

## Patient Group Direction for the Supply of Trimethoprim 200mg tablets

This Patient Group Direction (PGD) is a specific written instruction for the supply of trimethoprim 200mg tablets to groups of patients who may not be individually identified before presentation for treatment.

This will enable the appropriate registered healthcare professional to supply/administer treatment **in accordance with the following protocol, the recommendations of the Department of Health 1998, the codes and standards of conduct of their professional bodies and any guidelines issued by those bodies on the supply and administration of medicines.**

The majority of clinical care should be provided on an individual, patient specific basis. The supply of medicines under Patient Group Directions should be reserved for those limited situations where this offers an advantage for patients care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

<b>Definition of clinical situation/condition</b>	First line treatment of uncomplicated urinary tract infection (UTI) in females
<b>Name of organisation(s) within which the PGD will operate</b>	NHS Tayside Community Pharmacies contracted to supply the service 'Treatment of Uncomplicated UTI by Pharmacists working within NHS Tayside Community Pharmacies'.
<b>Name(s) of clinical areas and locations where the PGD will operate</b>	Qualifying Community Pharmacies within NHS Tayside boundaries.
<b>Criteria for inclusion</b>	Any female person aged between 16 and 65 years (inclusive) with at least 2 symptoms associated with an uncomplicated UTI i.e. dysuria, frequency, urgency, nocturia, suprapubic discomfort and/or offensive smelling urine.
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• Female less than 16 years or greater than 65 years of age</li> <li>• Known or suspected pregnancy</li> <li>• Presence of other genito-urinary symptoms including vaginal itch or discharge</li> <li>• Males</li> <li>• Diabetic patients</li> <li>• UTI associated with loin pain, pyrexia, malaise, rigors, or otherwise suggestive of upper UTI.</li> <li>• Symptoms of UTI lasting longer than 7 days</li> <li>• Previous hypersensitivity to</li> </ul>

NHS Tayside PGD – Trimethoprim 200 mg tablets,  
supply of - Community Pharmacy Supply

Date Effective: October 2017  
Review Date: October 2019

	<p>trimethoprim</p> <ul style="list-style-type: none"> <li>• Patients already taking a prescribed antibiotic</li> <li>• Patients with an indwelling catheter or who have had bladder instrumentation within the last 2 weeks</li> <li>• Patients who are immunocompromised</li> <li>• Patients with megaloblastic anaemia or other known blood disorders</li> <li>• Patients with recurrent UTI (<math>\geq 2</math>/month or <math>\geq 3</math>/year)</li> <li>• Recent (within last 28 days) UTI treated with an antibiotic</li> <li>• Known moderate to severe renal impairment or abnormality of the urinary tract or stent in urinary tract</li> <li>• The community pharmacist must check the patients most recent renal function as per protocol (Appendix 2)</li> </ul>
<b>Action if excluded</b>	<p>Women under the age of 16 or over the age of 65; and males should be referred to a GP.</p> <p>Women presenting who are pregnant or breast feeding, or where there is a risk of pregnancy should be referred to a GP.</p> <p>If symptoms are suggestive of complicated or upper UTI patients should be urgently referred to a GP.</p>
<b>Action if patient declines</b>	<p>Document advice given. Refer to own GP or out of hours services as appropriate.</p>
<b>Follow up of patient</b>	<p>None required.</p>

**CHARACTERISTICS OF STAFF AUTHORISED TO TAKE RESPONSIBILITY  
FOR THE SUPPLY OR ADMINISTRATION OF MEDICINES  
UNDER THIS PATIENT GROUP DIRECTION**

<b>Qualifications Required</b>	Member of GPhC
<b>Additional Requirements</b>	Undertake NHS Tayside accredited training specific to this PGD. Must have undergone training in the use of PGDs and the legal issues associated with prescribing medication under PGDs.
<b>Continuing Training Requirements</b>	The pharmacist must maintain their own level of competence and knowledge in this area to provide the service. They must also be familiar with the trimethoprim Summary of Product Characteristics.

<b>Profession</b>	Pharmacist
<b>Applicable professional codes and standards of conduct</b>	The current GPhC Standards of Conduct, Ethics and Performance - <a href="http://www.pharmacyregulation.org/standards/conduct-ethics-and-performance">http://www.pharmacyregulation.org/standards/conduct-ethics-and-performance</a>
<b>Applicable guidelines for supply and administration of medicines</b>	None, but guiding principles laid out in the above document

NHS Tayside PGD – Trimethoprim 200 mg tablets, supply of - Community Pharmacy Supply	Date Effective: October 2017 Review Date: October 2019
--	---

**DESCRIPTION OF TREATMENT AVAILABLE UNDER THIS  
PATIENT GROUP DIRECTION**

<b>Name of Medicine</b>	Trimethoprim
<b>POM/P/GSL</b>	POM
<b>Dose/s</b>	200mg TWICE DAILY for 3 days
<b>Route</b>	Oral
<b>Total dose number</b>	6
<b>Advice to be given to the patient</b>	<ul style="list-style-type: none"> <li>• Reinforce the need to take the medicine at regular intervals and to complete the course</li> <li>• Patient information leaflet provided with medication</li> <li>• Advise on ways to prevent re-infection - -e.g. double voiding, voiding after sexual intercourse, maintaining adequate fluid intake</li> <li>• Offer paracetamol for symptomatic relief if required</li> <li>• Advise patient to discontinue treatment if rash develops</li> <li>• Advise patient to seek further medical advice, if symptoms deteriorate, do not resolve after 3 days, if symptoms return or drug side effects are severe</li> </ul> <p>Advise patient that their GP will be informed the next working day that antibiotics have been supplied</p>
<b>Identification and management of possible adverse effects</b>	The most common side effects are gastrointestinal disturbances including nausea, vomiting and rash. Hyperkalaemia can also occur particularly in prolonged treatment, renal impairment and with co-prescription of ACE inhibitors, angiotensin II receptor antagonists or spironolactone.
<b>Referral for medical advice</b>	See 'action if excluded' information
<b>Facilities and supplies required</b> The designated hospital pharmacies <b>OR</b> community pharmacy are the sole procurement point for medicines	The medication will be supplied and dispensed by the community pharmacy.

NHS Tayside PGD – Trimethoprim 200 mg tablets, supply of - Community Pharmacy Supply	Date Effective: October 2017 Review Date: October 2019
--	---

<p><b>Treatment Records</b></p>	<p>In all cases an entry in the patient's record should include</p> <ul style="list-style-type: none"> <li>• Presenting complaint, relevant drug and medical history</li> <li>• Drug, dose and quantity supplied</li> <li>• Date issued and by whom</li> </ul>
<p><b>Patients on concurrent medication</b></p>	<p>Trimethoprim can increase the effect of warfarin and all patients on warfarin should have their INR checked within 3-5 days of starting trimethoprim.</p> <p>Patients taking ACE inhibitors, angiotensin II receptor antagonists or spironolactone are at increased risk of hyperkalemia with trimethoprim. Trimethoprim should not be used for longer than 3 days in these circumstances and nitrofurantoin is preferred if possible.</p>
<p><b>Patient Consent</b></p>	<p>Informed consent will be obtained from the patient prior to treatment. This will be recorded in the patient's records and in the treatment record form as either signed consent or verbal consent.</p>
<p><b>Audit Trail</b></p>	<p>The approved practitioner must ensure maintenance of records for each supply. The information relating to the supply of medication to each individual must include as a minimum</p> <ul style="list-style-type: none"> <li>• Patient's name and date of birth</li> <li>• Date given and by whom</li> <li>• Date and details of communication with patients GP</li> </ul> <p>All records must be clear and legible, and, ideally, in an easily retrievable format. This information should also be stored in the individual's medication records.</p>

<p><b>Adverse Reactions and adverse incidents</b></p>	<p>Pharmacists should document and report all adverse incidents through their own internal governance systems or the NHS Tayside Datix system if available. All adverse reactions (actual and suspected) will be reported to the appropriate medical practitioner and recorded in the appropriate place. Pharmacist should record in their PMR and send an SBAR to the GP as appropriate. Where appropriate a Yellow Card Report will be forwarded to the Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary. Online reporting is available at <a href="http://yellowcard.mhra.gov.uk/">http://yellowcard.mhra.gov.uk/</a></p>
---	--

<p>NHS Tayside PGD – Trimethoprim 200 mg tablets, supply of - Community Pharmacy Supply</p>	<p>Date Effective: October 2017 Review Date: October 2019</p>
---	---

**AUDIT OF PATIENT GROUP DIRECTION**

<p><b>Annual audit of documentation and recording of information</b></p> <ul style="list-style-type: none"> <li>- Who will carry this out and to whom will it be reported?</li> </ul>	<p>To be carried out locally within each pharmacy To be reported to Diane Robertson &amp; Hazel Steele</p>
<p><b>Periodic audit of clinical outcome(s)</b></p> <ul style="list-style-type: none"> <li>- Audit should be carried out at least annually; more often if required</li> <li>- What are the audit questions?</li> <li>- Who will carry out the audit(s)</li> <li>- To whom will the audit be reported?</li> </ul>	<p>Audit will be carried out annually by the pharmacy. Data to be collected will include</p> <ul style="list-style-type: none"> <li>• How many patients accessed this service?</li> <li>• How many patients had antibiotics supplied?</li> <li>• How many patients did not require antibiotics?</li> </ul>

<b>MANAGEMENT &amp; MONITORING OF PATIENT GROUP DIRECTION</b>
---

**Developed By:**

Medical Practitioner: Dr Andrew Russell                      Signature:

Pharmacist: Hazel Steele    Signature:

Antimicrobial Management Group: Dr Busi Mooka      Signature:

Approved By: Dr Andrew Russell

Lead Clinician

Name: Dr Andrew Russell    Signature:

Tayside Area Drug & Therapeutics Committee

Name: Professor Colin Fleming                                      Signature:

**Date Effective: October 2017**

**Review Date: October 2019**

Plans must be made to ensure completion of a review on or by the date above. The revised PGD will then follow on immediately. If the review date is reached and no review has taken place, then the PGD will be null and void. Interim review will be required as and when new safety information comes to light.
---



**Declaration**

This protocol is authorised for use with \_\_\_\_\_  
 (practice/hospital etc) by the individuals named below:

..... Doctor ..... Date

**I have read and understood this PGD and have received the specified local training to implement it effectively.**

Name ..... Designation .....

Signed ..... Date .....

Name ..... Designation .....

Signed ..... Date .....

Name ..... Designation.....

Signed ..... Date .....

Name ..... Designation .....

Signed ..... Date .....

A complete register of practitioners authorised to use this PGD will be held by Diane Robertson, NHS Tayside Community Pharmacy Development Pharmacist.

NHS Tayside PGD – Trimethoprim 200 mg tablets, supply of - Community Pharmacy Supply	Date Effective: October 2017 Review Date: October 2019
---	---

<b>REGISTER OF NAMED INDIVIDUALS WHO MAY SUPPLY CARE UNDER THIS PATIENT GROUP DIRECTION</b>
---

Date	Name	Qualifications

<b>PATIENT GROUP DIRECTION TREATMENT RECORD SHEET</b>
---

**PATIENT GROUP DIRECTION INDIVIDUAL PATIENT PROFORMA – see Appendix 1**

<b>PATIENT GROUP DIRECTION PATIENT INFORMATION SHEET</b>
--

**A patient information sheet has to be given to each patient treated under a Patient Group Direction. This will be supplied with the appropriate medication.**

**ACUTE UTI ANTIBIOTIC TREATMENT: CLIENT ASSESSMENT FORM APPENDIX 1**

Date:		Client Name:	
CHI:		Age: (include females aged 16-65 only)	
Gender:	M / F (exclude if male)	Patient consents to GP being informed:	YES/NO (exclude if no consent)

**PHARMACY STAMP & ADDRESS**

PATIENT INFORMATION	YES	NO	NOTES
Urinary catheter in situ or use of intermittent self catheterisation?			If YES do not treat and refer
Bladder instrumentation within previous 2 weeks?			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
Is the patient pregnant?			If YES do not treat and refer urgently (same day)
Does the patient have diabetes?			If YES do not treat and refer
Does the patient have recurrent UTI? (>2/month or >3/year)			If YES do not treat and refer due to the need for culture
Do symptoms suggest upper UTI (these may include loin pain, fever $\leq 38^{\circ}\text{C}$ , rigors or systemically very unwell)?			If YES do not treat and refer urgently (same day) due to risk of upper UTI or sepsis
Has the patient had a UTI within the last 28 days requiring an antibiotic?			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
Known moderate to severe renal impairment or abnormality of the urinary tract or ureteric stent			If YES do not treat and refer (if eGFR < 60ml/min, refer)
Is the patient on warfarin?			If YES advise INR check within 1 week of commencing treatment

SYMPTOM ASSESSMENT	YES	NO	NOTES
Symptoms severe (this is subjective but if symptoms are preventing activities of daily living they may be considered as severe)			If symptoms are severe treatment may be offered regardless of the number of symptoms.
Symptoms mild			If symptoms are mild but $\geq 3$ are present then treatment may be offered
Symptom of dysuria (pain or burning when passing urine)			If severe or 3 or more symptoms present consider treatment

NHS Tayside PGD – Trimethoprim 200 mg tablets, supply of - Community Pharmacy Supply	Date Effective: October 2017 Review Date: October 2019
--	---

Symptom of frequency (needing to pass urine more often than usual – pre-existing frequency alone does not merit treatment)			If severe or 3 or more symptoms present consider treatment
Symptom of suprapubic tenderness (pain/tenderness in lower abdomen)			If severe or 3 or more symptoms present consider treatment
Symptom of urgency (little warning of the need to pass urine)			If severe or 3 or more symptoms present consider treatment
Haematuria (blood in urine)			If YES do not treat and refer. The presence of haematuria requires infection to be confirmed by culture. 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%.

**WHICH OPTION? – Nitrofurantoin is the treatment of choice unless contra-indicated; consider trimethoprim as alternative unless contra-indication exists**

	NITROFURANTOIN	TRIMETHOPRIM
Previous hypersensitivity	AVOID if history of hypersensitivity to nitrofurantoin	AVOID if history of hypersensitivity to trimethoprim
Previous treatment failure within last 12 months	AVOID if history of treatment failure with nitrofurantoin	AVOID if history of treatment failure with trimethoprim
Clinically significant drug interactions with existing medication	AVOID if significant interaction exists with current medication	AVOID if significant interaction exists with current medication
Poorly controlled respiratory disease	AVOID due to difficulty in recognising pulmonary fibrosis secondary to nitrofurantoin	SUITABLE
Current use of alkalinising agents	AVOID	SUITABLE
Patient has porphyria (rare genetic disease where there is abnormal metabolism of haemoglobin) or glucose – 6- phosphate dehydrogenase deficiency	AVOID	SUITABLE
Patient is on concurrent ACE inhibitor, angiotensin II receptor antagonist or spironolactone	SUITABLE	AVOID
Patient has known blood disorders such as leucopenia, megaloblastic anaemia, thrombocytopenia, agranulocytosis, or methaemoglobinaemia	SUITABLE (but consider referral due to the nature of these conditions)	AVOID

NHS Tayside PGD – Trimethoprim 200 mg tablets, supply of - Community Pharmacy Supply	Date Effective: October 2017 Review Date: October 2019
--	---

**TREATMENT ISSUED**

Drug	Regime	Supply method	Supply details & reason for choice
Nitrofurantoin MR 100mg	One capsule twice daily x 6	PGD via CPUS	
Nitrofurantoin 50mg (use only if nitrofurantoin indicated but MR preparation not available)	One tablet four times a day x 12	PGD via CPUS	
Trimethoprim 200mg	One tablet twice daily x 6	PGD via CPUS	
Symptomatic management only	Appropriate analgesia	CPUS or OTC or existing supply	

**ADVICE CHECKLIST**

ADVICE	GIVEN
How to take medication	
Expected duration of symptoms - to seek medical assistance if symptoms worsen or are not resolving within 3 days	
Ensure adequate fluid intake (avoid very large amounts due to risk of inadequate bladder contact with antibiotic). Fluid intake should result in urine being a pale straw colour.	
Hygiene / toilet habits (do not 'hold on' – go to the toilet when you need to)	
Symptomatic management (use of analgesia)	

**COMMUNICATION**

CONTACT MADE WITH	DETAILS (INCLUDE TIME & METHOD OF COMMUNICATION)
Patients regular General Practice (details)	

ANTIBIOTIC SUPPLY

BATCH NUMBER

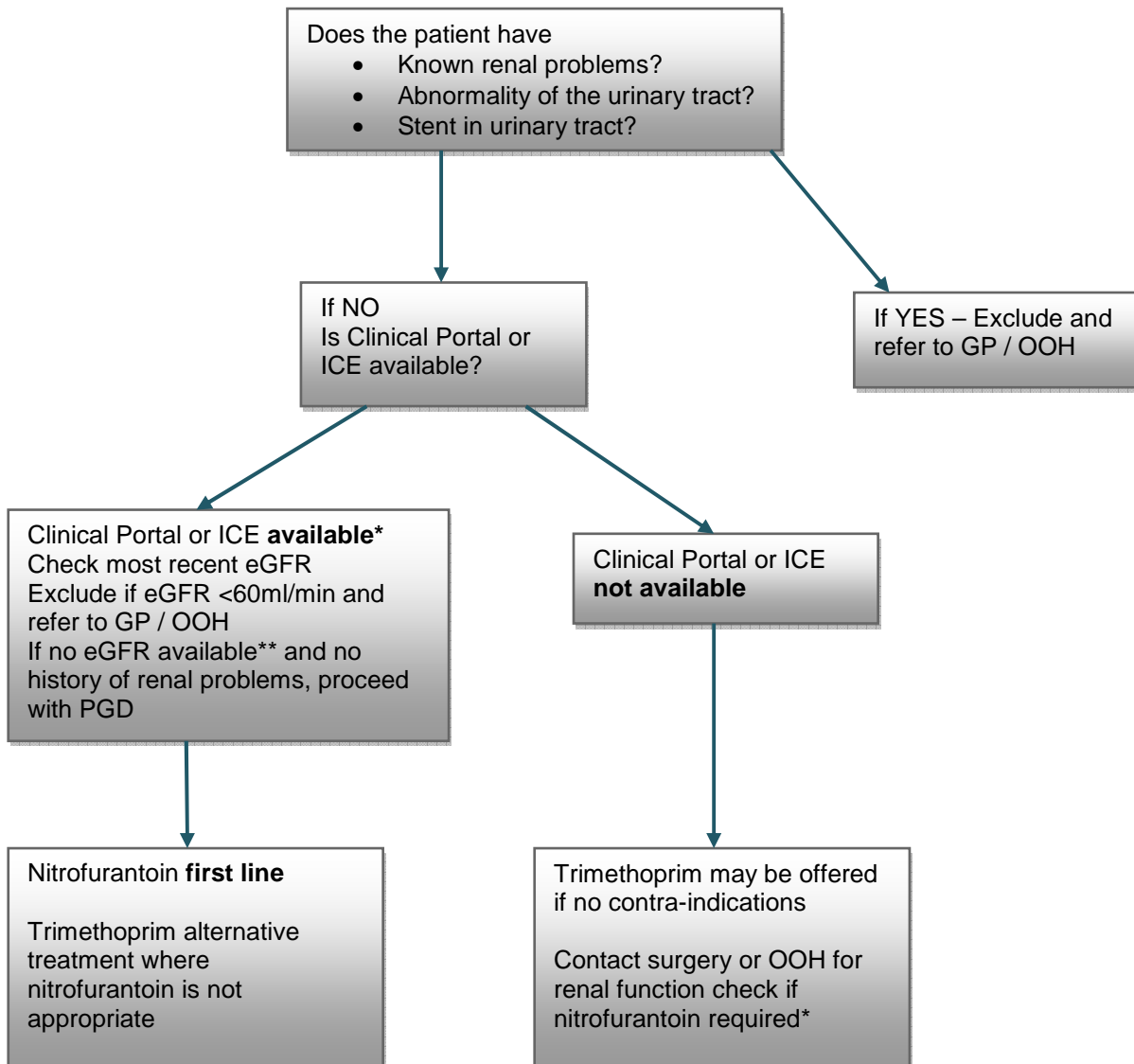
EXPIRY

SIGNATURE OF PHARMACIST

GPhC REGISTRATION

PRINT NAME

NHS Tayside PGD – Trimethoprim 200 mg tablets, supply of - Community Pharmacy Supply	Date Effective: October 2017 Review Date: October 2019
--	---



\*eGFR must be >60ml/min for inclusion in the service

\*\*If eGFR is not available on Clinical Portal or ICE because such a test appears never to have been performed, it can be assumed there has been no history or suspicion of renal problems and supply can be made if clinically appropriate.