NHS
Kernow
Clinical Commissioning Group

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

Documentation details

Reference no: Nitrofurantoin M/R capsules patient group direction
Version no: 12
Valid from: April 2021
Review date: December 2022
Expiry date: March 2023

Change history

Version number	Date	Details
11		• New template format Main changes listed below • Age range change to aged 16 years and over and under 65 • Further clarification for pregnancy • Updated for dermatological conditions and Spondyloarthropathies • New drug interactions added

Version number	Date	Details
12		• 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.

Patient group direction development

Date template comes into effect: April 2021
Version no: 12
Valid from: April 2021
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Patient group direction working group

This patient group direction (PGD) was developed by a working group involving pharmacists from NHS Kernow Clinical Commissioning Group (NHS Kernow), GP clinical leads from NHS Kernow and microbiology.

Name and role	Job title	Organisation
Fiona Lee Pharmacist and author	Pharmaceutical advisor	NHS Kernow
Georgina Praed Pharmacist	Head of prescribing and medicines optimisation	NHS Kernow
Amanda Pell Pharmacist	Senior pharmaceutical advisor	NHS Kernow
Mr M Wilcock Pharmacist	Head of prescribing support unit and clinical lead	Royal Cornwall Hospitals NHS Trust (RCHT) and NHS Kernow
Marco Motta Pharmacist	Pharmaceutical advisor	NHS Kernow
Paige Trethewey Pharmacist	Pharmaceutical advisor	NHS Kernow
Andre Evans Microbiologist	Microbiologist	RCHT

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.

NHS Kernow 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 NHS Kernow community pharmacy PGD service for minor ailments.

Limitations to authorisation: None.

Approved by	Name	Date of email approval
NHS Kernow head of prescribing and medicines optimisation	Georgina Praed	04 March 2021
NHS Kernow GP prescribing lead	Iain Chorlton	04 March 2021
NHS Kernow director of clinical and corporate affairs	Natalie Jones	04 March 2021

Local enquiries regarding the use of this PGD may be directed to kccg.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

- All men.
- 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 of its components or allergic tendencies.
- 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 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.
- 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.
- Any woman taking any of the following medicines: probenecid, sulphinpyrazone, carbonic anhydrase inhibitors for example acetazolamide.
- Amiodarone, isoniazid, lamivudine, metronidazole, phenytoin, stavudine — can increase risk of peripheral neuropathy.
- Dapsone, topical prilocaine (predicted to increase the risk of methaemoglobinaemia).
- Typhoid vaccine oral (antibacterial drugs inactivate oral typhoid vaccine) for 3 days before and after treatment.

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.

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.

Oral contraceptive treatments: additional contraceptive precautions are not required during or after courses of nitrofurantoin for patients taking oral contraception. However, women should be advised about the importance of correct contraceptive practice if they experience vomiting or diarrhoea. For further information, see the sections on vomiting or diarrhoea in the clinical knowledge summary (CKS) topics on combined hormonal methods and progestogen-only methods.

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 if suspected sepsis symptoms such as confusion, difficulty breathing, slurred speech, chest pain, cold extremities, lack of urinary output.
- If possible, 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
Nitrofurantoin 100mg modified release capsules are prescription only medicines (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:

1. Increased absorption with food or agents delaying gastric emptying.
2. Decreased absorption with magnesium trisilicate.
3. Decreased renal excretion of Nitrofurantoin by probenecid and sulfinpyrazone.
4. Decreased anti-bacterial activity by carbonic anhydrase inhibitors and urine alkalisation.
5. Anti-bacterial antagonism by quinolone anti-infectives.
6. Interference with some tests for glucose in urine.
7. 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

Give the treat antibiotics responsibly, guidance, education, tools and 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.

Patient advice and follow up treatment

- If unacceptable side effects occur, advise patient to discontinue taking the nitrofurantoin immediately and seek medical advice.
- 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.
- Advise patients to take medication at regular intervals and complete the 3 day course even if original infection appears to be better.
- Capsules should be swallowed whole with a glass of water.
- Capsules should be taken with food and/or milk.
- 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 cough, chest pain, dyspnoea, fever or chills develop.
- Treatment should be stopped if patients suffer from allergic skin reactions including urticarial and pruritus.
- Treatment should be stopped if patients suffer from 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 CKS urinary tract infection (lower) - women
- NHS urinary tract infection in adults
- Nitrofurantoin 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
- NHS Kernow management of infection guidelines
- TARGET antibiotic toolkit
- Electronic medicines compendium BNF
- Sepsis Alliance

- NHS conditions sepsis
- NHS conditions reactive arthritis
- NHS conditions behcets syndrome
- NICE guideline NG12 suspected cancer recognition and referral
- NICE medicines practice guideline PGD
- Specialist Pharmacy website

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 2021
Expiry: 31 March 2023

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
Click here to enter text.			
Click here to enter text.			
Click here to enter text.			
Click here to enter text.			

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