Patient Group Direction (PGD)
Supply of Nitrofurantoin for uncomplicated Urinary Tract Infections in females aged 16 years and over

Version Control
This document is only valid on the day it was printed
The current version of this document will be found within the PharmOutcomes module – Pharmacy First PGD Service 2018 UTI

Revision History
Date of this revision: 1st July 2018
Date of next revision: Before 31st March 2020 (or in response to new local/national guidelines)

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Change description</th>
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</thead>
<tbody>
<tr>
<td>5.0 / 2018</td>
<td>June 2018</td>
<td>Andrew Pickard</td>
<td>Review of date expired PGD (V4)</td>
</tr>
</tbody>
</table>

Authorisation
This document requires authorisation by the following individuals:

Management
PGD Author: Andrew Pickard, Pharmacy Advisor - NHS England North Midlands Staffordshire and Shropshire

Authorisation

<table>
<thead>
<tr>
<th>Name and Designation</th>
<th>Organisation</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
<td>Dr Ken Deacon – Medical Director</td>
<td>NHS England North Midlands</td>
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<td>30/07/2018</td>
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<tr>
<td>Rebecca Woods – Head of Primary Care</td>
<td>NHS England North Midlands</td>
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<td>30/07/2018</td>
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<tr>
<td>Andrew Pickard - Pharmacy Advisor</td>
<td>NHS England North Midlands</td>
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<td>30/07/2018</td>
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<tr>
<td>Staff Characteristics</td>
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<td>-----------------------------------------------------------</td>
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<tr>
<td>1. Professional qualifications to be held by staff</td>
<td>• Community pharmacists accredited by NHS England North Midlands to provide the Pharmacy First PGD Service</td>
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<td>undertaking PGD</td>
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<td>2. Competencies required to be held by staff undertaking</td>
<td>• Has a clear understanding of the legal requirements to operate a PGD.</td>
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<td>this PGD</td>
<td>• Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself.</td>
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<td>• Has a clear understanding of the drug to be administered including side effects and contraindications.</td>
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<td></td>
<td>• All clinicians operating within the PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills.</td>
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<td>3. Specialist qualifications, training, experience and</td>
<td>• The community pharmacist must be registered with the General Pharmaceutical Council.</td>
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<td>competence considered relevant to the clinical condition</td>
<td>• The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification – Pharmacy First PGD Service 2018</td>
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<td>treated under this PGD</td>
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<td>Clinical Details</td>
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<tr>
<td><strong>Indication</strong></td>
<td>Treatment of uncomplicated lower urinary tract infection in females aged 16 years and over.</td>
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</table>
| **Inclusion Criteria** | Treat otherwise healthy, non-pregnant women presenting with three or more (≥ 3) of the following symptoms;  
• Dysuria  
• Urinary frequency/urgency  
• Lower abdominal pain  
• Polyuria  
• Haematuria  
• Fever/chills  
Note: Vaginal discharge reduces the likelihood of the woman having a bacterial UTI.  
Use dipstick tests to guide treatment decisions in otherwise healthy, non-pregnant women presenting with two or less (≤ 2) symptoms of UTI. |
| **Exclusion Criteria** | • Male  
• Under 16 years of age  
• Patients aged 75 years and over  
• Back or loin pain and pyrexia – consider pyelonephritis and refer immediately  
• Elderly patients with confusion suggestive of UTI  
• Known hypersensitivity to nitrofurantoin  
• Acute porphyria  
• Recurrent UTI treated with antibiotics within previous 4 weeks  
• More than two episodes of UTI treated under this PGD within previous 12 months  
• Catheterised patients  
• Haematuria only  
• Blood dyscrasias (G6PD deficiency specifically)  
• Pregnancy and breast feeding  
• Moderate to severe renal impairment eGFR <45ml/min  
• Pulmonary disease  
• Peripheral neuropathy  
• History of kidney stones/renal colic  
• Concomitant use of medication that has a clinically significant interaction with nitrofurantoin.  
For a comprehensive list of interactions, please refer to SPC or BNF |
### Management of excluded clients
- If patient meets exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination.
- If pyelonephritis is suspected, urgent referral to seek medical advice is required.
- Record the reason for exclusion and any action taken on PharmOutcomes.

### Management of patients requiring referral
- If patient declines treatment or advice, ensure the following details are recorded on PharmOutcomes:
  - The advice given by the clinician
  - Details of any referral made
  - The intended actions of the patient (including parent or guardian).

### Drug Details

| Name, form & strength of medicine | Nitrofurantoin MR 100mg capsules  
  | Nitrofurantoin 50mg tablets  
  | Nitrofurantoin 25mg/5ml suspension |
|---|---|---|
| Legal classification | Prescription Only Medicine (POM) |
| Route/Method | Oral |
| Dosage/Frequency/Duration of Treatment | Nitrofurantoin MR 100mg capsules twice daily for 3 days with food  
  OR  
  Nitrofurantoin 50mg tablets four times a day for 3 days with food.  
  In exceptional circumstances if the patient is unable to swallow tablets/capsules, then Nitrofurantoin 25mg/5ml suspension can be supplied as an alternative.  
  Nitrofurantoin 25mg/5ml suspension – 50mg (10ml) to be taken four times a day for 3 days with food  
  Duration of treatment is 3 days for all formulations. |
| Quantity to supply/administer | 6 capsules (Nitrofurantoin MR 100mg capsules), or  
  12 tablets (Nitrofurantoin 50mg tablets), or  
  120ml suspension (Nitrofurantoin 25mg/5ml suspension) |
### Storage

Store in a dry place below 25°C

Suspension should be stored below 25°C and in the original container to protect from light

### Cautions

Patients with an underlying condition that may reduce renal function. This includes patients with the following conditions:
- Diabetes
- Hypertension
- Heart disease
- Known renal dysfunction

Concomitant use of medication that can adversely affect renal function, such as ACE inhibitors and diuretics.

For these groups of patients, the pharmacist should establish if the patient has had a recent renal function test, and that the eGFR level is above 45ml/min. If this information is not available, the patient should be excluded under this service and referred to their GP.


### Side Effects

Nitrofurantoin may cause dizziness and drowsiness. Patients should be advised not to drive or operate machinery if affected until such symptoms stop.

Discolouration of the urine to yellow or brown is common.

The following side effects have occasionally been reported. These are generally mild and reversible when nitrofurantoin is withdrawn.
- Nausea
- Vomiting
- Pruritus
- Skin rashes
- Abdominal pain and diarrhoea

Severe adverse reactions are rare, but there have been reports of the following effects:
- Acute pulmonary reactions
- Neurological effects including peripheral neuropathy
- Severe allergic skin reactions including erythema multiforme
- Haematological effects (generally reversible on cessation of treatment)

Please refer to SPC for uncommon and rare side effects
<table>
<thead>
<tr>
<th>Drug interactions</th>
<th>Use the Yellow Card System to report adverse drug reactions directly to the MHRA. <a href="http://yellowcard.mhra.gov.uk/">http://yellowcard.mhra.gov.uk/</a></th>
</tr>
</thead>
</table>

- Antacids for indigestion (e.g. magnesium trisilicate) decrease absorption of nitrofurantoin
- Oral typhoid vaccine can be inactivated by nitrofurantoin
- Probenecid and sulfinpyrazone decrease renal excretion
- Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine) can lead to increased absorption of nitrofurantoin.
- Carbonic anhydrase inhibitors (e.g. acetazolamide) can reduce the anti-bacterial activity of nitrofurantoin
- Medicines which make the urine less acidic (e.g. potassium citrate mixture) can reduce anti-bacterial activity.
- Quinolones can reduce anti-bacterial activity of nitrofurantoin

Please refer to current BNF [http://bnf.org/bnf](http://bnf.org/bnf) and SPC [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc) for full details

<table>
<thead>
<tr>
<th>Advice to patients</th>
<th>Provide the patient with the manufacturer’s Patient Information Leaflet and discuss as necessary.</th>
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<tbody>
<tr>
<td></td>
<td>• Take the MR capsules regularly at 12 hourly intervals if possible with food, and complete the course</td>
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<td>• Tablets or suspension should be taken 6 hourly with food to minimise GI reactions</td>
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<td>• Drink plenty of fluids, but avoid caffeine containing, and alcoholic drinks</td>
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<td>• Try to empty the bladder when urinating</td>
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<td>• Passing water following intercourse may also prevent recurrent attacks</td>
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<td>• Attacks may be precipitated by the use of fragranced products</td>
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<td></td>
<td>• If symptoms have not improved after 3 days, advise patient to contact their GP</td>
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<td>• If the condition becomes recurrent, contact GP for further investigation</td>
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<td></td>
<td>• Advise that in 50% of cases, symptoms clear up within 3 days without treatment</td>
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<td></td>
<td>• Paracetamol or ibuprofen can be taken to alleviate</td>
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</table>
### Follow up

- Seek medical attention immediately if condition deteriorates and/or patient becomes systemically unwell.
- Advise patient that if rash or other signs of hypersensitivity occur, stop taking the medicine and contact their medical practitioner immediately.
- Seek medical attention if there is little improvement after 3 days of treatment.

### Records/audit trail

- In discussion with the client enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation. All consultations must be entered onto PharmOutcomes on the day that the consultation takes place.
- Details of the supply must also be made in the patients (PMR) record.
- All supplies of nitrofurantoin must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended. In addition to the above, the label must also state the words “Supplied under a PGD” to help with audit purposes.
- Electronic patient records and/or the completed paper proforma should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records are recommended to be kept.
- If the client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given.
In every case when a supply of nitrofurantoin is made in accordance with this PGD, the pharmacist must inform the patients GP of the supply within two working days. This will be done through secure nhs.net email accounts via PharmOutcomes once the consultation data has been recorded within the specified module. Where no nhs.net account is available to PharmOutcomes, the pharmacist will be informed by the system and must make alternative arrangements to send the information (within two working days).

**Adverse drug reactions**

All serious adverse reactions must be reported to MHRA via the yellow card system [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk).

A client presenting with a suspected serious ADR should be referred to their medical practitioner.

<table>
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<tr>
<th>Date last reviewed:</th>
<th>June 2018</th>
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<tbody>
<tr>
<td>Date for next review:</td>
<td>January 2020</td>
</tr>
<tr>
<td>Expiry date:</td>
<td>31st March 2020</td>
</tr>
<tr>
<td>Version No:</td>
<td>5.0 / August 2018</td>
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</tbody>
</table>

**References**

- BNF – Current Version
- Antimicrobial prescribing guidelines in general practice (Staffordshire) – 2016
- Antibiotic guidance for Shropshire and Powys Primary Care – 2017
- Electronic Medicines Compendium - SPC Nitrofurantoin - 2018

**Glossary**

- BNF – British National Formulary
- CKS – Clinical Knowledge Summaries
- SPC – Summary of Product Characteristics
- PIL – Patient Information Leaflet
- PGD – Patient Group Direction
- PMR – Patient Medication Record
- POM – Prescription Only Medicine
- MHRA – Medicines and Healthcare Products Regulatory Agency
- ADR – Adverse Drug Reaction
- LPC – Local Pharmaceutical Committee
PGD Workgroup

The following individuals have been involved with the production and review of this PGD:

<table>
<thead>
<tr>
<th>Name</th>
<th>Role and Affiliation</th>
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<tbody>
<tr>
<td>Andrew Pickard MRPharmS</td>
<td>Pharmacy Advisor – NHS England North Midlands</td>
</tr>
<tr>
<td>Tania Cork MRPharmS</td>
<td>Chief Operating Officer – North Staffs and Stoke LPC</td>
</tr>
<tr>
<td>Hitesh Patel MRPharmS</td>
<td>Senior Pharmaceutical Advisor – Telford and Wrekin CCG</td>
</tr>
</tbody>
</table>
Register of practitioners qualified to supply Nitrofurantoin for the treatment of uncomplicated Urinary Tract Infection in females aged 16 years and over.

Operation of this PGD is the responsibility of the commissioner and service providers.

The practitioner must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Contractors who are commissioned to provide the service will be notified of any amendments, and provided with updated documentation for use by individual practitioners.

NHS England authorise this PGD for use by accredited community pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by NHS England.

This page must be completed and retained by each individual pharmacist who intends to work in accordance with this PGD.

Professional Responsibility and Declaration

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service
- I am a registered pharmacist with the General Pharmaceutical Council
- I confirm that indemnity insurance is in place to cover my scope of practice
- I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

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<thead>
<tr>
<th>Name of professional (please print)</th>
<th>Signature</th>
<th>Date of signing</th>
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PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY