The supply of **Trimethoprim 200mg Tablets** by registered community pharmacists for the **treatment of uncomplicated urinary tract infections (UTI)** in women on the Isle of Wight

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: 3**

<table>
<thead>
<tr>
<th>Version number</th>
<th>Change details</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Expiration of previous version – update and reformatting in new template</td>
<td>June 15</td>
</tr>
<tr>
<td>2.2</td>
<td>Changes suggested by CEC and LPC</td>
<td>Aug 15</td>
</tr>
<tr>
<td>3.0</td>
<td>Review</td>
<td>Feb 2018</td>
</tr>
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</table>

**PGD approval date/ Valid from:** 1.3.2018

**CCG implementation date:** 1.4.2018

**Review date:** 1.1.2020

**Expiry Date:** 31.3.2020
## Trimethoprim PGD Accountability Record

### PGD Review Group

<table>
<thead>
<tr>
<th>Name</th>
<th>Job title and organisation</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>
| Lead author           | Caroline Allen
Deputy Head of Medicines Management                          | Caroline Allen | 3-11-18 |
| Lead pharmacist        | David France
Medicines Management Pharmacist                                 | D. S. F.  | 1-3-18 |
| Community Pharmacy    | Richard Buxton
Professional Services Development Manager Community Pharmacy South Central |           |       |

### PGD Authorisation

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

#### Commissioning organisation – NHS IOW CCG Clinical Commissioning Committee Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Authorising Professional</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Oommen John</td>
<td>Clinical Commissioning Group (CCG) Clinical Governance lead</td>
<td></td>
<td>9/3/18</td>
</tr>
<tr>
<td>Melanie Rogers</td>
<td>CCG Director of Nursing and Quality</td>
<td></td>
<td>23/2/18</td>
</tr>
<tr>
<td>Tracy Savage</td>
<td>CCG Assistant Director of Medicines Optimisation / PGD Lead</td>
<td></td>
<td>27/2/18</td>
</tr>
</tbody>
</table>

#### Provider Organisation (adoption needed)

<table>
<thead>
<tr>
<th>Name</th>
<th>Authorising Professional</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>On behalf of Community Pharmacy company</td>
<td>Manager of healthcare professional</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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 of registered community pharmacists

<table>
<thead>
<tr>
<th>Requirements of registered pharmacist working under the PGD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Qualifications and professional registration</strong></td>
</tr>
</tbody>
</table>
| **Initial training & additional requirement** | • Completion of education in both the legal and professional aspects of PGD administration and the supply of medicines using:  
  o GPhC codes of Professional Conduct  
  o Legal framework of PGD’s  
  o Medicine, Ethics and Practice: Royal Pharmaceutical Society (RPS)  
  o Successful completion of self-assessment of competency form in the use of this medicine for the indications stated  
  • The Pharmacist must complete electronic declaration (enrolment) via PharmOutcomes, by clicking on Trimethoprim PGD tab. |
| **Competency assessment (CPPE Declaration of Competence)** | • College of Pharmacy Postgraduate Education (CPPE) distance learning pack ‘Responding to Minor Ailments’ [https://www.cppe.ac.uk/programmes/l/respmin-p-03](https://www.cppe.ac.uk/programmes/l/respmin-p-03)  
• CPPE learning assessment [https://www.cppe.ac.uk/programmes/l/minor2-a-08](https://www.cppe.ac.uk/programmes/l/minor2-a-08)  
• Guidelines for use of this PGD including NICE Clinical Knowledge Summary [https://cks.nice.org.uk/urinary-tract-infection-lower-women](https://cks.nice.org.uk/urinary-tract-infection-lower-women) |
| **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. |

*Retain a copy of each version of the Patient Group Direction for ten years. A copy of this PGD should be given to the CCG, the healthcare professional(s) listed above, their manager(s) and the original is to be retained by the Prescribing Advisor/Manager.*
### Clinical condition

<table>
<thead>
<tr>
<th>Clinical condition or situation to which this PGD applies</th>
<th>Treatment of otherwise healthy women presenting with uncomplicated urinary tract infection.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First line: Nitrofurantoin 100mg m/r bd for 3 days if GFR&gt;45mL/min or no known underlying renal condition</td>
</tr>
<tr>
<td></td>
<td>Second line: or if low risk of resistance - Trimethoprim 200mg bd for 3 days</td>
</tr>
</tbody>
</table>

**Risk factors for increased antibiotic resistance include:**
- care-home resident
- recurrent UTI
- hospitalisation for >7 days in the last 6 months
- unresolving urinary symptoms
- recent travel to a country with increased resistance
- previous UTI resistant to trimethoprim, cephalosporins, or quinolones.

### Inclusion criteria

| Women aged 16 years or over, presenting with symptoms associated with an uncomplicated urinary tract infection |
| Symptom included: |
| Dysuria |
| Increased urinary frequency and urgency of recent onset |
| Suprapubic pain |
| Nocturia of recent onset |

Evidence shows if dysuria and increased frequency are present the likelihood of being a UTI is >90% ¹,²

### Exclusion criteria

- Child aged under 16 years of age
- Men
- Pregnant women, or possible pregnancy
- Breast feeding mothers
- Known hypersensitivity to trimethoprim
- Known hypersensitivity to any ingredient of the trimethoprim product being supplied
- Women presenting with symptoms of pyelonephritis i.e. fever, flank pain, chills, nausea/ vomiting, rigors, loin or abdominal pains/ tenderness and headache
- Women who refuse treatment or do not consent to treatment.
- Known renal impairment or acute kidney injury
- Blood dyscrasias
- Acute porphyria
- Women with vaginal discharge
- Current prophylactic use of trimethoprim
- Women with indwelling catheter
- Haematuria (unless menstruating)
- Any patient who has been treated with trimethoprim for UTI on 2 or more occasions in the last 3 months or more than 5 during the previous 12 months.
<table>
<thead>
<tr>
<th>Patients currently taking a prescribed course of antibiotics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pts with history of recurrent UTI's</td>
</tr>
<tr>
<td>Pts who have received trimethoprim treatment in the last 2 week for a UTI</td>
</tr>
<tr>
<td>Women with urological abnormalities or who have had surgery involving the lower urinary tract</td>
</tr>
<tr>
<td>Patients who are currently taking any of the following:</td>
</tr>
<tr>
<td>- Antiepileptics – Phenytoin</td>
</tr>
<tr>
<td>- Antimalarials – pyrimethamine</td>
</tr>
<tr>
<td>- Azathioprine</td>
</tr>
<tr>
<td>- Ciclosporin</td>
</tr>
<tr>
<td>- Cytotoxics - mercaptopurine or methotrexate</td>
</tr>
</tbody>
</table>

**Cautions (including any relevant action to be taken)**

- If patient is taking any other medications, consult BNF Appendix 1: Interactions 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”.

**Arrangements for referral for medical advice**

Contact details of services available to be provided to patient, with hours of opening. Pharmacist to provide written summary of assessment for patient to via Pharm Outcomes electronic transfer to GP, including reason for referral.

**Action to be taken if patient excluded**

Refer patient to GP, GU clinic or out of hours centre as appropriate:

For patients already taking a prescribed antibiotic or who has recently completed a course of antibiotics for a UTI – refer back to own GP

Immunocompromised patients or patients taking immunosuppressants or DMARD’s - seek urgent medical attentions for full blood count

**Action to be taken if patient declines treatment**

None Necessary.
Details of the medicine/ Description of treatment

<table>
<thead>
<tr>
<th>Name, form and strength of medicine</th>
<th>Trimethoprim 200mg tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BNF Chapter Category</strong></td>
<td>5.2</td>
</tr>
<tr>
<td><strong>Legal category</strong></td>
<td>POM</td>
</tr>
<tr>
<td><strong>Indicate any off-label use (if relevant)</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Dose and frequency</strong></td>
<td>One 200mg tablet to be taken every 12 hours for three days</td>
</tr>
<tr>
<td><strong>Route/method of administration</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Total Quantity to be supplied</strong></td>
<td>6 tablets (3 days)</td>
</tr>
<tr>
<td><strong>Maximum treatment period</strong></td>
<td>3 days</td>
</tr>
</tbody>
</table>

**Adverse effects**

For full list of Adverse Drug reactions (ADR’s) see British National Formulary (BNF)/ Summary of Product Characteristics (SmPC)

**Common:**
Gastrointestinal disturbances including nausea and vomiting, pruitus and rashes, hyperkalaemia and depression of haematopoiesis (usually associated with long term use)

**Rarer:**
Photosensitivity, erythema multiforme, toxic epidermal necrosis and allergic reactions including angioedema and anaphylaxis

**Records to be kept**
The following will be recorded on Pharm Outcomes in the patient records:
- The diagnosis (UTI)
- Treatment recommended (Trimethoprim tablets 200mg)
- Quantity supplied (6)
- Batch number and expiry date
- Name of manufacturer
- Duration of treatment (3 days)
- Date of supply
- Name of the pharmacist assessing the patient and making the supply

Copies of records and consent forms must be kept for 2 years
Information must be sent to the GP for entry into the patient's records

Document any allergies and other adverse drug reactions clearly in the patient records and inform GP and other relevant practitioners/carers 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 in the clinical record and the CCG incident reporting system. 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) - [http://www.bnf.org/bnf/bnf/current/yellow.htm](http://www.bnf.org/bnf/bnf/current/yellow.htm).
### Written/verbal information to be given to patient or carer

- Highlight the patient information leaflet included in the box
- Advise patient to take at regular intervals
- Advise the patient to complete the 3 day course even if the original infection appears better
- Tablets should be swallowed whole with a full glass of water
- Trimethoprim may be taken with food if it causes stomach upset
- Encourage patient to maintain a good fluid intake
- 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.
  - 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
- PGD03 leaflet should be given to the patient

### Follow-up advice to be given to patient or carer

- Routine follow up is not necessary
- Advise to see GP if symptoms don’t resolve
- Give TARGET UTI leaflet: [http://www.rcgp.org.uk/TARGETantibiotics](http://www.rcgp.org.uk/TARGETantibiotics)
Appendix 1

Key references


2. NICE Clinical Knowledge Summary [https://cks.nice.org.uk/urinary-tract-infection-lower-women](https://cks.nice.org.uk/urinary-tract-infection-lower-women)

3. Southampton, Hampshire, Isle of Wight and Portsmouth along with Surrey Heath and Berkshire East Guidelines for Antibiotic Prescribing in the Community – updated 2017


5. emc SmPC Trimethoprim [https://www.medicines.org.uk/emc/product/4061](https://www.medicines.org.uk/emc/product/4061)


Appendix 2

Pharmacist Payment

<table>
<thead>
<tr>
<th>Pharmacist Clinical Consultation</th>
<th>Drug Tariff (Jan 2018)</th>
<th>PharmOutcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>£0.35 (6 Tablets / 3 days)</td>
<td>£15.00 (VAT exempt)</td>
</tr>
</tbody>
</table>

Appendix 3

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)
- £15.00 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.