

## **Patient Group Direction (PGD)**

### **Supply of Nitrofurantoin for uncomplicated Urinary Tract Infections in females aged 16 years and over**

#### **For the supply of Nitrofurantoin by currently registered pharmacists in accordance with the Pharmacy First Common Ailments (PGD) Service**

Reference: Nitrofurantoin PGD (NHS England North Midlands)  
Version no: V4  
Valid from: 31<sup>st</sup> March 2017  
Review date: 1<sup>st</sup> January 2018  
Expiry date: 31<sup>st</sup> March 2018 (extended to 30<sup>th</sup> June 2018)

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.

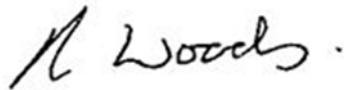
NHS England authorise this PGD for use by accredited Pharmacists delivering the service from Community Pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by NHS England.

## PGD Workgroup

The following individuals have been involved with the development of this PGD.

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| Andrew Pickard   | Pharmacy Advisor – NHS England North Midlands Staffordshire and Shropshire Area              |
| Dr Manir Hussain | Associate Director Medicines Optimisation – NHS Stoke-on-Trent and North Staffordshire CCG's |
| Dr Gill Hall     | Service Development Officer – South Staffordshire LPC  |
| Tania Cork       | Chief Officer- North Staffordshire local Pharmaceutical Committee                            |
| Richard Thorpe   | Clinical Pharmacist – NHS East Staffordshire CCG   |
| Sharuna Reddy    | Senior Pharmaceutical Advisor – NHS Cannock Chase CCG  |

### This PGD has been authorised and approved by;

| Clinical Authorisation               |                            |  |  |
|--------------------------------------|----------------------------|--|--|
| Name and Designation                 | Organisation               | Signature  | Date   |
| Dr Ken Deacon – Medical Director     | NHS England North Midlands |  | 31/03/2017<br>Extension agreed on 21/03/2018 |
| Andrew Pickard – Pharmacy Advisor    | NHS England North Midlands |   | 31/03/2017<br>Extension agreed on 21/03/2018 |
| Organisational Approval              |                            |  |  |
| Rebecca Woods – Head of Primary Care | NHS England North Midlands |  | 31/03/2017<br>Extension agreed on 21/03/2018 |

|                         |   |
|-------------------------|---|
| Supply of               | Nitrofurantoin  |
| Pharmaceutical form     | <ul style="list-style-type: none"> <li>• Nitrofurantoin MR 100mg capsules</li> <li>• Nitrofurantoin 50mg tablets</li> <li>• Nitrofurantoin 25mg/5ml suspension</li> </ul>   |
| Legal Classification    | Prescription Only Medicine (POM)  |
| Black triangle?         | No  |
| Storage                 | Below 25°C – all formulations   |
| Condition to be treated | Uncomplicated lower urinary tract infection in women  |
| Inclusion criteria      | <p>Treat otherwise healthy, non-pregnant women presenting with three or more (<math>\geq 3</math>) of the following symptoms;</p> <ul style="list-style-type: none"> <li>• Dysuria</li> <li>• Urinary frequency/urgency</li> <li>• Lower abdominal pain</li> <li>• Polyuria</li> <li>• Haematuria</li> <li>• Fever/chills</li> </ul> <p>Note: Vaginal discharge reduces the likelihood of the woman having a bacterial UTI.</p> <p>Use dipstick tests to guide treatment decisions in otherwise healthy, non-pregnant women presenting with two or less (<math>\leq 2</math>) symptoms of UTI.</p> <ul style="list-style-type: none"> <li>• Positive nitrite (+/- leucocyte, +/- protein) = Probable UTI</li> <li>• Negative nitrite (+ leucocyte) = Possible UTI</li> <li>• Negative nitrite and leucocyte (+ protein) = Unlikely UTI</li> <li>• All dipstick tests negative = UTI very unlikely</li> </ul> <p>Refer to dipstick testing guidance for further information.</p> |
| Exclusion criteria      | <ul style="list-style-type: none"> <li>• Male</li> <li>• Under 16 years of age</li> <li>• Patients aged 75 years and over</li> <li>• Back or loin pain and pyrexia – consider pyelonephritis and refer immediately</li> <li>• Elderly patients with confusion suggestive of UTI</li> <li>• Known hypersensitivity to Nitrofurantoin</li> <li>• Acute porphyria</li> <li>• Recurrent UTI treated with antibiotics within previous 4 weeks</li> </ul>   |

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|                                | <ul style="list-style-type: none"> <li>• More than two episodes of UTI treated under this PGD within previous 12 months</li> <li>• Catheterised patients</li> <li>• Haematuria only</li> <li>• Blood dyscrasias (G6PD deficiency specifically)</li> <li>• Pregnancy and breast feeding</li> <li>• Renal impairment eGFR &lt;45ml/min</li> <li>• Pulmonary disease</li> <li>• Peripheral neuropathy</li> <li>• History of kidney stones/renal colic</li> <li>• Concomitant use of medication that has a clinically significant interaction with Nitrofurantoin.</li> </ul> <p>For a comprehensive list of interactions, please refer to SPC or BNF</p>   |
| Use with caution               | <p>Patients with an underlying condition that may reduce renal function. This includes patients with the following conditions;</p> <ul style="list-style-type: none"> <li>• Diabetes</li> <li>• Hypertension</li> <li>• Heart disease</li> <li>• Known renal dysfunction</li> </ul> <p>Concomitant use of medication that can adversely affect renal function, such as ACE inhibitors and Diuretics.</p> <p>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.</p> |
| Action to be taken if excluded | <p>Refer to GP.</p> <p>If pyelonephritis is suspected, urgent referral to seek medical advice is required</p>   |
| Administration route           | Oral  |
| Dose                           | <p>Nitrofurantoin 50mg tablets four times a day for 3 days with food.</p> <p><b>OR</b></p> <p>Nitrofurantoin MR 100mg capsules twice daily for 3 days with food</p> <p>*If patient unable to swallow capsules, then Nitrofurantoin 25mg/5ml suspension can be supplied as an alternative</p>  |

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|                                     | <p>Nitrofurantoin 25mg/5ml suspension – 50mg (10ml) to be taken four times a day for 3 days with food</p>  |
| <p>Warnings and adverse effects</p> | <p>Nitrofurantoin may cause dizziness and drowsiness. Patients should be advised not to drive or operate machinery if affected until such symptoms stop.</p> <p>Discolouration of the urine to yellow or brown is common.</p> <p>The following side effects have occasionally been reported. These are generally mild and reversible when Nitrofurantoin is withdrawn.</p> <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Vomiting</li> <li>• Pruritus</li> <li>• Skin rashes</li> <li>• Abdominal pain and diarrhoea</li> </ul> <p>Severe adverse reactions are rare, but there have been reports of the following effects;</p> <ul style="list-style-type: none"> <li>• Acute pulmonary reactions</li> <li>• Neurological effects including peripheral neuropathy</li> <li>• Severe allergic skin reactions including erythema multiforme</li> <li>• Haematological effects (generally reversible on cessation of treatment)</li> </ul> <p>For a comprehensive list of cautions and side effects please refer to SPC</p> <p>Use the Yellow Card System to report adverse drug interactions to the MHRA</p> |
| <p>Advice and follow-up actions</p> | <p>Provide the patient with the manufacturer’s Patient Information Leaflet and discuss as necessary.</p> <ul style="list-style-type: none"> <li>• Take the MR capsules regularly at 12 hourly intervals if possible with food, and complete the course</li> <li>• Tablets or suspension should be taken with food to minimise GI reactions</li> <li>• Drink plenty of fluids, but avoid caffeine containing, and alcoholic drinks</li> <li>• Try to empty the bladder when urinating</li> <li>• Passing water following intercourse may also prevent recurrent attacks</li> </ul>  |

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|   | <ul style="list-style-type: none"> <li>• Attacks may be precipitated by the use of fragranced products</li> <li>• If symptoms have not improved after 3 days, advise patient to contact their GP</li> <li>• If the condition becomes recurrent, contact GP for further investigation</li> <li>• Advise that in 50% of cases, symptoms clear up within 3 days without treatment</li> <li>• Paracetamol or Ibuprofen can be taken to alleviate symptomatic pain or discomfort</li> <li>• Cranberry juice and urine alkalization products are not proven to be effective</li> </ul> <p>The Faculty of Sexual and Reproductive Healthcare no longer advises that additional precautions are required when using combined hormonal contraception (CHC) with antibiotics that are not enzyme inducers. The only proviso is that if the antibiotic (and/or the condition itself) cause vomiting or diarrhoea, then the usual additional precautions should be observed.</p>                                  |
| Records   | <p>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.</p> <p>In addition to the above, the label must also state the words “Supplied under a PGD” to help with audit purposes.</p> <p>Details of the supply must be made in the patients (PMR) record.</p> <p>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. On the rare occasion 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).</p> |
| <p><b>For full product information, always refer to the latest Summary of Product Characteristics</b></p> |   |

**Patient Group Direction (PGD) for the supply of Nitrofurantoin by accredited Pharmacists within Community Pharmacies commissioned to provide the service 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**

- I have successfully completed the relevant training as outlined in the Service Specification and have signed the Declaration of Competence (DoC)
- 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

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| Name      |  |
| Position  |  |
| Signature |  |
| Date      |  |