



This patient group direction (PGD) must only be used by registered health professionals 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.

## Patient Group Direction (PGD)

For the administration or supply of

### Nitrofurantoin 50mg Tablets / MR 100mg Capsules

By registered health care professionals for

### Treatment of uncomplicated lower urinary tract infections

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

## PGD NUMBER 165

### 1. Change history

Version number	Change details	Date
01	Original PGD ratified	June 2021

## 2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

## 3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

## 4. PGD authorisation

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

## 5. PGD adoption by the provider

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job title and organisation	Signature	Date	Applicable or not applicable to area

## 6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the [NICE PGD competency framework for health professionals using PGDs](#)

	Requirements of registered Healthcare professionals working under the PGD
<b>Qualifications and professional registration</b>	<ul style="list-style-type: none"> <li>Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy</li> <li>Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises</li> </ul>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria</li> <li>Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD</li> <li>Local training in the use of PGD's</li> </ul>
<b>Competency assessment</b>	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
<b>Ongoing training and competency</b>	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

## 7. Clinical Conditions

<b>Clinical condition or situation to which this PGD applies</b>	Treatment of uncomplicated lower urinary tract infections
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Patients between 16 and 65 years</li> <li>• Women presenting with any of the following symptoms:             <ul style="list-style-type: none"> <li>○ Dysuria</li> <li>○ Haematuria</li> <li>○ Lower abdominal pain</li> <li>○ Polyuria</li> <li>○ Signs of systemic illness, including fever and rigor</li> <li>○ Urinary frequency/urgency</li> </ul> </li> </ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Children under 16 years</li> <li>• Patients over 65 years</li> <li>• Males</li> <li>• Allergy or previous adverse reaction to Nitrofurantoin</li> <li>• Known chronic kidney disease</li> <li>• Pregnancy</li> <li>• Breast feeding</li> <li>• Catheterised patients</li> <li>• Known blood dyscrasias</li> <li>• Signs of systemic inflammatory response</li> <li>• Significant flank pain</li> <li>• Confused or dehydrated</li> <li>• Haematuria only</li> <li>• Pulmonary fibrosis</li> <li>• Peripheral neuropathy</li> <li>• History of kidney stones/renal colic</li> <li>• Known G6PD deficiency and acute porphyria</li> <li>• Recurrent UTI treated with antibiotics within previous 4 weeks</li> <li>• More than two episodes of UTI treated under this PGD within previous 12 months</li> <li>• Patient already taking prophylactic nitrofurantoin</li> <li>• Patient currently taking any of the following drugs: dapsone and prilocaine</li> </ul>
<b>Cautions (including any relevant action to be taken)</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>• Anaemia</li> <li>• Electrolyte imbalance</li> <li>• Folate or vitamin B deficiency</li> <li>• Pulmonary disease</li> <li>• Susceptibility to peripheral neuropathy</li> <li>• Patients known or suspected as having diabetes – frequent UTI's may be suggestive of poor blood glucose control</li> </ul> <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> </ul>

<b>Cautions (including any relevant action to be taken)</b> (continued)	<ul style="list-style-type: none"> <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 registered healthcare professional 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 referred to a more experienced clinical practitioner</p>
<b>Arrangements for referral for medical advice</b>	Patient should be referred to a more experienced clinical practitioner for further assessment
<b>Action to be taken if patient excluded</b>	Patient should be referred to a more experienced clinical practitioner for further assessment
<b>Action to be taken if patient declines treatment</b>	<ul style="list-style-type: none"> <li>• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment</li> <li>• This information must be documented in the patients' health records</li> <li>• Any patient who declines care must have demonstrated capacity to do so</li> <li>• Where appropriate care should be escalated</li> </ul>

## 8. Details of the medicine

<b>Name, form and strength of medicine</b>	Nitrofurantoin 50mg Tablets / MR 100mg Capsules
<b>Legal category</b>	Prescription Only Medicine (POM)
<b>Indicate any <u>off-label use</u> (if relevant)</b>	None
<b>Route/method of administration</b>	Oral
<b>Dose and frequency</b>	<p><b>Nitrofurantoin 50mg tablets:</b></p> <ul style="list-style-type: none"> <li>• Patients between 16 and 65 years</li> <li>• 50mg to be taken four times a day for 3 days with food</li> </ul> <p><b>Nitrofurantoin MR 100mg capsules:</b></p> <ul style="list-style-type: none"> <li>• Patients between 16 and 65 years</li> <li>• 100mg to be taken twice daily for 3 days with food</li> </ul>
<b>Quantity to be administered and/or supplied</b>	<p><b>Nitrofurantoin 50mg tablets:</b> 12 tablets</p> <p><b>Nitrofurantoin MR 100mg capsules:</b> 6 capsules</p>
<b>Maximum or minimum treatment period</b>	<ul style="list-style-type: none"> <li>• 3 days</li> <li>• complete the course</li> </ul>
<b>Storage</b>	Room temperature

<b>Adverse effects</b>	<ul style="list-style-type: none"> <li>• Dizziness</li> <li>• Drowsiness</li> <li>• Headache</li> <li>• Gas/indigestion</li> <li>• Itching</li> <li>• Loss of appetite</li> <li>• Nausea</li> <li>• Muscle or joint pain</li> <li>• Rash</li> <li>• Temporary hair loss</li> <li>• Vomiting</li> <li>• Weakness</li> </ul>
<b>Records to be kept</b>	The administration of any medication given under a PGD must be recorded within the patient's medical records

## 9. Patient information

<b>Verbal/Written information to be given to patient or carer</b>	<ul style="list-style-type: none"> <li>• Verbal information must be given to patients and or carers for all medication being administered under a PGD</li> <li>• Where medication is being supplied under a PGD, written patient information leaflet must also be supplied</li> <li>• A patient information leaflet is available on request</li> <li>• May cause dizziness and drowsiness and patient should not drive or operate machinery if affected this way</li> <li>• Additional information to be given to patient (see Appendix C)</li> </ul>
<b>Follow-up advice to be given to patient or carer</b>	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately

## 10. Appendix A

References
<ol style="list-style-type: none"> <li>1. British National Formulary (BNF) available online: <a href="https://bnf.nice.org.uk">https://bnf.nice.org.uk</a></li> <li>2. Nursing and Midwifery (2018) "The code" available online: <a href="https://www.nmc.org.uk">https://www.nmc.org.uk</a></li> <li>3. Current Health Care Professions Council standards of practice</li> <li>4. General Pharmaceutical Council standards</li> <li>5. The General Optical Council</li> <li>6. Electronic medicines compendium available online: <a href="https://www.medicines.org.uk">https://www.medicines.org.uk</a></li> <li>7. NHS England Patient Group Direction (PGD) re Supply of Nitrofurantoin for uncomplicated Urinary Tract Infections in females aged 16 years and over</li> <li>8. Isle of Wight CCG Patient Group Direction – supply of Nitrofurantoin 100mg MR capsules for the treatment of uncomplicated urinary tract infections (UTI) in women. <a href="https://www.isleofwightccg.nhs.uk/Downloads/Medicines%20Optimisation/PGDs/CCG%20Nitrofurantoin%20Patient%20Group%20Direction.pdf?UNLID=106">https://www.isleofwightccg.nhs.uk/Downloads/Medicines%20Optimisation/PGDs/CCG%20Nitrofurantoin%20Patient%20Group%20Direction.pdf?UNLID=106</a></li> <li>9. DHSC, Antimicrobial Guidelines for Management of infections in Primary Care 2019</li> </ol>

## 11. Appendix B

### Health professionals agreed to practice

- Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor
- A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

## 12. Appendix C

### Additional Advice

- Verbal information must be given to patients and or carers for all medication being administered under a PGD.
  - Where medication is being supplied under a PGD, written patient information leaflet must also be supplied.
  - A patient information leaflet is available on request.
  - The following advise should be given to the patient:
    - Advise patient to take at regular intervals and to complete the 3- day course even if the original infection appears better
    - Take capsules whole with a full glass of water and take with food
    - The activity of nitrofurantoin is reduced with increasing pH; avoid alkalinising agents e.g. potassium citrate. Not recommended OTC.
    - Nitrofurantoin may make your urine become coloured dark yellow or brown. This is quite normal and not a reason to stop taking the medicine.
    - 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.  
<https://www.fsrh.org/documents/ceu-clinical-guidance-druginteractions-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.