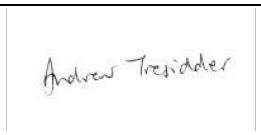
Patient Group Direction: For the supply of Nitrofurantoin capsules/tablets by Community Pharmacists in Somerset to patients for the treatment of uncomplicated urinary tract infections under the Somerset Minor Ailments Scheme (PGD MAS 2 Version 4.0)

Staff involved in the development of this PGD:

	Name	Signature	Date
Physician	Dr Andrew Tresidder NHS Somerset Medicines Programme Board Chair		02.06.2023
Pharmacist	Hels Bennett, Medicines Manager, NHS Somerset ICB		25.05.2023
Antimicrobial Specialist	Katie Heard Antimicrobial Consultant Pharmacist NHS Somerset FT		31.05.23

Name of original authors: Ana Alves, Pharmacist, Somerset CCG and Dr Robert Baker, Consultant Microbiologist, Taunton and Somerset NHS Foundation Trust.

Authorised for use across NHS Somerset ICB Practices by:

Shelagh Meldrum, Chief Nursing Officer for NHS Somerset ICB (Acting as Clinical Governance Lead)

Signed:……Shelagh meldrum…… Date:15 June 2023…….

Date of Implementation: 1st July 2023
Expiry Date: 30th June 2025

TO BE COMPLETED BY PHARMACY AUTHORISING MANAGER:

I, ……, as authorising manager for …… pharmacy, have read and approved this PGD for use by appropriate registered pharmacists working at my pharmacy. I understand that I am responsible for ensuring that pharmacy staff have adequate training to ensure that NITROFURANTOIN CAPSULES/TABLETS is supplied to patients in strict accordance with this PGD.

Signed…….. Dated……

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The registered pharmacists named below are authorised to supply Nitrofurantoin capsules/tablets as specified under this Patient Group Direction, while working at:

…… …… (INSERT PHARMACY NAME)

In signing this document I confirm the following:

- I have read and understood the above mentioned PGD.
- I agree to practice only within the bounds of my own competence and in accordance with my Code of Professional Conduct.
- I have the qualifications required under the staff characteristics detailed in the PGD
- I am competent to operate under this PGD.
- I will provide the service in accordance with the PGD

NAME *(please print)*	TITLE	SIGNATURE	AUTHORISING MANAGER *(please print)*	MANAGER'S SIGNATURE	DATE

- **Complete additional pages as necessary**
- **Retain original signed pages (1) and (2) with authorising manager.**

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N.B. You must be authorised by name, under the current version of this PGD before you attempt to work in accordance with it.

1. Clinical Condition

Definition of condition/situation	• Uncomplicated lower urinary tract infection (UTI) in females and people assigned female at birth (AFAB), aged 16 years to 64 years
Criteria for inclusion	• Informed consent • Non-pregnant females and people assigned female at birth (AFAB) aged 16 years to 64 years requiring treatment for a lower urinary tract infection, presenting with **two or more of the following symptoms***: - dysuria (burning pain when passing urine) - new nocturia (passing urine more often than usual at night) - urine cloudy to the naked eye • Patient is registered with a GP in the United Kingdom and gives permission to share relevant information with the GP and other health care professionals. *as per Diagnosis of urinary tract infections - Quick reference tool for primary care Women (under 65 years) with suspected UTI flowchart (page 6)
Exclusion criteria	• Consent not obtained (if capacity is a problem, refer to GP) • Males or people assigned male at birth (AMAB) • Under 16 years of age • 65 years of age or over • Known hypersensitivity to nitrofurantoin, other nitrofurans, or any of the components within the formulation - see Summary of Product Characteristics • Known or suspected pregnancy (refer to GP - 7 day course required in pregnancy) • Breastfeeding patients who are less than 1 month postpartum or who are breastfeeding an infant of any age with a known or suspected erythrocyte enzyme deficiency (including G6PD deficiency) • Catheterised patients • History of raised temperature, fever or chills within past 48 hours • Patients with symptoms which could indicate severe/life-threatening infection or sepsis e.g. significant flank pain, fever, chills, rigors, confusion, cyanosis of skin, lips or tongue, vomiting – **urgently refer to A & E** **THINK SEPSIS** - check for signs and symptoms using a recognised tool e.g. NICE - Sepsis: Risk stratification tools • Any individual identified with symptoms of pyelonephritis but not systemically unwell should be referred to a prescriber urgently for same day assessment and management. Signs of pyelonephritis include:

Exclusion criteria (continued)	○ kidney pain/tenderness in back under ribs ○ new/different myalgia, flu like illness ○ shaking chills (rigors) or temperature 37.9°C or above ○ nausea/vomiting • Abnormal vaginal discharge • Sexually transmitted infections • Urethritis inflammation post intercourse or associated with use of irritants • Genitourinary symptoms of menopause (vulvovaginal atrophy) • Individuals already taking prophylactic antibiotics for UTI • Failed previous antibiotic for this episode of UTI • Recurrent UTI (>2 in 6 months, >3 in 12 months) • Treatment for UTI with any antimicrobial in the past 3 months. • Known previous nitrofurantoin resistant UTI (recorded in accessible information e.g. SCR, clinical record if available) **OR** known previously resistant UTI to **any** antibiotic self-reported by the individual where records not available • Hospitalisation in a foreign country within last 3 months • Care home resident • Urological abnormalities or previous urological surgery • UK hospitalisation for > 7 days in last 6 months • Individuals with known or suspected: ○ G6PD deficiency ○ Renal stones or colic ○ Porphyria ○ Diabetes mellitus (Type 1 or 2) ○ Renal impairment (eGFR < 45ml/min/1.73m^2) – see MHRA guidance in references ○ Hepatic impairment ○ Pulmonary disease (including COPD, emphysema, chronic bronchitis) ○ Neurological disorders (including peripheral neuropathy) ○ Blood disorders or dyscrasias (including anaemia and folate deficiency) ○ Vitamin B deficiency ○ Electrolyte imbalance ○ Treatment for HIV ○ Significant immunosuppression ○ Malignancy • Patients receiving treatment with the following: ○ Dapsone, topical prilocaine (e.g. EMLA®) - predicted to increase the risk of methaemoglobinaemia ○ Probenecid, sulphinpyrazone (decreased renal excretion of nitrofurantoin) ○ Carbonic anhydrase inhibitors i.e. acetazolamide (decreased antibacterial activity by urine alkanisation) ○ Quinolone antibiotics eg ciprofloxacin ○ Oral typhoid vaccine: avoid nitrofurantoin for 3 days before and after (antibacterials inactivate oral typhoid vaccine)

Caution	• Visible haematuria – treat for UTI but inform to see clinician if haematuria continues after treatment • Allergic diathesis/allergic conditions • Consider drug interactions - refer to BNF and SPC for full details. • Amiodarone, isoniazid, lamivudine, metronidazole, phenytoin, stavudine — can increase risk of peripheral neuropathy. • Magnesium trisilicate or calcium salt-based antacids (reduced absorption of nitrofurantoin) • OTC cystitis treatments or alkalinising agents (e.g. potassium citrate) can reduce nitrofurantoin efficacy (due to reduced pH of the urine). • Oral hormonal contraception — additional contraceptive precautions are not required during or after courses of nitrofurantoin. However, patients should be advised about the importance of correct contraceptive practice if they experience vomiting or diarrhoea. • Nitrofurantoin can interfere with some tests for glucose in the urine. • Breastfeeding – refer to the Specialist Pharmacy Service for further guidance Nitrofurantoin – Medicines – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
Action if excluded	• Document reason for exclusion and any action taken or advice given in the clinical records • Provide advice on alternative non-antibiotic treatment and safety netting advice using TARGET leaflet • Refer to a prescriber if antibiotic appropriate but falls outside of this PGD • **Refer urgently to a prescriber if:** - individual immunocompromised - fever present or systemically unwell and/or symptoms of upper UTI or pyelonephritis • **If sepsis or life threatening illness is suspected – urgently refer to A&E**
Action if patient refuses medication	• Document on clinical record and refer to GP or for urgent medical attention as appropriate • Provide safety netting advice and advise on alternative treatment available using TARGET leaflet

2. Characteristics of Staff

Professional qualification to be held by staff working under this Patient Group Direction	Pharmacist currently registered with the General Pharmaceutical Council (GPhC)
Additional requirements	• Must have undertaken appropriate education and training and declared themselves competent to undertake clinical assessment of patient leading to diagnosis of the condition(s) listed in this PGD. Suggested minimum recommended training is completion of the RCGP Urinary Tract Infections webinar, presentation, podcast and quiz • Must have undertaken appropriate education and training and declared themselves competent for the identification of sepsis. • Individuals operating under this PGD should be familiar with the national guidance for diagnostic (UKHSA) and management (NICE) of urinary tract infections in the UK. • Must be familiar with NICE guidance on PGDs and competent in the use of PGDs (see NICE competency framework for health professionals using PGDs). Suggested recommended training - eLfH PGD elearning programme • Must have access to the PGD and associated online resources relating to the use of the PGD • Must have access to current BNF (BNF online is recommended) • Consultation room available for discussion • CPPE level 2 Safeguarding children and vulnerable adults (including updates), or equivalent • Must have completed initial training and/or be familiar with the current service level agreement for Somerset Minor Ailments Service. • Must only use this PGD in conjunction with the Somerset Minor Ailments Service. • Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD • Staff operating under this PGD should review their competency using the NICE Competency Framework for health professionals using patient group directions • It is the responsibility of the pharmacist to keep up-to-date with their continued professional development, in line with GPhC requirements. • The pharmacist must be alert to changes in Summaries of Product Characteristics, and Drug Safety Updates from MHRA.

3. Description of Treatment

Name of Medicine	• Nitrofurantoin 100 mg MR capsules • Nitrofurantoin 50mg tablets • Nitrofurantoin 50mg capsules
Legal Class	POM (Prescription Only Medicine)
Storage	• Store in light and moisture resistant containers. • Do not store above 25°C
Method or route of administration	• Oral • Should be taken with food
Dose to be used (including criteria for use of differing doses)	• ONE 100mg MR capsules twice a day (every 12 hours) with food, for 3 days **OR** if unavailable, supply: • ONE 50mg immediate release tablet or capsule four times a day (every 6 hours) with food, for 3 days **Treatment should be started immediately and all supplied doses taken.**
Frequency	see dose above
Total dose and number of times drug to be given. Details of supply (if supply made)	• 6 x 100mg MR capsules, labelled as above **OR** • 12 x 50mg immediate release tablets or capsules, labelled as above *NB: Although NICE PGD GPG states original pack should be supplied, antibiotic stewardship is considered to be more important, and so 6 or 12 doses (depending on preparation) should be dispensed with patient information leaflet*

Advice and information to patient/carer including follow-up	• Ensure that the Patient Information Leaflet (PIL) is provided and advise the patient to read the leaflet before using the medicine. • Advise patients to read carefully the advice in the PIL about symptoms of possible pulmonary and hepatic reactions and to seek medical advice if they experience these symptoms (MHRA Drug Safety Update April 2023) – see also 'Rare but serious side-effects' below • Provide the TARGET Treating your infection – urinary tract infection (UTI) leaflet (TARGET Leaflet translations can be found here) • Advise patient of the common side-effects and also rare but serious side-effects: **Common side effects include:** • nausea • vomiting • diarrhoea • loss of appetite • headaches • dizziness • drowsiness • discoloured dark yellow or brown urine. If breastfeeding, it may colour the milk yellow - this is not significant. **Rare but serious side effects:** **Respiratory disorders –** advise to seek urgent medical advice if patient experiences trouble breathing, shortness of breath, a lingering cough, coughing up blood or mucus, or pain or discomfort when breathing. These may be symptoms of a side effect affecting the lungs. Discontinue treatment immediately with nitrofurantoin if pulmonary reactions occur. **Hepatic reactions –** advise to seek urgent medical advice if patient develops yellowing of the skin or eyes, upper right abdominal pain, dark urine and pale or grey-coloured stools, itching or joint pain and swelling. These may be symptoms of a side effect affecting the liver. **Neurological disorders –** advise to seek urgent medical advice if peripheral neuropathy develops (skin tickling, tingling, burning, pricking or numbness). Discontinue treatment immediately. A detailed list of adverse reactions is available in the SPC www.medicines.org.uk and BNF www.bnf.org • Advise patient to take nitrofurantoin with food or milk and to swallow whole without crushing or chewing. • Nitrofurantoin may cause dizziness and drowsiness. Patients should be advised not to drive or operate machinery if affected in this way until such symptoms go away. • Advise patient on self-management strategies for cystitis and urinary tract infections including maintaining a good water intake, wearing loose fitting cotton underwear, avoiding scented soap etc – also refer to TARGET leaflet

- Advise patient of the importance of completing a course of antibiotics, and the importance of taking nitrofurantoin at regular intervals.
- If dose is missed advise to refer to PIL supplied with the product.
- Advise individual to complete the full course even if symptoms improve.
- Advise that nitrofurantoin is not a penicillin related antibiotic
- Medicines which make the urine less acidic such as OTC cystitis preparations containing potassium citrate, sodium bicarbonate or sodium citrate decreases the antibacterial action of nitrofurantoin and should not be taken during the course of nitrofurantoin.
- Antacids such as magnesium trisilicate can decrease the absorption of nitrofurantoin and should not be taken during the course of nitrofurantoin.
- Paracetamol or ibuprofen (if appropriate) may be used to relieve any pain or discomfort.
- Inform patient that about 50% cases will be free of symptoms within three days even if they take no treatment.
- Symptoms should start to improve within 48 hours of taking nitrofurantoin – advise individual to seek medical advice if no improvement within 48 hours, or if symptoms worsen rapidly or significantly at any time - refer to TARGET leaflet
- If recurrence of a UTI or suspected UTI within six months; the patient should seek further medical advice from their GP or a relevant specialist.
- The nitrofurantoin supplied is for use of the patient only. It should not be shared with anyone else.
- All medicines should be disposed of in an appropriate manner i.e. unwanted and out of date medicines should be returned to a pharmacy for appropriate disposal.

Adverse effects: Adverse reaction should be documented e.g. in the consent forms, patient's clinical record and the GP should also be informed. Unusual /persistent side effects should be followed up with a medical practitioner.

Any **serious** adverse events that may be attributable to nitrofurantoin should be reported to the MHRA using the yellow card system https://yellowcard.mhra.gov.uk/ and also follow the local incident reporting procedure.

See the Summary of Product Characteristics (SPC) (http://www.medicines.org.uk/emc/) and the current edition of the BNF for full details and updates.

Specify method of recording supply /administration including audit trail	It is a legal requirement to keep auditable records of administration and supply of medication via a PGD. All records should be clear, legible and contemporaneous. All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners. Information entered into a patient clinical record should include: • Patient's name, address and date of birth • Informed consent given • Indication • Specify how the individual has/has not met the criteria of the PGD • Name, strength, form and quantity of medication supplied • Date & time of supply • Relevant past and present medical history • Documentation of cautions as appropriate • Information and advice given to the patient. • Signature/name and GPhC number of pharmacist who supplied the medication, and name and address of pharmacy • Details of any drug interactions experienced • Details of any adverse reactions experienced • Any patient decline or reason for exclusion • Any referral arrangements (including self-care) • Record that medicine supplied via Patient Group Direction • Recording of any prescription charges / exemptions • Consultation details to be recorded on PharmOutcomes (ideally at time of consultation but must be within 48 hours) A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each pharmacy. Check with employer which method of recording is to be used. The GP practice should be informed of the consultation and supply of medication (this will be done automatically via PharmOutcomes). Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

References used in the development of this PGD:	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • Urinary tract infection (lower): antimicrobial prescribing NICE guideline [NG109] Published: 31 October 2018 https://www.nice.org.uk/guidance/ng109 • PHE Diagnosis of urinary tract infections Quick reference tool for primary care https://www.gov.uk/government/publications/urinary-tract-infection-diagnosis • TARGET Antibiotic Toolkit https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/target-antibiotic-toolkit.aspx • NICE CKS Urinary tract infection (lower) – women: https://cks.nice.org.uk/topics/urinary-tract-infection-lower-women/prescribing-information/nitrofurantoin/ • 'National Institute for Health and Care Excellence. Medicines Practice Guidelines, 'Patient Group Directions' last updated March 2017. https://www.nice.org.uk/Guidance/MPG2 • MHRA Drug Safety Update 12th February 2015 Nitrofurantoin now contraindicated in most patients with an estimated glomerular filtration rate (eGFR) of less than 45 ml/min/1.73m2 - GOV.UK (www.gov.uk) • MHRA Drug Safety Update 26the April 2023 Nitrofurantoin: reminder of the risks of pulmonary and hepatic adverse drug reactions - GOV.UK (www.gov.uk) • NICE NG51 - Sepsis: recognition, diagnosis and early management • UTI Nitrofurantoin National PGD Template Jan 2023 v1.0 FINAL available at: https://www.sps.nhs.uk/articles/nitrofurantoin-for-urinary-tract-infection-uti/ • SPS National Patient Group Direction (PGD) exemplar templates – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice • NHS Choices: Urinary tract infections in adults http://www.nhs.uk/conditions/Urinary-tract-infectionadults/Pages/Introduction.aspx • NHS Somerset ICB - Management & treatment of common infections – Guidance for primary care - May 2023 Available at: https://nhssomerset.nhs.uk/prescribing-and-medicines-management/antimicrobial/ • FSRH 2019: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ and https://www.fsrh.org/blogs/myth-antibiotics-stop-combined-hormonal-contraception-from/ • Drugs & Lactation Database (LactMed) accessed 03.05.23 https://www.ncbi.nlm.nih.gov/books/NBK501053/ • The Breastfeeding Network accessed 03.05.2023 https://www.breastfeedingnetwork.org.uk/antibiotics/ • General Pharmaceutical Council standards

Please refer to the Summary of Product Characteristics for full information

This Patient Group Direction is operational from 1st July 2023 and expires 30th June 2025

Version History

Version	Date	Brief Summary of Change	Owner's Name
0.0	19/6/2017	**NHSE PGD from Sue Mulvenna reviewed and put into CCG Format**	Catherine Henley
1.0	21/6/2017	**Reviewed by Somerset CCG Prescribing and Medicines Management Group**	Catherine Henley
1.1	3/5/2019	**Content reviewed and updated**	Catherine Henley
2.0	8/5/2019	**Reviewed by Somerset CCG Prescribing and Medicines Management Group - minor amendments made**	Catherine Henley
2.1	7/8/2019	**Minor Typos corrected**	Catherine Henley
2.2	21/8/2019	**Minor Typos corrected**	Catherine Henley
3	07/05/2021	**Content reviewed and updated. CCG Logo updated. Minor formatting changes.**	Hels Bennett
3.1	21/05/2021	**PGD updated (breastfeeding) following review by Somerset CCG Prescribing & Medicines Management (PAMM) and contributions from Sam Morris**	Hels Bennett, Medicines Manager, Somerset CCG
4.0	04.05.2023	**PGD updated to ICB format. Inclusion criteria aligned with UKHSA 'Diagnosis of urinary tract infections - Quick reference tool for primary care'. PGD updated to incorporate all the specific principles for antimicrobial PGDs set out in the APRHAI-approved national template. Immediate release tablets and capsules added. Reviewed & approved by NHS Somerset Medicines Programme Board**	Hels Bennett, Medicines Manager, NHS Somerset ICB