Cornwall and Isles of Scilly

Patient group direction for the supply of Nitrofurantoin M/R capsules by community pharmacists for the management of uncomplicated urinary tract infections

Documentation details

Reference no: PGD07
Version no: 13
Valid from: April 2023
Review date: December 2024
Expiry date: March 2025

Change history

Version number	Date	Details
12	April 2021	• Feedback from Paige Trethewey and Andree Evans. • Clarification on when to refer to emergency department 999 for sepsis or pyelonephritis women who have been in hospital for more than 7 days in the last 6 months. • Family history of urinary tract disease such as polycystic kidney disease. • Travel abroad.
13	December 2022	• Transfer to ICB stationery • Renumber to PGD07 • Review of PGD • Updates to exclusion criteria, cautions and written information and advice to patients to comply with recommendations of NHS England risk assessment framework for the supply of antimicrobials under PGD. • References expanded and updated

Patient group direction development

Date template comes into effect: April 2023
Version no: 13
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Patient group direction working group

This patient group direction (PGD) was developed by a working group involving pharmacists from NHS Cornwall and Isles of Scilly integrated care board (CIOS ICB), GP clinical leads from CIOS ICB and microbiology.

Name and role	Job title	Organisation
Mr M Wilcock Pharmacist	Head of prescribing support unit and clinical lead	Royal Cornwall Hospitals NHS Trust (RCHT) and Cornwall and Isles of Scilly ICB
Marco Motta Pharmacist	Interim head of prescribing and medicines optimisation	Cornwall and Isles of Scilly ICB
Andree Evans Microbiologist	Microbiologist	RCHT
Chris Burgin (reviewer) Pharmacist	Pharmaceutical advisor	Cornwall and Isles of Scilly ICB

Based on the previous version commissioned by NHS Kernow Clinical Commissioning Group and authored by Fiona Lee with contributions from Georgina Praed, Amanda Pell and Paige Trethewey.

Organisational authorisations

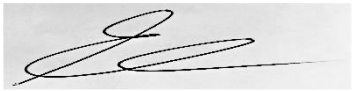
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

CIOS ICB authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services:
Community pharmacies contracted to provide the CIOS ICB community pharmacy PGD service for minor ailments.

Limitations to authorisation: None.

Approved by	Name	Date of email approval
CIOS ICB interim head of prescribing and medicines optimisation	Marco Motta 	28 February 2023
CIOS ICB chief medical officer	Chris Reid	Approved by email 26 February 2023
CIOS ICB chief nursing officer	Susan Bracefield 	7 March 2023
Consultant microbiologist	Andree Evans	Approved by email 28 February 2023

Local enquiries regarding the use of this PGD may be directed to ciosicb.prescribing@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets and templates may be used where appropriate in accordance with local policy.

Characteristics of staff

Qualifications and professional registration

Registered professional with one of the following bodies:

- Pharmacists registered with the General Pharmaceutical Council (GPhC)

Initial training

- Must be authorised by name as an approved practitioner under the current terms of this PGD before working to it.
- Has undertaken appropriate training and been assessed and declared competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD.
- Must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs).
- Must have access to the PGD and associated online resources.

Competency assessment

All pharmacists operating under this PGD are required to complete a declaration of competence for minor ailments via the Centre Pharmacy Postgraduate Education (CPPE) website and complete the declaration of competence on PharmOutcomes.

Staff operating under this PGD are encouraged to review their competency using the NICE competency framework for health professionals using PGDs.

Staff operating under this PGD are encouraged to attend specific commissioning organised training events on minor ailments and complete the CPPE common clinical conditions and minor ailments and e-assessment.

Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD.

Ongoing training and competency

Practitioners must ensure they are up to date with relevant issues and clinical skills relating to the management of urinary tract infections, with evidence of appropriate continued professional development (CPD).

The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.

Clinical condition or situation to which this PGD applies

Condition or situation: Treatment of uncomplicated urinary tract infections (UTI) in women.

Criteria for inclusion

Women aged 16 years and over and under 65 presenting with 2 or more of the following symptoms:

- Dysuria
- New nocturia
- Urine which is cloudy to the naked eye

Criteria for exclusion

- Patients assigned as male at birth
- All female patients under 16 years of age
- All female patients 65 years of age and over
- Previous treatment with any antimicrobial for UTI, including trimethoprim or nitrofurantoin, in the last 3 months
- Known allergy to nitrofurantoin or any excipient in the product to be supplied
- Women who refuse treatment or no consent or the inability to successfully undertake the clinical assessment
- Women who have had 2 or more urinary tract infections within the past 6 months or more than 3 during the previous 12 months
- Women presenting with symptoms of serious illness including pyelonephritis or sepsis such as, haematuria, fever, significant flank pain, kidney pain, loin pain, tenderness under the ribs, new or different flu like illness, high temperature, chills, rigors, nausea, vomiting, headache or altered mental state require immediate referral
    - THINK SEPSIS – check for signs and symptoms using a recognised tool such as the NICE algorithm
    - THINK PYELONEPHRITIS – check for signs and symptoms; see the NICE CKS for more details
- Women presenting with symptoms that could indicate malignancy such as weight loss, unexplained bleeding, persistent or frequent abdominal pain, or new lumps
- Pregnant or potentially pregnant - symptoms of a UTI could indicate an ectopic pregnancy: consider advising carrying out a pregnancy test if unsure

- Breastfeeding women
- Women currently on a course of antibiotics
- Women with associated vaginal discharge or urethral discharge, irritation or skin rash which may indicate a cause other than UTI
- Women who have visible haematuria with the naked eye.
- Women with urethritis inflammation post intercourse or associated with use of irritants or physical activity (such as cycling)
- History of sexually transmitted diseases.
- Diabetes mellitus
- Known renal disease with eGFR <45ml/min
- History of renal stones or bladder stones or renal colic
- Family history of urinary tract disease such as polycystic kidney disease
- Blood disorders or dyscrasias (G6PD deficiency specifically)
- Women who have any urological abnormalities or had surgery involving the lower urinary tract
- Women with an indwelling catheter or intermittent self-catheterisation
- Hepatic impairment
- Dermatological conditions such as psoriasis, irritant or contact dermatitis
- Spondyloarthropathies such as reactive arthritis or Bechet's syndrome:
    - reactive arthritis is a condition that causes redness and swelling (inflammation) in various joints in the body, especially the knees, feet, toes, hips and ankles
    - Bechet's syndrome which is a rare disease characterised by painful mouth ulcers, genital ulcers, eye problems and skin lesions
- Pulmonary disease such as chronic obstructive pulmonary disease (COPD), emphysema or chronic bronchitis
- Acute porphyria
- Treatment for HIV
- Significant immunosuppression
- Neurological disorders (including peripheral neuropathy)
- Women who have been in hospital for more than 7 days in the last 6 months.
- Women taking any of the following medicines:
    - Probenecid or sulphinpyrazone – reduce the excretion of nitrofurantoin
    - Carbonic anhydrase inhibitors for example acetazolamide – decrease anti-bacterial activity
    - Amiodarone, isoniazid, lamivudine, metronidazole, phenytoin or stavudine — can increase risk of peripheral neuropathy.
    - Dapsone or topical prilocaine –predicted to increase the risk of methaemoglobinaemia)
    - Oral typhoid vaccine for 3 days before and after treatment – antibacterial drugs inactivate oral typhoid vaccine

Cautions including any relevant action to be taken

- Patients with an underlying condition which may reduce renal function. This includes patients with:
    - Hypertension
    - Heart disease
    - Renal disease
- Concomitant use of medication that can adversely affect renal function, such as ACE inhibitors and diuretics.

- For these groups of patients, the pharmacist should check if the patient has had a recent renal function test and also advised that this test result was satisfactory. Test result should be >45ml/min.
    - If this information is not available for this particular group of patients, the pharmacist should consider if the patient should be excluded and referred to their GP.
- Concomitant use of:
    - Medication such as cyclophosphamide, opioids, and nifedipine which can cause urinary tract symptoms.
    - Magnesium trisilicate (decreased absorption of nitrofurantoin)
    - Over the counter (OTC) cystitis treatments or any other alkalinising agents which can reduce the effectiveness of nitrofurantoin
- Patients need not be excluded from treatment via PGD but caution is needed if patients are using or have taken above treatments. Patients should be advised not to take alkalinising agents whilst taking nitrofurantoin.
- Patients need not be excluded from treatment via PGD if they have travelled abroad but caution is needed if patients have travelled to countries where there is a potential risk of resistant urinary tract infection.

Action to be taken if the patient is excluded

- Record reasons for exclusion and any action(s) taken.
- Advise patient on alternative treatment.
- Call 999 or refer to emergency department if suspected sepsis symptoms such as confusion, difficulty breathing, slurred speech, chest pain, cold extremities, lack of urinary output.
- If pyelonephritis without sepsis suspected with symptoms such as haematuria, fever, significant flank pain, kidney pain, loin pain, tenderness under the ribs, refer urgently to GP or emergency department.
- Refer to a prescriber if appropriate (for example GP or NHS111 or out of hours (OOH) services).
- Give safety-netting advice.

Action to be taken if the patient or carer declines treatment

- Document advice given and the decision reached.
- Advise patient on alternative treatment if appropriate.
- Refer to a prescriber if appropriate.
- Give safety-netting advice.

Arrangements for referral for medical advice

Advise patient to refer to their GP practice, if symptoms persist or there is no improvement following completion of the treatment or if condition worsens.

Description of treatment

Name, strength and formulation of drug

Nitrofurantoin 100mg modified release capsules (Macrobid).

Legal category

Prescription only medicine (POM).

Route and method of administration

Oral.

Indicate any off-label use (if relevant)
Not applicable.

Dose and frequency of administration
1 x 100mg capsule by mouth every 12 hours for 3 days with food.

Duration of treatment
3 days.

Quantity to be supplied
6 doses of capsules.

Storage
- Stock must be stored in conditions in line with Summary Product Characteristics (SPC), which is available from the electronic medicines compendium website.
- Do not store above 25ºC.
- Capsules should be stored in light and moisture resistant containers.
- Storage temperature should not exceed 30°C.

Drug interactions
The SPC is available from the electronic medicines compendium website which lists the following interactions with other medicinal products and other forms of interaction:
- Increased absorption with food or agents delaying gastric emptying.
- Decreased absorption with magnesium trisilicate.
- Decreased renal excretion of nitrofurantoin by probenecid and sulfinpyrazone.
- Decreased anti-bacterial activity by carbonic anhydrase inhibitors and urine alkalisation.
- Anti-bacterial antagonism by quinolone anti-infectives.
- Interference with some tests for glucose in urine.
- As nitrofurantoin belongs to the group of antibacterials, it will have the following resulting interactions:
- typhoid vaccine (oral): antibacterials inactivate oral typhoid vaccine

Increased risk of adverse reactions
The NICE CKS UTI (lower) – women advises:
- Amiodarone, isoniazid, lamivudine, metronidazole, phenytoin, stavudine: can increase risk of peripheral neuropathy
- Dapsone, topical prilocaine: predicted to increase the risk of methaemoglobinaemia

Identification and management of adverse reactions
A detailed list of adverse reactions is available in the SPC, which is available from the electronic medicines compendium website.

Management of and reporting procedure for adverse reactions
- Healthcare professionals and patients or carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.
- Record all adverse drug reactions (ADRs) in the patient's medical record (and inform the patient's GP).
- Report via organisation incident policy.

Written information to be given to patient or carer

- The marketing authorisation holder's patient information leaflet provided with the product if treatment is to be supplied and advise patient to read the leaflet
- The treat antibiotics responsibly, guidance, education, tools (TARGET) “Treating your infection – Urinary Tract Infection (TYI-UTI)” leaflet for women under 65 years

Patient advice and follow up treatment

- If symptoms worsen and become indicative of sepsis, call 999 or refer to emergency department
- If unacceptable side effects occur, advise patient to discontinue taking the nitrofurantoin immediately and seek medical advice. Unwanted medication should be returned to a pharmacy for safe disposal.
- If symptoms do not respond within 48 to 72 hours the patient should make an appointment to see their GP and take an early morning midstream urine sample to this appointment.
- Encourage patients to see their GP if symptoms persist or do not improve as this could be a sign of bladder cancer (especially in patients 45 years and over with visible haematuria), requiring an urgent referral.
- Persisting symptoms depending on age of the patient could also be possible genitourinary symptoms of the menopause.
- If symptoms are mild, advise patients to watch and wait and keep hydrated.
- Inform patients that about half of women with cystitis will be free of symptoms within three days even if they take no treatment.
- Paracetamol or ibuprofen (as clinically appropriate) can be taken to alleviate symptomatic pain or discomfort
- If the patient is allergic to penicillin, reassure that nitrofurantoin is not a penicillin antibiotic.
- Advise patients to take medication at regular intervals and complete the 3 day course even if original infection appears to be better.
- Advise patients that if a dose is missed, they should take the dose when they remember unless it is nearly time for the next dose. In such cases, advise patients leave out the missed dose and take the next one at the usual time. Patients should not take a double dose to make up for missed doses.
- Capsules should be swallowed whole with a glass of water.
- Capsules should be taken with food and/or milk.
- Advise patients that nitrofurantoin may colour their urine yellow or brown
- Whilst there is no interaction between alcohol and nitrofurantoin, alcohol can irritate the bladder and is best avoided until the infection is resolved.
- There is no interaction between nitrofurantoin and oral hormonal contraception, thus additional contraceptive precautions are not required during or after the course of treatment. However, women should be advised about the importance of correct contraceptive practice if they experience vomiting or diarrhoea (see CKS for progesterone-only pill or CKS for combined oral contraceptives).
- Advise on personal hygiene.
- Encourage patient to maintain a high fluid intake (6 to 8 glasses of clear fluids each day).
- Mild side effects may be experienced; these may include stomach upset, nausea and vomiting.
- Advise patient that nitrofurantoin can colour the urine yellow or brown.
- Treatment should be stopped at the first sign of neurological involvement for example paraesthesiae (skin tickling, tingling, burning, pricking or numbness) and patients should make an appointment to see their GP.
- Treatment should be stopped and patients should seek medical advice if they develop:
    - cough, chest pain, dyspnoea, fever or chills.

    - allergic skin reactions including urticarial and pruritus.
    - jaundice or pale stools (rare side effect).
- Treatment may cause drowsiness or dizziness; if affected, do not drive or operate machinery until symptoms have gone.

Records

- Completion of PGD checklist on PharmOutcomes.
- Completion of patient medication record (PMR).
- Label the pack being supplied appropriately:
    - Dose, form and route of supply or administration
    - Quantity supplied or administered
    - Supplied via PGD
- Record details of any adverse drug reactions and actions taken.
- Referral arrangements (including self-care).
- Batch number and expiry date (if applicable).
- Completion of consent form and completion of the audit claim on PharmOutcomes.
- Records should be signed and dated (or a password controlled e-records).
- All records should be clear, legible and contemporaneous.
- A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Audit trail

- PMR entry.
- Patient's GP should be notified using the notification form on PharmOutcomes within 48 hours of supply for inclusion in the patients notes.

Key references

- Public Health England diagnosis of urinary tract infections quick reference tool
- NICE UTI (lower) antimicrobial prescribing visual summary
- NICE guideline [NG109]: urinary tract infection (lower): antimicrobial prescribing
- NICE CKS: urinary tract infection (lower) - women
- NHS conditions: urinary tract infection in adults
- Nitrofurantoin MR capsules (MacroBiD) SPC
- MRHA drug safety update September 2014: Nitrofurantoin now contraindicated in most patients with an estimated glomerular filtration rate (eGFR) of less than 45 ml/min/1.73m2
- CIOS ICB management of infection guidelines
- TARGET antibiotic toolkit
- Electronic medicines compendium BNF
- Sepsis Alliance
- NHS conditions: sepsis
- NHS conditions: reactive arthritis
- NHS conditions: Bechet's syndrome
- NICE CKS: progesterone-only pill
- NICE CKS: combined oral contraceptives
- FRSH CEU guidance: drug Interactions with hormonal contraception (May 2022)
- NICE guideline [NG12]: suspected cancer recognition and referral
- NICE medicines practice guidance: patient group directions
- Specialist Pharmacy website

All last accessed January 2023

Registered health professional authorisation sheet

PGD: Supply of Nitrofurantoin M/R Capsules by community pharmacists in the management of uncomplicated urinary tract infections

Valid from: 1 April 2023
Expiry: 31 March 2025

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Authorisation

By signing this patient group direction, you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.