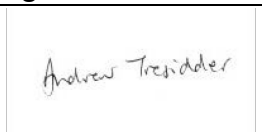
NHS
Somerset
Clinical Commissioning Group

Patient Group Direction: For the supply of Nitrofurantoin 100mg MR capsules 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 3.1)

Staff involved in the development of this PGD:

	Name	Signature	Date
Physician	Dr Andrew Tresidder Somerset CCG Prescribing and Medicines Management Group Chair		21.5.2021
Pharmacist	Hels Bennett, Medicines Manager, Somerset CCG		21.05.2021

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

Expiry Date: 30th June 2023

Authorised for use across NHS Somerset CCG Practices by:

Val Janson, Director of Quality and Nursing for NHS Somerset CCG (Acting as Clinical Governance Lead)

Signed:  **Date:**25.05.2021

Date of Implementation: 1st July 2021

TO BE COMPLETED BY PHARMACY AUTHORISING MANAGER:

I, ……, as authorising manager for …… pharmacy, have read and approved this PGD for use by appropriate healthcare professionals employed at my pharmacy. I understand that I am responsible for ensuring that pharmacy staff have adequate training to ensure that NITROFURANTOIN 100MG MR CAPSULES is supplied to patients in strict accordance with this PGD.

Signed…….. Dated……

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The healthcare professionals named below are authorised to supply Nitrofurantoin 100mg MR capsules as specified under this Patient Group Direction, being employees of …… …… (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 agree to administer/supply the above preparations in accordance with this 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	• The treatment of urinary tract infection in females aged between 16 years and 65 years.
Criteria for inclusion	• All women aged between 16 years and 65 years requiring treatment for an uncomplicated lower urinary tract infection • Informed consent obtained and documented in patient's clinical record and/or notes • Patient is registered with a GP in the United Kingdom and gives permission to share relevant information with other health care professionals.

Exclusion criteria	• Consent not obtained (if capacity is a problem, refer to GP)
	• Males
	• Under 16 years of age
	• Over 65 years of age
	• Pregnant (refer to GP - 7 day course required in pregnancy)
	• Breastfeeding women 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
	• Patients with symptoms which could indicate sepsis e.g. significant flank pain, fever, chills, rigors, confusion, vomiting – refer for urgent medical attention
	• Individuals with known or suspected
	  ○ G6PD deficiency
	  ○ Diabetes mellitus
	  ○ Renal impairment (eGFR < 45ml/min/1.73m2 – see MHRA guidance in references)
	  ○ Hepatic impairment
	  ○ Acute porphyria
	  ○ Pulmonary disease
	  ○ Neurological disorders
	  ○ Blood disorders or dyscrasias
	  ○ Treatment for HIV
	  ○ Significant immunosuppression
	• Known hypersensitivity to nitrofurantoin or any component of nitrofurantoin capsules – see SPC for full list (link in references)

Caution	• Nitrofurantoin can interfere with some tests for glucose in the urine
	• Individuals currently taking any of the following drugs:
	  ○ Probenecid
	  ○ Sulphinpyrazone
	  ○ Carbonic anhydrase inhibitors i.e. acetazolamide
	  ○ Quinolone antibiotics eg ciprofloxacin
	  ○ Magnesium trisilicate or calcium salt-based antacids (reduce absorption)
	• Refer to BNF for full list of interactions
	• Oral typhoid vaccine: avoid Nitrofurantoin for 3 days before and after
	• 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 • Refer to GP or for urgent medical attention as appropriate. • Refer to GP if patient excluded or if no valid consent
Action if patient refuses medication	• Refer to GP or for urgent medical attention as appropriate

2. Characteristics of Staff

Professional qualification to be held by staff working under this Patient Group Direction	Pharmacist registered with the General Pharmaceutical Council (GPhC) and competent to work with this patient group direction (PGD), including familiarity with NICE guidance on PGDs (see references).
Additional requirements	• 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. • Must have access to a current copy of the BNF • Consultation room available for discussion • The individual pharmacist's competence with respect to their practice under this PGD will be assessed by their mentor/manager on a regular basis. • 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
Legal Class	POM (Prescription Only Medicine)
Storage	• Capsules should be stored in light and moisture resistant containers. • Storage temperature should not exceed 30°C (aluminium/ aluminium). • Do not store above 25°C (For PVC/ polyethylene/aclar/aluminium blisters)
Method or route of administration	• Oral
Dose to be used (including criteria for use of differing doses)	• 100mg
Frequency	• 100mg Twice a day (every 12 hours) for three days
Total dose and number of times drug to be given. Details of supply (if supply made)	• 6 capsules, labelled as above for three days treatment *NB: although NICE PGD GPG states original pack should be supplied, antibiotic stewardship is considered to be more important, and so 6 capsules 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 and that the pharmacy can be contacted if any queries arise. • Advise patient that nitrofurantoin can colour the urine yellow or brown. If breastfeeding, it may colour the milk yellow. This is not significant. • Advise patient to take nitrofurantoin with food and to swallow the capsules 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 of loose fitting clothes/underwear, wearing cotton underwear, and avoidance of vaginal douches/deodorants etc. • Advise patient of the importance of completing a course of antibiotics, and the importance of taking Nitrofurantoin at 12 hourly intervals. • If during treatment the symptoms worsen, the patient experiences significant flank pain, becomes systemically unwell, or develops a fever the patient should seek further medical advice. • If no improvements in symptoms have been observed after three days of treatment, the patient should seek further medical advice. • Recurrence of a UTI or suspected UTI within six months; the patient should seek further medical advice from their GP or a relevant specialist. • Drinking potassium citrate mixture or similar products are often recommended to reduce the symptom of 'burning urine.' Such products are available 'over-the-counter.' • Paracetamol or ibuprofen (if appropriate) may be used to relieve any pain or discomfort. • Inform patient that about half of women with cystitis will be free of symptoms within three days even if they take no treatment. • Treatment should be stopped at the first sign of neurological involvement i.e. paraesthesiae (skin tickling, tingling, burning, pricking, or numbness) • The nitrofurantoin capsules 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:** Any serious adverse reaction should be documented e.g. in the consent forms, patient's medical record and the GP should also be informed. Unusual /persistent side effects should be followed up with a medical practitioner. The following are well known side effects of nitrofurantoin; See SPC and the current edition of the BNF for full details and updates. • Acute pulmonary reactions which are reversible with cessation of therapy; symptoms include fever, chills, cough, chest pain, dyspnoea; • Peripheral neuropathy (including optical neuritis) with symptoms of sensory as well as motor involvement, which may become severe or irreversible, has been reported infrequently; • Allergic skin reactions: angioneurotic oedema, maculopapular, erythematous or

eczematous eruptions, urticaria, and pruritus;
- Hepatic reactions including cholestatic jaundice and chronic active hepatitis occur rarely;
- Nausea and anorexia; emesis, abdominal pain and diarrhoea are less common gastrointestinal reactions; Advise that gastrointestinal reactions may be minimised by taking the drug with food or milk,
- Blood dyscrasias which generally return to the normal blood picture with cessation of therapy;

Any **serious** adverse events that may be attributable to nitrofurantoin MR capsules 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. Inform the patient of the possible side-effects and their management (see SPC, current BNF and “Adverse reactions” section above);

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. Information entered into a patient clinical record should include: • Patient's name, address and date of birth • Consent given • Indication • Name strength form and pack size of medication supplied • Date supplied • 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 • Record that medicine supplied via Patient Group Direction A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each practice. Check with employer which method of recording is to be used. The GP practice should be informed of the consultation and supply of medication. Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

References used in the development of this PGD:	• BNF SPC References for nitrofurantoin 100mg MR capsules. Latest versions on electronic Medicines Compendium accessed www.medicines.org.uk • Current edition of British National Formulary (BNF) • General Pharmaceutical Council standards • '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 on nitrofurantoin September 2014 http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON452539 • NHS Choices: Urinary tract infections in adults http://www.nhs.uk/conditions/Urinary-tract-infectionadults/Pages/Introduction.aspx • NHS Somerset CCG - Management & treatment of common infections – Guidance for primary care May 2021 https://www.somersetccg.nhs.uk/wp-content/uploads/2021/04/Managing-common-infections-Guidance-for-Primary-Care-May-21-v1.1.pdf • Drugs & Lactation Database (LactMed) accessed 20.05.21 https://www.ncbi.nlm.nih.gov/books/NBK501053/ • The Breastfeeding Network accessed 20.05.2021 https://www.breastfeedingnetwork.org.uk/antibiotics/

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 1st July 2021 and expires 30th June 2023

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