARGET Treating your infection – urinary tract infection (UTI) leaflet</a>.</li> <li>➤ to visit the <a href="#">NHS website</a> on trimethoprim for more information.</li> <li>➤ to visit the <a href="#">NHS 111 Wales</a> site for further information on kidney infection.</li> </ul> <p>Lifestyle measures such as:</p> <ul style="list-style-type: none"> <li>➤ avoid lots of sugary foods and or drinks.</li> <li>➤ avoid spermicides.</li> <li>➤ wash the genital area with warm water (including before and after sex) and avoid using scented or perfumed soap and shower gel.</li> <li>➤ avoid vaginal douching.</li> <li>➤ urinate as soon as possible after sex.</li> <li>➤ wear cotton or breathable underwear instead of tight, synthetic underwear such as nylon.</li> <li>➤ promptly change sanitary or incontinence pads if they're soiled.</li> </ul> <p>Some hygiene behaviours which may help prevent UTIs include:</p> <ul style="list-style-type: none"> <li>➤ do not hold urine in if you feel the urge to go; when you do go, ensure you empty your bladder fully.</li> <li>➤ wipe from front to back when you go to the toilet.</li> <li>➤ keep the genital area clean and dry.</li> </ul>
<p><b>Records</b></p>	<p>The consultation details including any medication supplied under the 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 onto the Choose Pharmacy Urinary Tract Infection module as soon as practically possible following the consultation.</p> <p>If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes.</p>



## Appendices

### Appendix A: Key references

- All Wales Medicines Strategy Group. All Wales Common Ailments Formulary. August 2023  
Available from: <https://awttc.nhs.wales> [accessed 22 December 2023].
- British National Formulary (BNF) – current edition. Available from: <https://bnf.org.uk> [accessed 22 December 2023].
- Clinical Knowledge Summaries. Urinary Tract Infection (lower) women. Revised June 2023  
Available from <https://cks.nice.org.uk> [accessed 22 December 2023].
- BMJ Publishing Group. BMJ Best Practice. Urinary tract infections in women. Last reviewed 03 Dec 2023. Updated 21 Feb 2023. Available from: <https://www.bestpractice.bmj.com> [accessed 22 December 2023]
- BMJ Publishing Group. BMJ Best practice. Assessment of non-visible haematuria. Last reviewed 03 Dec 2023. Updated 19 October 2023. Available from: <https://www.bestpractice.bmj.com> [accessed 22 December 2023]
- General Pharmaceutical Council. In Practice: Guidance on Confidentiality. Revised June 2018.  
Available from: <https://www.pharmacyregulation.org> [accessed 22 December 2023].
- General Pharmaceutical Council. In Practice: Guidance on Consent. Revised June 2018. Available from: <https://www.pharmacyregulation.org> [accessed 22 December 2023].
- 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: <https://www.nice.org.uk/guidance/mpg2/resources> [accessed 22 December 2023].
- Diabetes UK. Diabetes when you're unwell. Available from: <https://www.diabetes.org.uk/guide-to-diabetes/life-with-diabetes/illness> [accessed 10 November 2023].
- National Institute for Health and Care Excellence (NICE). Urinary tract infection (lower): antimicrobial prescribing [NG109]. Published 31 October 2018. Available from: <https://www.nice.org.uk/guidance/ng109> [accessed 22 December 2023]
- Public Health England. Urinary tract infection: diagnostic tools for primary care. Published 21 November 2007. Last updated 19 October 2020. Available from: <https://www.gov.uk/government/publications/urinary-tract-infection-diagnosis> [accessed 22 December 2023]
- Scottish Intercollegiate Guidelines Network (SIGN). Management of suspected bacterial lower urinary tract infection in adult women. SIGN 160 September 2020. Available from: <https://www.sign.ac.uk> [accessed 22 December 2023]
- NHS 111 Wales. Health A-Z. Urinary Tract Infection. Updated 27 September 2023. Available from: <https://111.wales.nhs.uk> [accessed 22 December 2023].
- NHS Medicines A-Z. Available from: <https://www.nhs.uk> [accessed 22 December 2023].
- NHS 111 Wales. Health A-Z. Peripheral neuropathy. Updated 28 March 2022. Available from: <https://111.wales.nhs.uk> [accessed 22 December 2023]
- Patient UK. Urinary Tract Infection in Adults. Updated 31 March 2023. Available from: <https://patient.info> [accessed 22 December 2023].

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- Summary Product Characteristics (SmPC). Available from: <https://www.medicines.org.uk/emc/> and <https://products.mhra.gov.uk> [accessed 22 December 2023]
- Drug Safety Update. Nitrofurantoin: reminder of the risks of pulmonary and hepatic adverse drug reactions. Published 26 April 2023. Available from: <https://www.gov.uk> [accessed 22 December 2023]
- Preston, CL (ed). Stockley's Drug Interactions. London: Pharmaceutical Press. Available from: <https://www.medicinescomplete.com> [accessed 22 December 2023]
- All Wales Medicines Strategy Group. All Wales Primary Care Antimicrobial Guidelines. Updated September 2023. Available from: <https://awttc.nhs.wales> [accessed 22 December 2023]
- Specialist Pharmacy Service. Trimethoprim. Lactation Safety Information. Reviewed 14 September 2021. Available from: <https://www.sps.nhs.uk> [accessed 22 December 2023]
- Yellow Card Reporting. Available from: <https://yellowcard.mhra.gov.uk/> [accessed 22 December 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:  
Nitrofurantoin or trimethoprim by community pharmacists under the Clinical Community  
Pharmacy Service: Urinary Tract Infection service 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](#).