Supply of Trimethoprim 200mg tablets
By Community Pharmacists for the
Management of Uncomplicated Urinary Tract Infections in Female Patients Protocol number 473 Version 1

Date protocol prepared: November 2015

Date protocol due for review: November 2017

This patient group direction must be signed by all health care professionals involved in its use. The NHS organisation should hold the original signed copy. The PGD must be easily accessible in the clinical setting.

<table>
<thead>
<tr>
<th>Organisation</th>
<th>NHS Forth Valley</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director of Nursing</td>
<td>Angela Wallace</td>
<td>Signed by Angela Wallace</td>
<td>18/12/15</td>
</tr>
<tr>
<td>Medical Director</td>
<td>Tracey Gillies</td>
<td>Signed by Tracey Gillies</td>
<td>17/12/15</td>
</tr>
<tr>
<td>Director of Pharmacy</td>
<td>Gail Caldwell</td>
<td>Signed by Gail Caldwell</td>
<td>18/12/15</td>
</tr>
</tbody>
</table>

This document authorises the supply of **trimethoprim** by appropriate practitioners to patients who meet the criteria for inclusion under the terms of the document.

Practitioners seeking to trimethoprim must ensure that they assess all clients to make sure they meet the criteria before supplying the product.

The purpose of this Patient Group Direction is to help patients by ensuring that they have ready access to a quality assured service which provides a timely, consistent and appropriate supply of trimethoprim for the treatment of uncomplicated UTI in female patients.
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Signatures of those developing the Patient Group Direction

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Name</th>
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<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>Leslie Cruickshank</td>
<td>Signed by Leslie Cruickshank</td>
<td>17/12/15</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>Kirstin McIntosh</td>
<td>Signed by Kirstin McIntosh</td>
<td>15/12/15</td>
</tr>
<tr>
<td>Nurse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microbiologist (if appropriate)</td>
<td>Sara Jamdar</td>
<td>Signed by Sara Jamdar</td>
<td>16/12/15</td>
</tr>
<tr>
<td>Paediatrician (if appropriate)</td>
<td></td>
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</table>

Approval from Patient Group Directions Group

<table>
<thead>
<tr>
<th>Chair</th>
<th>Signed on behalf of group</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Group Directions Group</td>
<td>Signed by Gail Caldwell</td>
<td>18/12/15</td>
</tr>
</tbody>
</table>

Signature of one GP on behalf of Practice OR Head of Service OR Employer to indicate that other professionals may undertake the work within the confines of the Patient Group Direction

<table>
<thead>
<tr>
<th>Name</th>
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</table>
The following Patient Group Direction for Supply of Trimethoprim 200mg tablets by Community Pharmacists for the Management of Uncomplicated Urinary Tract Infections in Female Patients may be used from the following business/practice:

Name:

Address:

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

**CLINICAL CONDITION**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Treatment of Urinary Tract Infection (UTI) in females aged between 16 years and 65 years.</th>
</tr>
</thead>
</table>
| **Inclusion Criteria** | 1. Severe symptoms or ≥ 3 symptoms below  
  - Dysuria  
  - Frequency  
  - Blood in urine  
  - Suprapubic tenderness  
  - Urgency  
  - Polyuria  
  AND absence of vaginal discharge / irritation – vaginal discharge reduces the likelihood of bacterial urinary infection |
| **Exclusion Criteria** | - Informed consent not obtained  
- Males  
- Age <16yrs and >65 years  
- Patient on prophylactic antibiotics for recurrent UTIs.  
- Systemically unwell – e.g vomiting, dehydrated, confused, dizzy, loin pain, fever, chills, rigors.  
- Catheterised patients  
- Haematuria only  
- Pregnancy or breast feeding  
- Known renal impairment or dialysis  
- History of renal stones / renal colic  
- Hypersensitivity to trimethoprim  
- Recent (within 1 month) treatment with antibiotic for a UTI  
- Severe hepatic insufficiency  
- Blood dyscrasias  
- Folate deficiency  
- Porphyria  
- Immunosuppression – e.g. chemotherapy treatment, long term oral corticosteroids, other immunosuppressant therapies  
- Recent hospital in-patient stay (in the previous three months) |
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### Recurrent UTIs ≥ 3 per year
- Current uveitis or recurrent uveitis
- Vaginal discharge/irritation
- Concomitant use of
  - Procainamide
  - Amiodarone
  - Phenytoin
  - Ciclosporin
  - Azathioprine
  - Mercaptopurine
  - Methotrexate
  - Warfarin
  - Pyrimethamine

### Caution/ Need for further advice

### Action if Patient declines or is excluded
Refer patient to GP / OOH for review

### DRUG DETAILS

<table>
<thead>
<tr>
<th>Name, form &amp; strength of medicine</th>
<th>Trimethoprim 200mg tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal Status</td>
<td>POM</td>
</tr>
<tr>
<td>Route/ Method</td>
<td>Oral</td>
</tr>
<tr>
<td>Dosage</td>
<td>200mg</td>
</tr>
<tr>
<td>Frequency</td>
<td>Twice daily</td>
</tr>
<tr>
<td>Duration of treatment</td>
<td>3 days</td>
</tr>
<tr>
<td>Maximum or minimum treatment period</td>
<td>3 days – not be repeated within 1 month or more than 3 supplies per year –</td>
</tr>
<tr>
<td>Quantity to Supply/administer</td>
<td>6 x 200mg tablets</td>
</tr>
</tbody>
</table>

### Side Effects
The most frequent adverse effects at usual doses are pruritus and skin rash (in about 3 to 7% of patients) and mild, gastrointestinal disturbances including nausea, vomiting and glossitis. These effects are generally mild and quickly reversible on withdrawal of the drug.

Blood and lymphatic system disorders
- Leucopenia, megaloblastic anaemia, thrombocytopenia,
- agranulocytosis, hyperkalaemia (particularly in the elderly and in HIV patients), methaemoglobinemia. Trimethoprim therapy may affect haematopoiesis.

Cases of megaloblastic anaemia during prolonged therapy with trimethoprim in doses higher than those recommended rarely occur but are reversible with discontinuation of therapy and administration of folinic acid.
| Nervous system disorders                        |  |
| Aseptic meningitis.                             |  |
| Gastrointestinal disorders                     |  |
| Nausea, vomiting, glossitis, gastrointestinal disturbances, sore mouth. |

| Hepatobiliary disorders                        |  |
| Disturbances in liver enzyme values, cholestatic jaundice. |
| Renal and Urinary disorders                    |  |
| Raised serum creatinine and blood urea nitrogen levels. It is not known however, whether this represents inhibition of creatinine tubular secretion or genuine renal dysfunction. |

| Skin and subcutaneous tissue disorders         |  |
| Pruritus, skin rashes, exfoliative dermatitis, urticaria. More severe skin sensitivity or allergic reactions such as photosensitivity, angioedema, erythema multiforme, Stevens Johnson syndrome and epidermal necrolysis have been reported rarely. |

| Musculoskeletal system disorders               |  |
| Myalgia.                                      |  |

| General disorders and administration site conditions |  |
| Anaphylaxis, anaphylactoid reactions, drug fever, headache. |

For a full list of side effects – refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on [www.medicines.org.uk](http://www.medicines.org.uk).

All adverse reactions that are serious or result in harm should be reported to the MHRA through the Yellow Card Scheme.

**Advice to patient/carer**

Ensure patient is aware that if symptoms worsen, the patient experiences significant flank pain, becomes systemically unwell, or develops a fever, then they should seek medical advice that day.

If symptoms have not improved after three days treatment, then patients should be advised to seek further medical advice.

Simple analgesia such as paracetamol or ibuprofen is recommended to manage pain and discomfort.

Advise patient or self-management strategies for urinary tract infections including maintaining a good fluid intake, wearing loose fitting underwear/clothing, wearing cotton underwear and avoidance of vaginal deodorants.
Inform patient of possible side effects and their management and who to contact should they be troublesome.

Advise patient of the importance of taking the tablets regularly and completing the course.

The patient should be signposted appropriately if they have any concerns regarding Sexually Transmitted Infections.

The Drug Manufacturer Patient Information Leaflet should be given.

Patients should be informed who to contact should they experience an adverse drug reaction.

**Follow up**

Advise patient to seek medical advice should symptoms worsen or not improve

<table>
<thead>
<tr>
<th>STAFF CHARACTERISTICS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Qualifications</strong></td>
</tr>
</tbody>
</table>
| **Specialist competencies or Qualifications** | Has read current guidance on the management of urinary tract infections e.g SIGN, PHE  
Has undertaken NES case study on UTI [http://www.nes.scot.nhs.uk/media/347108/antimicrobial_case_study Urinary Tract Infection.doc](http://www.nes.scot.nhs.uk/media/347108/antimicrobial_case_study Urinary Tract Infection.doc)  
Has undertaken an antimicrobial / infection management CPD event in previous 12 months |
| **Continuing Training & Education** | Up to date knowledge in therapeutic area  
Undertakes an antimicrobial/infection management CPD event annually |

<table>
<thead>
<tr>
<th>REFERRAL ARRANGEMENTS &amp; AUDIT TRAIL</th>
</tr>
</thead>
</table>
| **Referral arrangements** | Ensure patient is aware that if symptoms worsen, the patient experiences significant flank pain, becomes systemically unwell, or develops a fever, then they should seek medical advice that day either from their GP or through OOH centre.  
If symptoms have not improved after three days treatment, then patients should be advised to seek further medical advice. |
| **Records/audit trail** | A record of supply should be made on PMR which includes Name, strength, form and pack size of medicine supplies  
Dose and route of administration  
Date of supply and name of person making supply |
The medicine must be labelling in accordance with requirements detailed in the current version of Medicines, Ethics and Practice.

The patient’s GP must be notified that a supply has taken place. The patient’s GP must be informed if the patient experiences an adverse drug reaction.

A computer or manual record of all individuals receiving a supply under this PGD should also be kept for audit purposes.

Any adverse events/incidents should be reported to the PGD group in addition to any existing pharmacy processes.

Records of supply should be kept for 8 years.

Reference sources and comments


PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

Supply of Trimethoprim 200mg tablets by Community Pharmacists for the management of uncomplicated urinary tract infections working in Forth Valley Pharmacies

Protocol number 473 version 1

Individual Authorisation

This 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 their own Code of Professional Conduct. It is also your responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

I have read and fully understand the Patient Group Direction for the supply of Trimethoprim 200mg tablets and agree to provide this medicine only in accordance with this PGD in NHS Forth Valley Community Pharmacies.

Name of Pharmacist

GPhC Number

Normal Pharmacy Location

Signature

Date

The above person has been authorised to use this protocol

Signature of Authorising Pharmacist on behalf of Employing Organisation

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

Note:
A copy of this agreement must be signed by each pharmacist who wishes to be authorised to use the PGD for Supply of Trimethoprim 200mg tablets by Community Pharmacists working in Forth Valley Pharmacies. Please return this form (page 8) to Pharmacy Services, Falkirk Community Hospital, Westburn Avenue, Falkirk. FK1 5QE and retain a copy in each pharmacy premises they wish to provide the medicine from. A copy of the PGD must also be available in the pharmacy for reference.

Each authorised pharmacy practitioner should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.