

**Patient Group Direction**

For the supply of **Nitrofurantoin 100mg MR Capsules**

by registered, trained and authorised community pharmacists and locum pharmacists

for the **treatment of uncomplicated urinary tract infections (UTI) in women**

on the Isle of Wight

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| 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: 2.0**

**Change history**

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| **Version number** | **Change details** | **Date** |
| 1.0 | First Version | Feb 2018 |
| 2.0 | Review | Jan 2020 |
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| PGD approval date/ Valid from: | 1.3.2018  |
| CCG implementation date: | 1.4.2018 |
| Review date: | 1.1.2020 / 1.1.2022 |
| Expiry Date: | 31.3.2020 / 31.3.2022 |

**Nitrofurantoin PGD Accountability Record 2020**

**PGD Review Group**

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| --- | --- | --- | --- |
| **Name**  | **Job title and organisation** | **Signature**  | **Date** |
| Lead author & pharmacist | Caroline Allen Deputy Head of Medicines Management  |  | 10.03.2020 |
| Clinical Pharmacist | Mel StevensAntimicrobial Pharmacist, IOW Trust |  |  |

**PGD Authorisation**

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

**CCG Clinical Approval**

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| **Name** | **Authorising Professional** | **Signature** | **Date** |
| **Dr Adam Poole** | Clinical Commissioning Group (CCG) GP Prescribing Lead |  | 10.03.2020 |
| **Louise Spenser** | CCG Deputy Director of Nursing and Quality |  | 18.03.2020 |
| **Tracy Savage** | CCG Locality Director and Head of Medicines Optimisation and Primary Care  |  | 17.03.2020 |

**Provider Organisation**

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|  | **Name** | **Authorising Professional** | **Signature** | **Date** |
| **On behalf of Community Pharmacy** |  | **Manager of the healthcare professionals using the PGD** |  |  |
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| **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**

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|  | **Requirements of registered pharmacist working under the PGD** |
| Qualifications and professional registration | Pharmacist currently registered with General Pharmaceutical Council<https://www.pharmacyregulation.org/registers/pharmacist> |
| Training  | **Centre for Pharmacy Postgraduate Education (CPPE) distance learning:*** CPPE distance learning pack ‘Common clinical conditions and minor ailment: distance learning’ (8hrs)

<https://www.cppe.ac.uk/programmes/l?t=RespMin-P-03&evid=45133> * CPPE learning assessment ‘Minor Ailments; a clinical approach (2020) <https://www.cppe.ac.uk/programmes/l/minor2-a-10>

**NICE Guidance:*** NICE CKS Urinary Tract Infection (lower) –women <https://cks.nice.org.uk/urinary-tract-infection-lower-women>
* Treatment for women with lower UTI who are not pregnant: <https://www.nice.org.uk/guidance/ng109/chapter/Recommendations#treatment-for-women-with-lower-uti-who-are-not-pregnant>
 |
| Competency  | **Completion of education in both the legal and professional aspects of PGD administration and the supply of medicines using:*** + GPhC Standards For Pharmacy Professionals
	+ Legal framework of PGD’s <https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017.pdf>
	+ Medicine, Ethics and Practice: Royal Pharmaceutical Society (RPS) <https://www.rpharms.com/publications/the-mep>

**CPPE Declaration of competence:*** Minor ailments – this includes Consultation skills, Common Clinical Conditions and Minor Ailments <https://www.cppe.ac.uk/services/declaration-of-competence#navTop>

**Self-Declaration that this training has been completed on PharmOutcomes**.The Pharmacist must complete electronic declaration (enrolment) via PharmOutcomes, by clicking on Nitrofurantoin PGD tab. |
| 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.
* The pharmacist is required to complete the required training and competency declaration every time a new contract is signed as this may change slightly in line with current evidence.
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**Clinical Condition –uncomplicated urinary tract infection in women**

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| **Clinical condition or situation to which this PGD applies**  | Treatment of otherwise healthy women presenting with uncomplicated urinary tract infection.**FIRST LINE:****Nitrofurantoin 100mg M/R bd (Macrobid®) for 3 days if no known renal condition (or GFR>45mL/min)** |
| **Inclusion criteria**Evidence shows that if dysuria and frequency are present the likelihood of being a UTI is >90% 1,2 | **Eligibility criteria:*** Female
* Aged 16 years or over/aged 65 years or under
* No complications e.g. catheter

**Present in the pharmacy (or contactable by telephone) to provide information regarding symptoms associated with an uncomplicated urinary tract infection:*** Dysuria
* Increased urinary frequency and urgency of recent onset
* Suprapubic pain
* Nocturia of recent onset
* No signs of a complicated UTI:

haematuria or symptoms of pyelonephritis i.e. fever, flank pain, chills, nausea/ vomiting, rigors, loin or abdominal pains/ tenderness and headachePatients must consent to sharing their details and the consultation with their registered GP. The consent can be verbal and will be recorded on PharmOutcomes® as part of the consultation process. |
| **Exclusion criteria**Treat as complex patients and refer to 111/GP. | **Not meeting eligibility criteria:*** Male
* Aged 16 years or under/aged 65 years or over
* Any complications
* Pregnant/possible pregnancy or breast feeding
* Living in residential care facility
* Refused / not consented to treatment.

**Signs of a complicated UTI:** * Symptoms of pyelonephritis i.e. fever, flank pain, chills, nausea/ vomiting, rigors, loin or abdominal pains/ tenderness and headache
* Unresolving urinary symptoms
* Vaginal discharge or itch
* Haematuria (unless menstruating)
* Urological abnormalities or who have had surgery involving the lower urinary tract
* Indwelling catheter
* Known renal impairment or acute kidney injury

**Increased risk of Nitrofurantoin antibiotic resistance:*** Current prophylactic use of nitrofurantoin
* Currently taking a prescribed antibiotic
* Recurrent UTI - a frequency of 2 or more UTIs in the last 6 months or 3 or more UTIs in the last 12 months.

**Sensitivity:*** Known hypersensitivity to nitrofurantoin or to any ingredient of the nitrofurantoin product being supplied

**Medical risks:*** Immunocompromised patients or patients taking immunosuppressant medicines or Disease Modifying Antirheumatic Drugs) DMARDs - seek urgent medical attention for full blood count and liver function tests
* Hepatic impairment
* Renal impairment or acute kidney injury
* G6PD deficiency (see also BNF Section 4.6)
* Acute porphyrias

**Drug Interactions:****Refer to BNF interactions for full list:** [**https://bnf.nice.org.uk/interaction/nitrofurantoin-2.html**](https://bnf.nice.org.uk/interaction/nitrofurantoin-2.html)Patients who are currently taking any of the following are at risk of a severe interaction:* + Dapsone
	+ Prilocane

Risk of neurotoxicity with:* + Phenytoin
	+ Amiodarone
	+ Cytotoxics

Treat as complex patients and refer to GP. |

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| **Cautions for information**Treat as complex patients and refer to 111/GP. | * Interaction with other medicinal products and other forms of interaction
	+ Increased absorption with food or agents delaying gastric emptying.
	+ Decreased absorption with magnesium trisilicate – avoid co-administration
	+ Decreased renal excretion of Nitrofurantoin by probenecid and sulphinpyrazene.
	+ Decreased anti-bacterial activity by carbonic anhydrase inhibitors and urine alkalization –don’t sell OTC.
	+ Anti-bacterial antagonism by quinolone anti-infectives.
	+ Interference with some tests for glucose in urine.
	+ Typhoid Vaccine (oral): Antibacterials inactivate oral typhoid vaccine.

Complex patients – refer to GP if in doubt* Nitrofurantoin should be used with caution in patients with pulmonary disease, hepatic dysfunction, neurological disorders, and tendency to allergies. Complex patient – refer to GP.
* Discontinue treatment with Nitrofurantoin if otherwise unexplained pulmonary, hepatic, haematological or neurological syndromes occur
* Peripheral neuropathy and susceptibility to peripheral neuropathy, which may become severe or irreversible, has occurred and may be life threatening. Therefore, treatment should be stopped at the first signs of neural involvement (paraesthesiae).
* Nitrofurantoin should be used in caution with patients with anaemia, diabetes mellitus, electrolyte imbalance, debilitating conditions and vitamin B (particularly folate) deficiency.
* Acute, subacute and chronic pulmonary reactions have been observed in patients treated with Nitrofurantoin. If these reactions occur, nitrofurantoin should be discontinued immediately.
* Chronic pulmonary reactions (including pulmonary fibrosis and diffuse interstitial pneumonitis) can develop insidiously, and may occur commonly in elderly patients. Close monitoring of pulmonary conditions of patients receiving long-term therapy is warranted (especially in the elderly).
* Patients should be monitored closely for signs of hepatitis (particularly in long-term use). Urine may be coloured yellow or brown after taking Nitrofurantoin. Patients on Nitrofurantoin are susceptible to false positive urinary glucose (if tested for reducing substances).
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| **Arrangements for referral for medical advice** | Contact details of services available to be provided to patient, with hours of opening.Pharmacist to provide summary of assessment via PharmOutcomes.PharmOutcomes message to GP.Pharmacy First card for referral if required. |
| **Action to be taken if patient excluded**  | **For complex UTI refer patient to GP.****If suspect pyelonephritis call 111 for advice.****Immunocompromised patients or patients taking immunosuppressant medicines or Disease Modifying Antirheumatic Drugs) DMARDs** - seek urgent medical attention via 111 for full blood count. |
| **Action to be taken if patient declines treatment** | None necessary.  |

**Details of the medicine – Nitrofurantoin 100mg MR**

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| **Name, form and strength of medicine***Include ▼for* [*black triangle medicines*](http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/BlackTriangleproducts/index.htm) | Nitrofurantoin 100mg capsules MR (Macrobid®) |
| **BNF Chapter Category** | 5.2 |
| **Legal category** | POM |
| ***Indicate any*** [***off-label use***](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#off-label-use) ***(if relevant)***  | N/A |
| **Dose and frequency** | One 100mg MR capsule to be taken TWICE a day (12 hourly) for 3 days (with food) |
| **Route/method of administration** | Oral |
| **Total Quantity to be supplied** | 6 capsules (3 days) |
| **Maximum treatment period** | 3 days |
| **Adverse effects** | ***For full list of Adverse Drug reactions (ADRs) see British National Formulary (BNF)/ Summary of Product Characteristics (SmPC)***Nitrofurantoin may cause dizziness and drowsiness and the patient should not drive or operate machinery if affected this way.**BNF** [**https://bnf.nice.org.uk/drug/nitrofurantoin.html**](https://bnf.nice.org.uk/drug/nitrofurantoin.html)**Frequency not known**Agranulocytosis; alopecia; anaemia; angioedema; aplastic anaemia; appetite decreased; arthralgia; asthenia; chest pain; chills; circulatory collapse; confusion; cough; cyanosis; depression; diarrhoea; dizziness; drowsiness; dyspnoea; eosinophilia; euphoric mood; fever; granulocytopenia; haemolytic anaemia; headache; hepatic disorders; idiopathic intracranial hypertension; increased risk of infection; leucopenia; lupus-like syndrome; nausea; nerve disorders; nystagmus; pancreatitis; psychotic disorder; pulmonary hypersensitivity; pulmonary reaction (possible association with lupus erythematosus-like syndrome); respiratory disorders; skin reactions; Stevens-Johnson syndrome; thrombocytopenia; urine discolouration; vertigo; vomiting |
| **Records to be kept by PharmOutcomes for 2 years** | The following will be recorded on PharmOutcomes:* Patient name, age, gender
* Name of registered GP
* The diagnosis (UTI)
* Treatment recommended (Nitrofurantoin MR capsules 100mg) C
* Quantity supplied (6)
* Batch number and expiry date
* Name of manufacturer
* Duration of treatment (3 days)
* Date of supply
* Name of the individual assessing the patient and making the supply

*Information must be sent to the GP by PharmOutcomes for entry into the patients records*Document any allergies and other adverse drug reactions clearly in the pharmacy patient records and inform GP and other relevant practitioners 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 to the CCG* *iwccg.mot@nhs.net* *.*

*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) -* [*https://yellowcard.mhra.gov.uk*](https://yellowcard.mhra.gov.uk)

**Patient Information**

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| **Information to be given to patient**  | * Highlight the patient information leaflet included in the box
* 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.5 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-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.
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| **Follow-up advice to be given to patient**  | * Routine follow up is not necessary
* Advise to call 111 if complex patient/concerns
* Advise to see GP if symptoms don’t resolve
* Refer to NHS Choices for more information: <https://www.nhs.uk/conditions/cystitis/>
* e MC Patient Information Nitrofurantoin 100mg capsules <https://www.medicines.org.uk/emc/files/pil.429.pdf>
* Give [TARGET UTI](http://www.rcgp.org.uk/clinical-and-research/toolkits/~/link.aspx?_id=9FCF9DA4B4A045519593320478DFD9E7&_z=z) leaflet: <https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/amr/target-antibiotics-toolkit/-/media/85AAD1D4DDEF455A85E0416C3BB714AE.ashx>
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**Appendix A - Key References**

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| 1. NICE CKS Urinary Tract Infection (lower) –women <https://cks.nice.org.uk/urinary-tract-infection-lower-women>
2. NICE Guidance: Urinary tract infection(lower):antimicrobial prescribing [NG109] Published date: October 2018 <https://www.nice.org.uk/guidance/ng109>
3. SCAN – South Central Antimicrobial Network Guidelines for Antibiotic Prescribing in the Community <http://www.nhsantibioticguidelines.org.uk/downloads/CS47131-NHSNHCCG-Antibiotic-Guidelines-2018-WHOLE-PRF5.pdf?fbclid=IwAR2M_ACCx2G17VvvYwwZkJiss6KhOjDLt4w0wTFIBWFRxOkg71OvK6rZw3M>
4. BNF On-Line: <https://bnf.nice.org.uk/drug/nitrofurantoin.html>
5. e MC Summary of Product Characteristics (SmPC) Nitrofurantoin 100mg MR capsules <https://www.medicines.org.uk/emc/product/429>
6. e MC Patient Information Nitrofurantoin 100mg capsules <https://www.medicines.org.uk/emc/files/pil.429.pdf>
7. Faculty of Sexual and Reproductive Health Clinical Guidance. Clinical Effectiveness Unit Drug Interactions with Hormonal Contraception J- Updated 2017 Reviewed January 2019: <https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/>
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**Appendix B - Nitrofurantoin PGD Sign-Off Sheet 2020-22**

This is the health professionals’ agreement to practise and is to be signed by individual pharmacists agreeing to practice under the PGD.

***I have read and understood the patient group direction, completed the prerequisite training and agree to supply and/or administer this medicine only in accordance with this PGD.***

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| **Name** | **GPhC Number** | **Date**  | **Signature** |
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*A copy of this Patient Group Direction (PGD) should be given to the pharmacists listed above, and the original retained by the Pharmacy providing the service for ten years.*

**Appendix C- Pharmacy Payment**

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|  | Drug Tariff (Jan 2020) | PharmOutcomes |
| Consultation and supply for patient self-referrals | 6 Macrobid ®100mg MR capsules / 3 days £  | £ (VAT exempt) |
| Consultation and supply if directed via 111 and CPCS  | 6 Macrobid ®100mg MR capsules / 3 days £ | £ (VAT exempt) |

**Appendix D - PharmOutcomes**

The system will factor invoices:

* *Where ‘Nitrofurantoin Supplied’ =* The value of ‘*Product Supplied (DM&D)*’ x ‘*Quantity Supplied*’ *in pence* plus VAT at Standard rate (Product Reimbursement)
* £/£ 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.