

**Patient Group Direction**

For the supply of Trimethoprim **200mg Tablets**

by registered, trained and authorised community pharmacists and locum pharmacists

for the **treatment of uncomplicated urinary tract infections (UTI) in women**

on the Isle of Wight

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| This Patient Group Direction (PGD) must only be used by registered community pharmacists who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. |

**Version number: 4.0**

**Change history**

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| **Version number** | **Change details** | **Date** |
| 2.1 | Expiration of previous version – update and reformatting in new template | June 15 |
| 2.2 | Changes suggested by CEC and LPC | Aug 15 |
| 3.0 | Review  | Feb 2018 |
| 4.0 | Review | Jan 2020 |

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| PGD approval date/ Valid from: | 1.3.2018 |
| CCG implementation date: | 1.4.2018 |
| Review date: | 1.1.2020 / 2022 |
| Expiry Date: | 31.3.2020 / 2022 |

**Trimethoprim PGD Accountability Record 2020**

**PGD Review Group**

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| **Name**  | **Job title and organisation** | **Signature**  | **Date** |
| Lead author & pharmacist | Caroline Allen Deputy Head of Medicines Management  |  | 10.03.2020 |
| Clinical Pharmacist | Mel StevensAntimicrobial Pharmacist, IOW Trust |  |  |

**PGD Authorisation**

***This PGD has been approved and authorised for use by:***

**CCG Clinical Approval**

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| **Name** | **Authorising Professional** | **Signature** | **Date** |
| **Dr Adam Poole** | Clinical Commissioning Group (CCG) GP Prescribing Lead |  | 10.03.2020 |
| **Louise Spenser** | CCG Deputy Director of Nursing and Quality |  | 18.03.2020 |
| **Tracy Savage** | CCG Locality Director and Head of Medicines Optimisation and Primary Care  |  | 17.03.2020 |

**Provider Organisation**

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|  | **Name** | **Authorising Professional** | **Signature** | **Date** |
| **On behalf of Community Pharmacy** |  | **Manager of the healthcare professionals using the PGD** |  |  |
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| **Please note:****Individuals signing as the ‘manager of the healthcare professionals using the PGD’ have the responsibility to ensure ALL staff working to the PGD legally recognised to do so. Staff should be trained and competent, and their competency should be regularly updated** |

**Training and Competency**

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|  | **Requirements of registered pharmacist working under the PGD** |
| Qualifications and professional registration | Pharmacist currently registered with General Pharmaceutical Council (GPhC)<https://www.pharmacyregulation.org/registers/pharmacist> |
| Training  | **College of Pharmacy Postgraduate Education (CPPE) distance learning:*** CPPE distance learning pack ‘Common clinical conditions and minor ailment: distance learning’ (8hrs)

<https://www.cppe.ac.uk/programmes/l?t=RespMin-P-03&evid=45133> * CPPE learning assessment ‘Minor Ailments; a clinical approach (2020) <https://www.cppe.ac.uk/programmes/l/minor2-a-10>

**NICE Guidance:*** NICE CKS Urinary Tract Infection (lower) –women <https://cks.nice.org.uk/urinary-tract-infection-lower-women>
* Treatment for women with lower UTI who are not pregnant: <https://www.nice.org.uk/guidance/ng109/chapter/Recommendations#treatment-for-women-with-lower-uti-who-are-not-pregnant>
 |
| Competency  | **Completion of education in both the legal and professional aspects of PGD administration and the supply of medicines using:*** + GPhC Standards For Pharmacy Professionals
	+ Legal framework of PGD’s <https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017.pdf>
	+ Medicine, Ethics and Practice: Royal Pharmaceutical Society (RPS) <https://www.rpharms.com/publications/the-mep>

**CPPE Declaration of competence:*** <https://www.cppe.ac.uk/services/declaration-of-competence#navTop>

Minor ailments – this includes Consultation skills, Common Clinical Conditions and Minor Ailments**Self-Declaration that this training has been completed on PharmOutcomes**.The Pharmacist/technicians must complete electronic declaration (enrolment) via PharmOutcomes, by clicking on Trimethoprim PGD tab. |
| Ongoing training and competency | * The Pharmacist is responsible for keeping him/herself aware of any changes to the recommendations for the medicine listed.
* It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of their own individual scope of practice.
* The pharmacist is required to complete the required training and competency declaration every time a new contract is signed as this may change slightly in line with current evidence.
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**Clinical Condition - uncomplicated urinary tract infections in women**

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| **Clinical condition or situation to which this PGD applies** | Treatment of otherwise healthy women presenting with uncomplicated urinary tract infection.**First line:** Nitrofurantoin 100mg m/r BD for 3 days if GFR>45mL/min or no known underlying renal condition**Second line: Trimethoprim PGD only applies to women who are unable take nitrofurantoin and have a low risk of resistance** * + Living in the community - not residential care
	+ Not taken Trimethoprim in the preceding 3 months

**Trimethoprim 200mg bd for 3 days**  |
| **Inclusion criteria**Evidence shows if dysuria and increased frequency are present the likelihood of being a UTI is >90% 1,2 | **Eligibility criteria:*** Female
* Aged 16 years or over
* Aged 65 years or under
* Not pregnant or breastfeeding
* No catheter or complications
* Nitrofurantoin not appropriate
* Intolerant to nitrofurantoin in the past
* Low risk of resistance
	+ Living in the community not residential care
	+ Not taken Trimethoprim in the preceding 3 months

**Present in the pharmacy (or contactable by telephone) to provide information regarding symptoms associated with an uncomplicated urinary tract infection:*** Dysuria
* Increased urinary frequency and urgency of recent onset
* Suprapubic pain
* Nocturia of recent onset
* No signs of a complicated UTI:

haematuria or symptoms of pyelonephritis i.e. fever, flank pain, chills, nausea/ vomiting, rigors, loin or abdominal pains/ tenderness and headachePatients must consent to sharing their details and the consultation with their registered GP. The consent can be verbal and will be recorded on PharmOutcomes® as part of the consultation process. |
| **Exclusion criteria** Treat as complex patients and refer to 111/GP. | **Not meeting eligibility criteria:*** Male
* Aged 16 years or under
* Aged 65 years or over
* Pregnant or possible pregnancy or breast feeding
* Living in residential care facility
* Refused / not consent to treatment.

**Signs of a complicated UTI:*** Symptoms of pyelonephritis i.e. fever, flank pain, chills, nausea/ vomiting, rigors, loin or abdominal pains/ tenderness and headache
* Unresolving urinary symptoms
* Vaginal discharge or itch
* Haematuria (unless menstruating)
* Urological abnormalities or who have had surgery involving the lower urinary tract/ indwelling catheter
* Known renal impairment or acute kidney injury
* Indwelling catheter
* Urological abnormalities or surgery involving the lower urinary tract

**Increased risk of Trimethoprim antibiotic resistance:*** Current prophylactic use of trimethoprim
* Currently taking a prescribed antibiotic
* Recurrent UTI - a frequency of 2 or more UTIs in the last 6 months or 3 or more UTIs in the last 12 months.
* Previous known UTI resistant to antibiotics
* Hospitalisation for >7 days in the last 6 months
* Recent travel to a country with increased antibiotic resistance rates

**Sensitivity:*** Known hypersensitivity to trimethoprim, or to any ingredient of the trimethoprim product being supplied

**Medical risks:*** Blood dyscrasias/ Acute porphyria

**Drug Interactions:****Refer to BNF interactions for full list:**[**https://bnf.nice.org.uk/interaction/trimethoprim-2.html**](https://bnf.nice.org.uk/interaction/trimethoprim-2.html)* Patients who are currently taking any of the following are at risk of a sever interaction:
	+ Acenocoumarol
	+ Colistimethate
	+ Dapsone
	+ Methotrexate
	+ Pyrimethamine
	+ Warfarin

Treat as complex patients and refer to GP. |
| **Cautions for information**Treat as complex patients and refer to 111/GP. | If patient is taking any other medications, consult BNF [**https://bnf.nice.org.uk/interaction/trimethoprim-2.html**](https://bnf.nice.org.uk/interaction/trimethoprim-2.html)for any potential interactions with trimethoprim.* Patients with actual or potential folate deficiency
* Patients taking Warfarin or other anticoagulants requiring INR monitoring
* Although the change in INR may be small the patient should be warned of the possibility that the anticoagulant effect may be altered and the signs to watch for – see patient advice section –(Ref: Stockley’s Drug Interactions)
* Patients taking anticoagulants with haematuria should be investigated. Anticoagulants are more likely to provoke, rather than be the cause of haematuria.
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| **Arrangements for referral for medical advice** | Contact details of services available to be provided to patient, with hours of opening.Pharmacist to provide summary of assessment via PharmOutcomes.PharmOutcomes message to GP.Pharmacy First card for referral if required. |
| **Action to be taken if patient excluded**  | **For complex UTI refer patient to GP.****If suspect pyelonephritis call 111 for advice.****Immunocompromised patients or patients taking immunosuppressant medicines or Disease Modifying Antirheumatic Drugs) DMARDs** - seek urgent medical attention via 111 for full blood count. |
| **Action to be taken if patient declines treatment** | None necessary.  |

**Details of the medicine - Trimethoprim 200mg**

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| **Name, form and strength of medicine***Include ▼for* [*black triangle medicines*](http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/BlackTriangleproducts/index.htm) | Trimethoprim 200mg tablets |
| **BNF Chapter Category** | 5.2  |
| **Legal category** | POM |
| ***Indicate any*** [***off-label use***](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#off-label-use) ***(if relevant)***  | N/A |
| **Dose and frequency** | One 200mg tablet to be taken TWICE a day (every 12 hours) for three days |
| **Route/method of administration** | Oral |
| **Total Quantity to be supplied** | 6 tablets (3 days) |
| **Maximum treatment period** | 3 days |
| **Adverse effects** | ***For full list of Adverse Drug reactions (ADRs) see British National Formulary (BNF)/ Summary of Product Characteristics (SmPC)*****BNF** [**https://bnf.nice.org.uk/drug/trimethoprim.html**](https://bnf.nice.org.uk/drug/trimethoprim.html)**Common or very common**Diarrhoea; electrolyte imbalance; fungal overgrowth; headache; nausea; skin reactions; vomiting**Rare or very rare**Agranulocytosis; angioedema; anxiety; appetite decreased; arthralgia; behaviour abnormal; bone marrow disorders; confusion; constipation; cough; depression; dizziness; dyspnoea; eosinophilia; erythema nodosum; fever; haemolysis; haemolytic anaemia; haemorrhage; hallucination; hepatic disorders; hypoglycaemia; lethargy; leucopenia; meningitis aseptic; movement disorders; myalgia; neutropenia; oral disorders; pancreatitis; paraesthesia; peripheral neuritis; photosensitivity reaction; pseudomembranous enterocolitis; renal impairment; seizure; severe cutaneous adverse reactions (SCARs); sleep disorders; syncope; systemic lupus erythematosus (SLE); thrombocytopenia; tinnitus; tremor; uveitis; vasculitis; vertigo; wheezing**Frequency not known**Gastrointestinal disorder; megaloblastic anaemia; methaemoglobinaemia |
| **Records to be kept by PharmOutcomes for 2 years** | The following will be recorded on PharmOutcomes:* Patient name, age, gender
* Name of registered GP
* The diagnosis (UTI)

Treatment recommended (Trimethoprim tablets 200mg) **For complex UTI refer patient to GP.****If suspect pyelonephritis call 111 for advice.****Immunocompromised patients or patients taking immunosuppressant medicines or Disease Modifying Antirheumatic Drugs) DMARDs** - seek urgent medical attention via 111 for full blood count.* Quantity supplied (6)
* Batch number and expiry date
* Name of manufacturer
* Duration of treatment (3 days) and BD dose
* Date of supply
* Name of the pharmacist assessing the patient and making the supply

*Information must be sent to the GP by PharmOutcomes for entry into the patients records*Document any allergies and other adverse drug reactions clearly in the pharmacy patient records and inform GP and other relevant practitioners for further reporting and action if needed. |

***Procedure for reporting Adverse Drug Reactions (ADRs)***

*All ADRs/ significant events/ near misses occurring in relation to the administration of this medicine under the PGD must be reported to the CCG* *iwccg.mot@nhs.net* *.*

*The GP must be informed and, in a case requiring hospital admission or resulting in serious harm, the incident reported on a yellow card to the Committee on the Safety of Medicines (CSM) -* [*https://yellowcard.mhra.gov.uk*](https://yellowcard.mhra.gov.uk)

**Patient Information**

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| **Information to be given to patient**  | * Highlight the patient information leaflet included in the box
* Advise patient to take at regular intervals and to complete the 3 day course even if the original infection appears better
* Take tablets whole with a full glass of water and may be taken with food if it causes stomach upset
* Advise patient that if they experience any unacceptable side effects they should see their GP for further advice
* Advise patient that if a rash appears to stop the medicine and seek medical advice
* Antibiotics and oral contraceptives:

World Health Organisation (WHO) no longer advise that additional precautions are required when using combined hormonal contraceptives with antibiotics that are not enzyme inducers for a duration of less than 3 weeks. This is supported by the Faculty of Sexual and Reproductive Healthcare.5 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/Advice should be provided around the usual precautions if nausea and vomiting should arise from taking the antibiotics * Advise patient to see GP if symptoms do not resolve after completion of course, and to take an early morning urine sample with them to the appointment.
* Provide advice on ways to reduce recurrence of further episodes – Voiding after intercourse, maintaining adequate fluid intake.
* Give the patient any available literature available on cystitis management

**Self-care:*** Advise people with lower UTI about using paracetamol for pain, or if preferred and suitable ibuprofen.
* Advise people with lower UTI about drinking enough fluids to avoid dehydration.
* Be aware that no evidence was found on cranberry products or urine alkalinising agents to treat lower UTI.
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| **Follow-up advice to be given to patient**  | * Routine follow up is not necessary
* Advise to call 111 if complex patient/concerns
* Advise to see GP if symptoms don’t resolve
* e MC Trimethoprim PIL: <https://www.medicines.org.uk/emc/files/pil.4061.pdf>
* Refer to NHS Choices for more information: <https://www.nhs.uk/conditions/cystitis/>
* Give [TARGET UTI](http://www.rcgp.org.uk/clinical-and-research/toolkits/~/link.aspx?_id=9FCF9DA4B4A045519593320478DFD9E7&_z=z) leaflet: <https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/amr/target-antibiotics-toolkit/-/media/85AAD1D4DDEF455A85E0416C3BB714AE.ashx>
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**Appendix A - Key References**

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| 1. NICE CKS Urinary Tract Infection (lower) –women <https://cks.nice.org.uk/urinary-tract-infection-lower-women>
2. NICE Guidance: Urinary tract infection(lower):antimicrobial prescribing [NG109] Published date: October 2018 <https://www.nice.org.uk/guidance/ng109>
3. SCAN – South Central Antimicrobial Network Guidelines for Antibiotic Prescribing in the Community <http://www.nhsantibioticguidelines.org.uk/downloads/CS47131-NHSNHCCG-Antibiotic-Guidelines-2018-WHOLE-PRF5.pdf?fbclid=IwAR2M_ACCx2G17VvvYwwZkJiss6KhOjDLt4w0wTFIBWFRxOkg71OvK6rZw3M>
4. BNF On-Line: <https://bnf.nice.org.uk/drug/trimethoprim.html#indicationsAndDoses>
5. e MC SmPC Trimethoprim <https://www.medicines.org.uk/emc/product/4061>
6. e MC Patient Information Trimethoprim <https://www.medicines.org.uk/emc/files/pil.4061.pdf>
7. Faculty of Sexual and Reproductive Health Clinical Guidance. Clinical Effectiveness Unit Drug Interactions with Hormonal Contraception J- Updated 2017 Reviewed January 2019: <https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/>
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**Appendix B - PGD Sign-Off Sheet 2020-22**

This is the health professionals’ agreement to practise and is to be signed by individual pharmacists agreeing to practice under the PGD.

***I have read and understood the patient group direction, completed the prerequisite training and agree to supply and/or administer this medicine only in accordance with this PGD.***

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| **Name** | **GPhC Number** | **Date**  | **Signature** |
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*A copy of this Patient Group Direction (PGD) should be given to the pharmacists listed above, and the original retained by the Pharmacy providing the service for ten years.*

**Appendix C - Pharmacy Payment**

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|  | Drug Tariff (Jan 2020) | PharmOutcomes |
| Consultation and supply Consultation and supply for patient self-referrals |  (CAT M) (6 Tablets / 3 days) £0.39 | £14.00 (VAT exempt) |
| Consultation and supply if directed via 111 and CPCS (in addition to CPCS £14.00) |  (CAT M) (6 Tablets / 3 days) £0.39 | £10.00 (VAT exempt) |

**Appendix D - PharmOutcomes**

The system will factor invoices:

* Where ‘ Trimethoprim Supplied’ = the value of ‘*Product Supplied (DM&D)*’ x ‘*Quantity Supplied*’ *in pence* plus VAT at Standard rate (Product Reimbursement)
* £14.00/£10.00 per recorded service provision (VAT Exempt) (Consultation)
* ‘*FP10 charges collected*’ *= Yes* x *- the NHS Prescription Levy for the period appropriate to the provision* (Zero VAT) (Levy Charge)

The system will allow data to be claimed for at the time of issue. Payment by Commissioner will be quarterly.