


**Patient Group Direction For The Supply Of Trimethoprim Tablets By  
Community Pharmacists Under The 'Pharmacy First' Service**

<b>Co-ordinators:</b>  Adapted from National PGD. Developed by the Healthcare Improvement Scotland Area Drug and Therapeutics Committee Collaborative		<b>Approver:</b>  Medicine Guidelines and Policies Group
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		<b>Signature:</b> 
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<b>Identifier:</b>  NHSG/PGD/Trimethoprim/ MGPG1101	<b>Review Date:</b>  April 2022	<b>Date Approved:</b>  April 2020
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**Version 1**

**Executive Sign-Off**

**This document has been endorsed by the Director of Pharmacy and Medicines  
Management**

**Signature:** \_\_\_\_\_ 

## PGD Trimethoprim Tablets




### Authorisation

This specimen Patient Group Direction (PGD) has been produced by the Scottish Antimicrobial Prescribing Group and the Primary Care Community Pharmacy Group to assist NHS Boards provide uniform services under the 'NHS Pharmacy First' banner across NHS Scotland. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

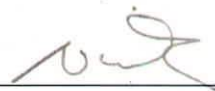

The qualified health professionals who may supply Trimethoprim tablets under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

### This PGD has been reviewed for NHS Grampian by

Doctor	Dr Graham Gauld	Signature	
Pharmacist	Sarah Buchan	Signature	
Staff Group Representative	Anne Marshall	Signature	

### Approved on behalf of NHS Grampian by

Medical Director	Professor Nick Fluck	Signature	
Director of Pharmacy/Senior Pharmacist	David Pflieger	Signature	
Date Approved	April 2020		
Effective from	April 2020	Review Date	April 2022

## Clinical Situation

Indication	Acute uncomplicated urinary tract infection (UTI) in non-pregnant females between 16 and 65 years of age (inclusive).
Inclusion Criteria	<p>Non-pregnant females, assigned as female at birth who have not had any reassignment procedures, aged between 16 and 65 years presenting with three or more of the following symptoms:</p> <ul style="list-style-type: none"> <li>• Dysuria</li> <li>• Frequency</li> <li>• Urgency</li> <li>• Suprapubic tenderness</li> </ul> <p>or <b>BOTH</b> dysuria and frequency are present. Support the diagnostic process with dipstick testing if available.</p>
Exclusion Criteria	<ul style="list-style-type: none"> <li>• Patients assigned as male at birth</li> <li>• Females under 16 years or over 65 years</li> <li>• Allergy or serious adverse effect from co-trimoxazole, trimethoprim or to any other components of the medication</li> <li>• Symptoms are suggestive of upper urinary tract infection (fever and chills, rigors, nausea, vomiting, diarrhoea, loin pain, flank tenderness, back pain of acute onset or systemically unwell).</li> <li>• Frank haematuria</li> <li>• Confused</li> <li>• Indwelling catheter</li> <li>• Known abnormality of the urinary tract</li> <li>• Pregnancy</li> <li>• Breastfeeding</li> <li>• Diabetes</li> <li>• Known renal impairment</li> <li>• Known haematological abnormalities, porphyria/folate deficiency</li> <li>• Known hyperkalaemia, severe hepatic insufficiency, megaloblastic anaemia, galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption</li> <li>• Immunosuppressed</li> <li>• Taking any medication which interacts with trimethoprim - refer to BNF for full list of interactions</li> <li>• Risk of treatment failure due to one or more of the following: <ul style="list-style-type: none"> <li>○ Received antibiotic treatment for UTI within 1 month;</li> <li>○ 2 or more UTI episodes in the last 6 months or 3 or more episodes in the last 12 months; taking antibiotic prophylaxis for recurrent UTI</li> </ul> </li> <li>• Decline to provide consent or non-capacity to consent</li> <li>• Symptoms of UTI lasting longer than 7 days</li> <li>• Presence of vaginal discharge or itch</li> </ul>

Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	Any doubt as to inclusion/exclusion criteria being met.
Action if Excluded	Refer to GP Practice/Out-of-hours service and document in Patient Medication Record (PMR) or Pharmacy Care Record (PCR).
Action if Patient Declines	<ul style="list-style-type: none"> <li>• Note that self-care may be considered as an option depending on symptom severity.</li> <li>• If patient declines treatment, advise on self-care to relieve symptoms and advise to see their GP if symptoms fail to resolve within 3 days or if symptoms worsen.</li> <li>• The reason for declining treatment and advice given must be documented.</li> <li>• Ensure patient is aware of risks and consequences of declining treatment.</li> <li>• Record outcome in Patient Medication Record (PMR) or Pharmacy Care Record (PCR) if appropriate.</li> </ul>

### Description of Treatment

Name of Medicine	Trimethoprim
Form/Strength	200mg (or 2 x 100mg) Tablets
Route of administration	Oral
Dosage	200mg
Frequency	Twice a day (12 hourly)
Duration of treatment	3 days
Maximum or minimum treatment period	1200mg
Quantity to supply/administer	6 x 200mg tablets or 12 x 100mg tablets
▼ additional monitoring	No
Legal Category	PoM (Prescription-only Medicine)

Is the use outwith the SPC	No
Storage requirements	As per manufacturer's instructions. Store below 25°C in a cool dry place. Ensure tablets are within expiry date.
Additional information	None
Warnings including possible adverse reactions and management of these	The most frequent adverse effects at usual dose are pruritis and skin rash (in about 3 to 7% of patients). These effects are generally mild and quickly reversible on withdrawal of the drug.  For a full list of side effects – refer to the marketing authorisation holder's Summary of Product Characteristics (SmPC). A copy of the SmPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>
Reporting procedure for adverse reactions	Pharmacists should document and report all adverse incidents through their own internal governance systems.  All adverse reactions (actual and suspected) will be reported to the appropriate medical practitioner and recorded patient's medical record. Pharmacists should record in their PMR and send an SBAR to the GP as appropriate.  Where appropriate, use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at <a href="http://yellowcard.mhra.gov.uk/">http://yellowcard.mhra.gov.uk/</a>
Advice to Patient/carer including written information	<ul style="list-style-type: none"> <li>• Advise patient about the importance of hydration in relieving symptoms.</li> <li>• Provide information on cystitis/UTI and signpost patient to the <a href="http://www.nhs.uk">NHS Inform</a> site where more information is available.</li> <li>• The patient information leaflet contained in the medicine should be made accessible to the patient. Where this is unsuitable, sufficient information should be given to the patient in a language that they can understand.</li> <li>• Inform patient of possible side effects and their management and who to contact should they become troublesome.</li> <li>• Explain the benefits and risks of taking antibiotics for this condition.</li> </ul>

	<ul style="list-style-type: none"> <li>• If on combined oral contraception, no additional contraceptive precautions are required unless vomiting or diarrhoea occur. (See reference section for Faculty of Reproductive and Sexual Healthcare Guidance).</li> <li>• Advise patient of self-management strategies including maintaining a good fluid intake, wearing loose fitting underwear/clothing, wearing cotton underwear and avoidance of vaginal deodorants.</li> <li>• Advise patient on ways to prevent re-infection, e.g. double voiding, voiding after sexual intercourse.</li> <li>• Paracetamol and ibuprofen may relieve dysuric pain and discomfort.</li> <li>• Ensure patient is aware that if symptoms worsen, they experience significant flank pain, become systemically unwell, or develop a fever, then they should seek medical advice that day.</li> <li>• Advise patient to seek further medical advice, if symptoms do not resolve after 3 days, if symptoms return or drug side effects are severe.</li> <li>• Advise patient to discontinue treatment if rash develops and seek medical advice.</li> <li>• Advise patient that their GP will be informed the next working day that antibiotics have been supplied.</li> <li>• Advise patient that if they require to seek further advice from the out-of-hours service they should make staff aware of their trimethoprim treatment.</li> </ul> <p>Information on medicines can be found at:  <a href="https://www.medicines.org.uk/emc/browse-medicines">https://www.medicines.org.uk/emc/browse-medicines</a> or  <a href="https://www.gov.uk/pil-spc">https://www.gov.uk/pil-spc</a></p>
Monitoring	Not applicable
Follow-up	Not applicable
Additional Facilities	<p>The following should be available where the medication is supplied:</p> <ul style="list-style-type: none"> <li>• An acceptable level of privacy to respect patient’s right to confidentiality and safety.</li> <li>• Access to medical support (this may be via the telephone).</li> <li>• Approved equipment for the disposal of used materials.</li> <li>• Clean and tidy work areas, including access to hand washing facilities.</li> <li>• Access to current BNF (online version preferred).</li> </ul>

## Characteristics of staff authorised under the PGD

Professional qualifications	<p>Registered pharmacist with current General Pharmaceutical Council (GPhC) registration.</p> <p><b>Under PGD legislation there can be no delegation. Supply of the medication has to be by the same practitioner who has assessed the patient under this PGD.</b></p>
Specialist competencies or qualifications	<p>Has successfully completed NES Pharmacy e-learning module on “Pharmacy First”.</p> <p>Able to assess the person’s capacity to understand the nature and purpose of the medication in order to give or refuse consent.</p> <p>Must be familiar with the trimethoprim Summary of Product Characteristics (SmPC).</p>
Continuing education and training	<p>Has read current guidance on the management of urinary tract infections, e.g. Health Protection Scotland, PHE, NICE or SIGN and <a href="#">SAPG</a>.</p> <p>Aware of local treatment recommendations.</p> <p>Attends approved training and training updates as appropriate.</p> <p>Undertakes CPD or NES Pharmacy module updates.</p>

## Audit Trail

Record/Audit Trail	<p>All records must be clear, legible and in an easily retrieval format.</p> <p>Pharmacists must record in Patient Medication Record (PMR) or Pharmacy Care Record (PCR).</p> <p>The following records should be kept (paper or computer based) and are included in the patient assessment form:</p> <ul style="list-style-type: none"> <li>• Patient’s name/parent/guardian/person with parental responsibility, address, date of birth and consent given</li> <li>• Patient’s CHI number</li> <li>• Contact details of GP (if registered)</li> <li>• Presenting complaint and diagnosis</li> <li>• Details of medicine supplied</li> <li>• The signature and printed name of the healthcare professional who supplied the medicine</li> </ul>
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	<ul style="list-style-type: none"> <li>• Advice given to patient (including side effects)</li> <li>• The patient group direction title and/or number</li> <li>• Whether the patient met the inclusion criteria and whether the exclusion criteria were assessed</li> <li>• Details of any adverse drug reaction and actions taken including documentation in the patient's medical record</li> <li>• Referral arrangements (including self-care).</li> </ul> <p><b>The patient's GP, where known, should be provided with a copy of the GP assessment form for the supply of trimethoprim on the same, or next available working day.</b></p> <p>These records should be retained in accordance with local/national guidance. For young people older than 16 years, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment. For 17 years and over, retain for 6 years after date of supply. Or for 3 years after death, where this is greater than above.</p> <p>All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each service. A designated person within each service will be responsible for auditing completion of drug forms and collation of data</p>
Additional references	<p>British National Formulary (BNF) current edition Trimethoprim SPC</p> <p>PHE/NICE. Managing common infections: guidance for primary care</p> <p>PHE Urinary tract infection: diagnostic tools for primary care</p> <p>RCGP TARGET Antibiotic toolkit</p> <p>HPS Scottish UTI Network Faculty of Sexual and Reproductive Health - <a href="#">Clinical Guidance: Drug Interactions with Hormonal Contraception</a> Jan 2019</p>



**Appendix 1 - Patient Group Direction For The Supply Of Trimethoprim Tablets By Community Pharmacists Under The 'Pharmacy First' Service**

**Individual Authorisation**

*PGD does not remove inherent professional obligations or accountability*

**It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals.**

**Note to Authorising Authority:** authorised staff should be provided with access to the clinical content of the PGD and a copy of the document showing their authorisation.

I have read and understood the Patient Group Direction authorised by each of the individual NHS Boards that I wish to operate in and agree to provide Trimethoprim Tablets

Name of Pharmacist \_\_\_\_\_

GPhC Registration Number \_\_\_\_\_

Normal Pharmacy Location

**(Only one Pharmacy name and contractor code is required for each Health Board (HB) area where appropriate. If you work in more than 3 HB areas please use additional forms.)**

Name & Contractor code HB (1) \_\_\_\_\_

Name & Contractor code HB (2) \_\_\_\_\_

Name & Contractor code HB (3) \_\_\_\_\_

Please indicate your position within the pharmacy by ticking one of the following:

Locum  Employee  Manager  Owner

Signature \_\_\_\_\_ Date \_\_\_\_\_

Please tick and send to each Health Board you work in. Fax numbers, email and postal addresses are given overleaf.

- |                     |                          |                    |                          |               |                          |
|---------------------|--------------------------|--------------------|--------------------------|---------------|--------------------------|
| Ayrshire & Arran    | <input type="checkbox"/> | Grampian           | <input type="checkbox"/> | Orkney        | <input type="checkbox"/> |
| Borders             | <input type="checkbox"/> | Gr Glasgow & Clyde | <input type="checkbox"/> | Shetland      | <input type="checkbox"/> |
| Dumfries & Galloway | <input type="checkbox"/> | Highland           | <input type="checkbox"/> | Tayside       | <input type="checkbox"/> |
| Fife                | <input type="checkbox"/> | Lanarkshire        | <input type="checkbox"/> | Western Isles | <input type="checkbox"/> |
| Forth Valley        | <input type="checkbox"/> | Lothian            | <input type="checkbox"/> |               |                          |

## Appendix 2 – Health Boards

NHS Board	Address	Fax Number
Ayrshire & Arran	Mr Allan Thomas, NHS Ayrshire & Arran, Eglinton House, Ailsa Hospital, Dalmellington Road, Ayr, KA6 6AB <a href="mailto:Angela.oumoussa@aapct.scot.nhs.uk">Angela.oumoussa@aapct.scot.nhs.uk</a>	Please e-mail or post
Borders	Adrian Mackenzie, Lead Pharmacist Pharmacy Department, Borders General Hospital, Melrose, TD6 9BS <a href="mailto:communitypharmacy.team@borders.scot.nhs.uk">communitypharmacy.team@borders.scot.nhs.uk</a>	Please e-mail or post
Dumfries & Galloway	NHS Dumfries & Galloway, Primary Care Development, Ground Floor North, Mountainhall Treatment Centre, Bankend Rd, Dumfries, DG1 4TG <a href="mailto:dumf-uhb.pcd@nhs.net">dumf-uhb.pcd@nhs.net</a>	Please e-mail or post
Fife	PGD Administrator, Pharmacy Services, NHS Fife, Pentland House, Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UW <a href="mailto:Fife-uhb.pgd@nhs.net">Fife-uhb.pgd@nhs.net</a>	Please e-mail or post
Forth Valley	Community Pharmacy Development Team, Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR <a href="mailto:FV-UHB.communitypharmacysupport@nhs.net">FV-UHB.communitypharmacysupport@nhs.net</a>	Please email or post
Grampian	Pharmaceutical Care Services Team NHS Grampian, Pharmacy & Medicines Directorate, Westholme, Woodend, Queens Road, Aberdeen, AB15 6LS <a href="mailto:nhsq.pharmaceuticalcareservices@nhs.net">nhsq.pharmaceuticalcareservices@nhs.net</a>	Please e-mail or post
Greater Glasgow & Clyde	Janine Glen, Contracts Manager, Community Pharmacy, NHS Greater Glasgow & Clyde, Clarkston Court, 56 Busby Road, Glasgow G76 7AT <a href="mailto:GG-UHB.cpdevteam@nhs.net">GG-UHB.cpdevteam@nhs.net</a>	0141 201 6044 Or email
Highland	Community Pharmaceutical Services, NHS Highland, Assynt House, Beechwood Park, Inverness. IV2 3BW <a href="mailto:high-uhb.cpsoffice@nhs.net">high-uhb.cpsoffice@nhs.net</a>	Please e-mail or post
Lanarkshire	Pharmacy/Prescribing Admin Team, NHS Lanarkshire Headquarters, Kirklands, Fallside Road, Bothwell, G71 8BB	01698 858271
Lothian	Bob Taylor, Primary Care Contractor Organisation, 2 <sup>ND</sup> Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG <a href="mailto:CommunityPharmacy.Contract@nhslothian.scot.nhs.uk">CommunityPharmacy.Contract@nhslothian.scot.nhs.uk</a>	Please e-mail or post
Orkney	Sylvia Robertson, Primary Care Pharmacist, NHS Orkney, Balfour Hospital, New Scapa Road, Kirkwall, Orkney KW15 1BH	01856 888 061
Shetland	Mary McFarlane, Principle Pharmacist, NHS Shetland, Gilbert Bain Hospital, Lerwick, Shetland, ZE1 0TB	01595 743356
Tayside	Diane Robertson Pharmacy Department, East Day Home, Kings Cross Hospital, Clepington Road, Dundee, DD3 8AE	No fax, please post
Western Isles	Stephan Smit, Primary Care Dept, The Health Centre, Springfield Road, Stornoway, Isle of Lewis, HS1 2PS	No fax, please post

### Appendix 3 - Patient Group Direction for antibiotic treatment of acute Urinary Tract Infection (UTI) in adult women (16-65 years): Patient assessment form

<b>Patient Name:</b>		<b>CHI:</b>	
<b>Date:</b>		<b>Age: (16-65 years inclusive only)</b>	
<b>Gender:</b>	M / F (exclude if male)	<b>Patient consents to GP being informed:</b>	YES/NO (exclude if no consent)

#### Patient symptoms and related appropriate actions

Symptom assessment	Yes	No	Actions
Frank haematuria (blood in urine)			If YES do not treat and refer. Other more serious causes require to be excluded.
Vaginal discharge or irritation			If this is present treatment must <b>not</b> be offered as presence of vaginal symptoms reduces the likelihood of UTI to about 20%.
Symptom of dysuria (pain or burning when passing urine)			Consider treatment if <b>three or more</b> of the following symptoms present: <ul style="list-style-type: none"> <li>• Dysuria</li> <li>• Frequency</li> <li>• Urgency</li> <li>• Suprapubic tenderness</li> </ul> Or if <b>BOTH</b> dysuria and frequency present. Support the diagnostic process with dipstick testing if available.
Symptom of frequency (needing to pass urine more often than usual)			
Symptom of suprapubic tenderness (pain/tenderness in lower abdomen)			
Symptom of urgency (little warning of the need to pass urine)			

#### Patient clinical picture and related appropriate actions

Clinical features	Yes	No	Actions
Do symptoms suggest upper UTI (these may include loin pain, fever $\geq$ 38°C, rigors or systemically very unwell)?			If YES do not treat and refer urgently (same day) due to risk of upper UTI or sepsis
Urinary catheter in situ or use of intermittent self-catheterisation?			If YES do not treat and refer

Clinical features	Yes	No	Actions
Does the patient have recurrent UTI? ( $\geq 2$ episodes in last 6 months or $\geq 3$ episodes in last year)			If YES do not treat and refer due to the need for culture
Has the patient had a UTI requiring an antibiotic within the last 28 days?			If YES do not treat and refer due to risk of resistant organisms
Duration of symptoms $\geq 7$ days?			If YES do not treat and refer
Is the patient immunocompromised? e.g. auto-immune disease, chemotherapy, immunosuppressant medication or HIV positive?			If YES do not treat and refer
Pregnant?			If YES do not treat and refer urgently (same day)
Breast feeding?			If YES do not treat and refer
Diabetes?			
Confused or dehydrated			
Known renal impairment or abnormality of the urinary tract or ureteric stent?			If YES do not treat and refer
Is the patient on warfarin?			If YES do not treat and refer
Known haematological abnormalities, porphyria, folate deficiency, glucose-6-phosphate deficiency?			
Known electrolyte imbalance?			
Known hepatic insufficiency?			
Patient has known blood disorders such as leucopenia, megaloblastic anaemia, thrombocytopenia, agranulocytosis, or methaemoglobinaemia?			If YES do not treat and refer

## Treatment option

Clinical features affecting choice to treat with trimethoprim	SUITABLE/AVOID
Clinically significant drug interactions with existing medication	AVOID if significant interaction exists with current medication
Known interstitial lung disease or poorly controlled respiratory disease	SUITABLE
Current use of alkalinising agents	SUITABLE
Allergy or adverse effect to trimethoprim	AVOID
Allergy or adverse effect to nitrofurantoin	SUITABLE

## Preparation and supply method

Medicine and strength	Regime	Supply method
Trimethoprim 200mg	One tablet twice daily x 6	PGD via UCF
Trimethoprim 100mg	Two tablets twice a day x 12	
Symptomatic management only	Appropriate analgesia	UCF or OTC or existing supply

## Patient advice checklist

Advice	Provided (tick as appropriate)
Ensure adequate fluid intake (2L per day but avoid very large amounts due to risk of inadequate bladder contact with antibiotic). Fluid intake should result in urine being a pale straw colour.	<input type="checkbox"/>
Prevention of UTI - Hygiene / toilet habits (do not 'hold on' – go to the toilet when you need to)	<input type="checkbox"/>
How to take medication	<input type="checkbox"/>
Expected duration of symptoms - to seek medical assistance if symptoms worsen or are not resolving within 3 days	<input type="checkbox"/>
Symptomatic (use of analgesia)	<input type="checkbox"/>

## Communication

Contact made with	Details (include time and method of communication)
Patients regular General Practice (details)	

## Details of supply and pharmacist supplying under the PGD

Batch number and expiry	
Print name of pharmacist	
Signature of pharmacist	
GPhC registration details	

## Appendix 4 - Notification Of Supply Of Trimethoprim To Treat Uncomplicated Urinary Tract Infection Via Community Pharmacy

Name of pharmacist	GPhC registration number	Date of supply

### Data protection confidentiality

This message is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.

GP name	
GP practice address	
The following patient has attended this pharmacy for assessment and treatment of an uncomplicated urinary tract infection.	
Patient name	
Patient address	
Date of birth	

Pharmacy stamp
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### Presenting symptoms:

Dysuria  Urgency   
 Frequency  Suprapubic tenderness

### Urine dipstick results (if taken, optional)

Nitrite '+ve'  Leucocyte '+ve'  Blood '+ve'  Not required

### Following assessment your patient has been given a 3 day course of trimethoprim 200mg

Your patient has been advised to contact the practice if symptoms fail to resolve following treatment. You may wish to include this information in your patient records

<b>Patient consent</b>	
I agree to the pharmacy sharing this information with my GP	
Patient signature:	Date: