National Patient Group Direction (PGD)

Supply of Nitrofurantoin Capsules MR 100mg / Tablets 50mg

Version – 2.0
PGD No: 2022/2409

The purpose of the PGD is to allow management of acute uncomplicated urinary tract infection (UTI) in non-pregnant females aged 16 years and over, by registered pharmacists within Community Pharmacies.

This PGD authorises pharmacists delivering the NHS Pharmacy First Service Level Agreement to supply nitrofurantoin to non-pregnant females aged 16 years and over presenting with symptoms of an acute uncomplicated urinary tract infection (UTI) who meet the criteria for inclusion under the terms of the document.

Change History – see table at end of document for more details

Change to eligibility

1. Eligible age range – extended to 16 years and over
2. Haematuria – can now be considered for treatment in community pharmacy under certain circumstances (some exclusions still apply)
3. Diabetes – patients with diabetes can now be considered for treatment in community pharmacy
4. Symptoms of UTI lasting longer than 7 days – can now be considered for treatment in community pharmacy with guidance to report to GP practice
5. Breastfeeding – patients who are breastfeeding can now be considered for treatment in community pharmacy
6. Presence of vaginal discharge or itch – can now be considered for treatment in community pharmacy unless "presence of new, unexplained vaginal discharge or itch suggestive of other pathology"

Clarification for community pharmacy network

7. Renal impairment – clarified as known "moderate to severe"
8. Folate deficiency – clarified as known folate deficiency "which has not been corrected"
9. Hepatic insufficiency – clarified as "severe known liver fibrosis/encephalopathy"
10. Immunosuppressed – clarified as "current immunosuppression e.g. chemotherapy, long term oral corticosteroids, other immunosuppressant therapies"

If this PGD is past the review date, the content shall remain valid until such time that the review is complete and a new version has been published. **It is the responsibility of the person using the PGD to ensure they are using the most recent issue.**

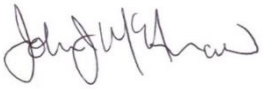
PGD Nitrofurantoin MR Capsules 100mg / tablets 50mg Authorisation

This PGD has been produced in collaboration with the Scottish Antimicrobial Prescribing Group and the Primary Care Community Pharmacy Group to assist NHS Boards in the provision of uniform services under the 'NHS Pharmacy First Scotland' banner across NHS Scotland

The qualified health professionals who may supply nitrofurantoin capsules or tablets under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

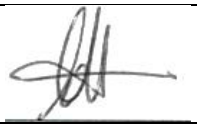
This specimen PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor	Dr Laura Ryan	Signature	
Pharmacist	Dr John McAnaw	Signature	
NHS Scotland Representative	Mr Jim Miller	Signature	

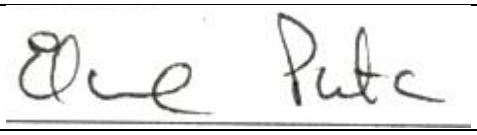
NHS Greater Glasgow & Clyde Patient Group Direction (PGD) for Health Care Professionals	NHS Greater Glasgow and Clyde

Trimethoprim 200mg Tablets

AUTHORISATION:

NHSGG&C PGD Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	**Signature:**	**Date:**
Dr Craig Harrow		**18/08/2022**

NHSGG&C PGD Sub-Committee of ADTC		
Lead Nurse, North Sector, NHS GGC in BLOCK CAPITALS	**Signature:**	**Date:**
John Carson		**18/08/2022**

Pharmacist representative of PGD Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	**Signature:**	**Date:**
Elaine Paton		**18/08/2022**

Antimicrobial use

If the PGD relates to an antimicrobial agent, the use must be supported by the NHS GG&C Antimicrobial Management Team (AMT). A member of this team must sign the PGD on behalf of the AMT.

Microbiology approval	Name: Michael Neto	Designation: Antimicrobial Pharmacist
	 Signature: (on behalf of NHS GG&C AMT)	Date: 17/08/2022

Date Approved 17/08/2022

Effective from 01/08/2022 Review Date August 2024

Clinical Situation

Indication	Acute uncomplicated urinary tract infection (UTI) in non-pregnant females aged 16 years and over.
Inclusion Criteria	Non-pregnant females, assigned as female at birth who have not had any reassignment procedures, aged 16 years and over. Older women should be fit, ambulatory and self-caring. If no dipstick testing available or patient is over 65 years, patient must present with three or more of the following symptoms: • Dysuria • Frequency • Urgency • Suprapubic tenderness • or **BOTH** dysuria and frequency are present. Otherwise: Diagnose a UTI in the presence of two or more urinary symptoms (dysuria, frequency, urgency, visible haematuria or nocturia) and a positive dipstick test result for nitrite. **Note: A positive dip stick in women over 65 is not an indication of UTI as asymptomatic bacteriuria is common in older women.** A renal function assessment should be considered prior to supplying nitrofurantoin.

Exclusion Criteria	• Patients assigned as male at birth • Females under 16 years • Patients living in long term care facilities • Allergy or serious adverse effect from nitrofurantoin or to any other components of the preparation • If **upper** urinary tract infection is more likely i.e. flank pain radiating towards the groin, feel systemically unwell (fever and chills, rigors, nausea, vomiting), as well as with other symptoms of lower UTI. (Patients presenting with such symptoms should be urgently referred to GP/OOH) • Patients over 45 years with unexplained visible haematuria without symptoms of UTI • Visible haematuria which persists or recurs after successful treatment of UTI • Unexplained non-visible haematuria if found on urine dipstick if no UTI symptoms present • Patients over 40 years who present with recurrent UTI with any haematuria • Risk of treatment failure due to one or more of the following: Received antibiotic treatment for UTI within 1 month; 2 or more UTI episodes in the last 6 months or 3 or more episodes in the last 12 months; taking antibiotic prophylaxis for recurrent UTI • Presence of new unexplained vaginal discharge or itch suggestive of other pathology • Confused • Patient utilises urethral or suprapubic catheters (either indwelling or intermittently) • Pregnancy – known or suspected • Known moderate to severe renal impairment (where pharmacists are able to independently access relevant patient records/blood results e.g. via Clinical Portal to establish levels of renal impairment when required, a supply of treatment can be considered. If this is not possible, patient should be referred to GP/OOH) • History of renal stones / renal colic, abnormal urinary tract e.g. vesicoureteric reflux, reflux nephropathy, neurogenic bladder, urinary obstruction, stent, recent instrumentation. • Known severe liver fibrosis/encephalopathy (where pharmacists are able to independently access relevant patient records/blood results e.g. via Clinical Portal to establish levels of hepatic impairment when required, a supply of treatment can be considered. If this is not possible, patient should be referred to GP/OOH). • Known haematological abnormalities, blood dyscrasias, known porphyria, vitamin B (particularly folate) deficiency known folate which has not been corrected, G6PD deficiency, electrolyte imbalance

	• Known or susceptibility to peripheral neuropathy, or known neurological disorder • Current immunosuppression e.g. chemotherapy, long term oral corticosteroids, other immunosuppressant therapies • Known interstitial lung disease or poorly controlled respiratory disease • Taking any medication which interacts with nitrofurantoin– refer to BNF for full list of interactions. • Decline to provide consent or non-capacity to consent.

Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	Any doubt as to inclusion/exclusion criteria being met. • Recent hospital in-patient stay (in the previous three months) - consider the reason for this admission. • Known previous nitrofurantoin-resistant isolates or multi-drug-resistant isolates or recent travel to a country with known increased incidence of antimicrobial resistance Patient over 65 years • Manage suspected UTI in ambulant women aged 65 years and over who are able to look after themselves independently with no comorbidities as in those aged under 65 years, taking into account the increasing background incidence of asymptomatic bacteriuria. Diabetes • Patients with known diabetes are not excluded from treatment from community pharmacy. If concerned about recurrent UTIs or that this may be a side effect of medication e.g. SGLT2 inhibitors, please consider signposting for GP practice follow up. Symptoms of UTI lasting longer than 7 days • Prolonged symptoms suggestive of a UTI may be considered for treatment, but clinical judgement may be required regarding onward referral. Breastfeeding • Patients who are breastfeeding and displaying symptoms of UTI can be considered for treatment in community pharmacy • As a general rule, if a medication is licensed for use in paediatrics (neonatal age onward) then it should be safe for use in breastfeeding as the dose the infant/child receives via the breastmilk will be significantly less than therapeutic doses. • National Institute for Health and Care Excellence. British National Formulary for Children. Available at: NITROFURANTOIN | Drug | BNFc content published by NICE (Accessed 23rd February 2022) • UK Drugs in Lactation Service states the following: o Nitrofurantoin can be used with caution. o Small amounts in breast milk, moderate level of evidence of use in breastfeeding o Avoid in known G6PD deficiency, hyperbilirubinaemia, and in jaundiced premature infants because of risk of kernicterus o Available at: Nitrofurantoin – Medicines – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice (Accessed 23rd February 2022)
Action if Excluded	Refer to GP Practice/Out-of-hours service and document in Patient Medication Record (PMR).

Action if Patient Declines	Note that self-care should be considered as an option depending on symptom severity. If patient declines treatment, advise on self-care to relieve symptoms and advise to see their GP if symptoms fail to resolve within 3 days or if symptoms worsen. Patients can be directed to NHS Inform for guidance on self-care at: Urinary tract infection (UTI) - Illnesses & conditions | NHS inform (accessed 20th January 2022) The reason for declining treatment and advice given must be documented. Ensure patient is aware of risks and consequences of declining treatment. Record outcome in Patient Medication Record (PMR) if appropriate.

Depending on availability either of the 2 treatment choices can be used

Description of Treatment

Name of Medicine	Nitrofurantoin
Form/Strength	100 mg MR capsules
Route of administration	Oral
Dosage	100 mg
Frequency	Twice a day (12 hourly) (with or just after food)
Duration of treatment	3 days
Quantity to supply/administer	6 x 100 mg MR capsules
▼ additional monitoring	No
Legal Category	POM (Prescription Only Medicine)
Is the use outwith the SPC	No
Storage requirements	As per manufacturer's instructions Store below 25°C in a cool dry place
Additional information	None

Description of Treatment

Name of Medicine	Nitrofurantoin
Form/Strength	50 mg tablets
Route of administration	Oral
Dosage	50 mg
Frequency	Four times a day (with or just after food)
Duration of treatment	3 days
Quantity to supply/administer	12 x 50 mg tablets
▼ additional monitoring	No
Legal Category	POM (Prescription Only Medicine)
Is the use outwith the SPC	No
Storage requirements	As per manufacturer's instructions Store below 25°C in a cool dry place
Additional information	None

Warnings including possible adverse reactions and management of these	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
Reporting procedure for adverse reactions	Pharmacists should document and report all adverse incidents through their own internal governance systems. All adverse reactions (actual and suspected) should be reported to the appropriate medical practitioner and recorded in the patient's medical record. Pharmacists should record in their PMR and inform the patient's GP as appropriate. Where appropriate, use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/

Advice to Patient/carer including written information	• Advise patient about the importance of hydration in relieving symptoms. • Offensive smelling urine/cloudy – may be suggestive of dehydration • Increasing fluid intake to around 2.5 L per day (6-8 mugs containing approximately 350 ml) is thought to reduce UTI by dilution and flushing of bacteriuria. (While no evidence was identified for benefit, increasing fluid intake with water in women with urinary symptoms is a low-cost intervention without evidence of harm that may provide symptomatic relief) Provide a cystitis/UTI patient information leaflet and discuss contents with patients. Cystitis- Patient Leaflet | BMJ Best Practice (accessed 2nd May 2022) The patient information leaflet contained in the medicine should be made accessible to the patient. Where this is unsuitable, sufficient information should be given to the patient in a language that they can understand. • Inform patient of possible side effects and their management and who to contact should they become troublesome. • Explain the benefits and risks of taking antibiotics for this condition. • Urinary alkalinising agents should be avoided with nitrofurantoin as these reduce the antibacterial activity of nitrofurantoin • Avoid concomitant administration of magnesium trisilicate as this may reduce nitrofurantoin absorption. • Nitrofurantoin may colour the urine yellow or brown. This is harmless. • If on combined oral contraception, no additional contraceptive precautions are required unless vomiting or diarrhoea occur. (See reference section for Faculty of Reproductive and Sexual Healthcare Guidance) • Advise patient of self-management strategies including maintaining a good fluid intake, wearing loose fitting underwear/clothing, wearing cotton underwear and avoidance of vaginal deodorants.

	• Advise patient on ways to prevent re-infection – e.g. double voiding, voiding after sexual intercourse. • Paracetamol and ibuprofen may relieve dysuric pain and discomfort. • Ensure patient is aware that if symptoms worsen, they experience significant flank pain, become systemically unwell, or develop a fever, they should seek medical advice that day. • Advise patient to seek further medical advice, if symptoms do not resolve after 3 days, if symptoms return or drug side effects are severe. • Advise patient with haematuria which persists or recurs after successful treatment of UTI to contact their GP for follow up. • Advise patient to discontinue treatment if rash develops and seek medical advice. • Advise patient to stop taking immediately and seek medical advice if develops pulmonary, hepatic, haematological or neurological reactions e.g. breathing difficulties, abdominal pain discomfort, bruising and bleeding and seek advice from GP, OOH or NHS 24. • Advise patient that their GP will be informed the next working day that antibiotics have been supplied or appropriate referral has been made. • Advise patient that if they require to seek further advice from the Out-of-hours service they should make staff aware of their nitrofurantoin treatment. Information on medicines can be found at https://www.medicines.org.uk/emc/browse-medicines or https://www.gov.uk/pil-spc
Monitoring	Not applicable
Follow-up	Not applicable
Additional Facilities	The following should be available where the medication is supplied: • An acceptable level of privacy to respect patient's right to confidentiality and safety. • Access to medical support (this may be via the telephone). • Approved equipment for the disposal of used materials. • Clean and tidy work areas, including access to hand washing facilities. • Access to current BNF (online version preferred).

Characteristics of staff authorised under the PGD

Professional qualifications	Registered pharmacist with current General Pharmaceutical Council (GPhC) registration. ***Under PGD legislation there can be no delegation. Supply of the medication has to be by the same practitioner who has assessed the patient under this PGD.***
Specialist competencies or qualifications	Has successfully completed NES Pharmacy e-learning module on "Urinary Tract Infections for NHS Pharmacy First Scotland". https://learn.nes.nhs.scot/33556/pharmacy/cpd-resources/urinary-tract-infections-utis-for-nhs-pharmacy-first-scotland Able to assess the person's capacity to understand the nature and purpose of the medication in order to give or refuse consent. Must be familiar with the relevant nitrofurantoin Summary of Product Characteristics (SPC).
Continuing education and training	Has read current guidance on the management of urinary tract infections e.g.PHE/NICE,SIGN,SAPG Health Improvement Scotland. *SIGN 160: Management of suspected bacterial lower urinary tract infection in adult women. A national clinical guideline.* September 2020. Available at sign-160-uti-0-1_web-version.pdf (accessed 20th January 2022) Health Improvement Scotland: Scottish Antimicrobial Prescribing Group (SAPG). *Urinary Tract Infections*. Available at: Urinary tract infections (sapg.scot) (accessed 20th January 2022) Aware of local treatment recommendations. Attends approved training and training updates as appropriate. Undertakes CPD when PGD or NES Pharmacy module updates.

Audit Trail

Record/Audit Trail	All records must be clear, legible and in an easily retrieval format. Pharmacists must record in Patient Medication Record (PMR). The following records should be kept (paper or computer based) and are included in the patient assessment form: • Patient's name/parent/guardian/person with parental responsibility, address, date of birth and consent given • Patient's CHI number • Contact details of GP (if registered) • Presenting complaint and diagnosis • Details of medicine supplied • The signature and printed name of the healthcare professional who supplied the medicine. • Advice given to patient (including side effects) • The patient group direction title and/or number • Whether the patient met the inclusion criteria and whether the exclusion criteria were assessed • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record • Referral arrangements (including self-care) ***The patient's GP, where known, should be provided with a copy of the client assessment form for the supply of nitrofurantoin or appropriate referral on the same, or next available working day.*** These records should be retained in accordance with national guidance[1] (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead. All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each service. A designated person within each service will be responsible for auditing completion of drug forms and collation of data. 1. Scottish Government. *Scottish Government Records Management.* Edinburgh 2020. Available at SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf (Accessed on 29th November 2021)

Additional references	British National Formulary (BNF) current edition Electronic Medicines Compendium. *Nitrofurantoin SPC*. Available at Home - electronic medicines compendium (emc) (Accessed 24th February 2022) Public Health England. *Summary of antimicrobial prescribing guidance.* May 2021. Available at: Summary of antimicrobial prescribing guidance (publishing.service.gov.uk) (Accessed 24th February 2022) National Institute for Clinical Excellence / Public Health England. *Summary of antimicrobial prescribing guidance – managing common infections.* Jan 2022. Available at: Antimicrobial prescribing table (bnf.org) (accessed 24th February 2022) Public Health England. *Diagnosis of urinary tract infections.* October 2021. Available at: Diagnosis of urinary tract infections - quick reference tool for primary care (publishing.service.gov.uk) (accessed 24th February 2022) Royal College of General Practitioners. *TARGET Urinary tract infection resource suite.* Available at: Urinary tract infection resource suite: Patient facing materials (rcgp.org.uk) (Accessed 24th February 2022) Health Protection Scotland. Scottish Urinary Tract Infection Network. Available at: HPS Website - Scottish Urinary Tract Infection Network (accessed 24th February 2022) Faculty of Sexual and Reproductive Health. Clinical Guidance – Drug Interactions with Hormonal Contraception. Jan 2019. Available at: https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/fsrh-guidance-drug-interactions-hormonal-contraception-jan-2019.pdf (Accessed on 23rd February 2022)

Version	Date	Summary of Changes
1.0	March 2020	Version 1.0 Original PGD

2.0	August 2022	The following sections have been updated:
		• Addition of covering statement regarding validity of PGD when approaching date for review of content
		• Indication
		  ○ Removal of upper age limit
		• Inclusion criteria
		  ○ Clarification that “older women should be fit, ambulatory and self-caring” and that “a positive dip stick in women over 65 is not an indication of UTI as asymptomatic bacteriuria is common in older women.”
		  ○ Inclusion of visible haematuria in list of symptoms when testing urine with dipstick
		• Exclusion criteria
		  ○ Upper age limit removed
		  ○ Clarification that patients living in long term care facilities are excluded
		  ○ Clarification of definition of “upper” UTI
		  ○ Haematuria – specific criteria now apply
		  ○ Clarification of definition of vaginal discharge/itch
		  ○ Clarification of catheter use
		  ○ Clarification of definition and associated actions required for patients with renal or hepatic impairment
		  ○ Clarification of definition of immunosuppression
		• Cautions/further advice
		  ○ Removal from exclusion, insertion into cautions/further advice with provision of additional information for patients over 65 years, with diabetes, symptoms lasting more than 7 days, breastfeeding
		• Advice to patient
		  ○ Update to information for patients
		• Action if patient is excluded
		  ○ Removal of requirement to record in Pharmacy Care Record (PCR)
		• Action if patient declines
		  ○ Inclusion of link to NHS Inform for guidance on self-care
		  ○ Removal of requirement to record in PCR
		• Specialist competencies or qualifications
		  ○ Updated link to training module
		• Record/audit trail
		  ○ Removal of requirement to record in PCR
		  ○ Clarification that notification form should be sent to GP for patients being referred as well as those being treated by community pharmacy.
		  ○ Update to information on retention of records
		  ○ Update to additional references