Patient Group Direction (PGD) for the Supply of

Nitrofurantoin for uncomplicated Urinary Tract Infections in females aged 16 years and over but under 65 years by community pharmacists accessing UTI PGD NHS Service in North East North Cumbria with

Newcastle Gateshead CCG acting as lead commissioner for NENC

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

Direction Number: - **PGD-03**

Valid from: 01 03 2022

Review date: 01 09 2023

Expiry date: 31 03 2024

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Head of Services & Support for North of Tyne Local Pharmaceutical Committee	Ann Gunning MRPharmS		31/03/2022
Regional Antimicrobial Stewardship Lead North-East & Yorkshire Region	Prof Philip Howard OBE		31/03/2022
Medical Director NHS Newcastle Gateshead CCG	Dr Dominic Slowie		31/03/2022

This PGD has been approved for use across NENC ICB:				
Title	Name	Signature	Date	Organisation
Medical Director	Dr Janet Walker		12/06/2023	North East and North Cumbria Integrated Care Board
Director of Medicines and Pharmacy	Ewan Maule		12/06/2023	North East and North Cumbria Integrated Care Board

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

Treatment of uncomplicated lower urinary tract infection in females aged 16 years and over but under 65 years of age

Objectives of care

To allow treatment of included women by community pharmacists without the need for a prescription or the need to attend another service to obtain a prescription

Inclusion criteria

Healthy, non-pregnant women aged 16-64 years, presenting with:

- Two or more of the 5 key diagnostic signs or other severe urinary symptoms below:
    - dysuria (burning pain when passing urine)
    - nocturia (passing urine more often than usual at night)
    - Urgency
    - Frequency
    - Visible haematuria
- And a positive dipstick test for nitrites

Note: Use dipstick tests for women presenting for treatment in line with updated SIGN guideline sign-160-qrg-uti_web-version.pdf

Exclusion criteria (Refer to current SPC)

- Only one of the key diagnostic symptoms
- Two or more of the key diagnostic symptoms AND a negative dipstick test for nitrites
- Male
- Under 16 years of age
- Patients aged 65 years and over
- Immunocompromised complex multiple morbidities
- Patients currently taking oral antibiotics
- Consider pyelonephritis and refer immediately if suspected:
    - Kidney pain/ tenderness in back under the ribs
    - New / different myalgia, flu like illness
    - Shaking, chills (rigors), temperature 37.9˚C or above
    - Nausea and vomiting
- Elderly patients with confusion suggestive of UTI
- Known hypersensitivity to nitrofurantoin
- Exclude vaginal and urethral causes of urinary symptoms:

- Vaginal discharge
- Urethritis
- Exclude STIs
- Genitourinary syndrome of menopause

• Acute porphyria
• UTI treated with antibiotics within previous 4 weeks
• More than two episodes of UTI treated under this PGD within previous 12 months
• Catheterised patients
• Haematuria only
• Blood dyscrasias (G6PD deficiency specifically)
• Pregnancy and breast feeding
• Moderate to severe renal impairment (eGFR <45 ml/min/1.73m^2) – also see precautions section below
• Pulmonary disease
• Peripheral neuropathy
• History of kidney stones/renal colic
• Concomitant use of medication that has a clinically significant interaction with nitrofurantoin.

THINK SEPSIS – check for signs/ symptoms using local / national tool e.g. NICE or NEWS2

For a comprehensive list of interactions, please refer to SPC or BNF

Precautions

Patients with an underlying condition that may reduce renal function. This includes patients with the following conditions:

• Diabetes
• Hypertension
• Heart disease
• Known renal dysfunction
• Concomitant use of medication that can adversely affect renal function, such as ACE inhibitors and diuretics.

For these groups of patients, the pharmacist should establish if the patient has had a recent renal function test, and that the eGFR level is above 45 ml/min/1.73m^2. If this information is not available, the patient should be excluded under this service and referred to their Primary Care Clinician.

Please refer to current BNF BNF Online - BNF Publications and SPC for full details Home - electronic medicines compendium (emc)

Action if excluded

- If patient has only one key diagnostic symptom, provide self-care advice and advise the patient to return if further symptoms develop
- If patient has two or more key diagnostic symptoms AND has a negative dipstick test for nitrites, refer to the patient's own GP or urgent treatment centre to consider sending a urine specimen for culture to inform the diagnosis
- If patient meets exclusion criteria, refer to a Primary Care Clinician. In hours contact own GP and out of hours see PharmOutcomes module for list of urgent treatment centres. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination.
- If pyelonephritis or sepsis is suspected, urgent referral to seek medical advice is required
- Record the reason for exclusion and any action taken on PharmOutcomes.

Circumstances in which further advice should be sought from doctor

For excluded patients who have been referred, ensure the following details are recorded on PharmOutcomes:

- The advice given by the pharmacist; both written via patient leaflet and verbal advice recorded as given.
- Details of any referral made

Action if patient declines treatment

If patient declines treatment provide safety netting advice:

- Seek medical attention immediately if condition deteriorates and/or patient becomes systemically unwell
- Seek medical attention if there is little improvement after 3 days of treatment

If patient declines treatment or advice, ensure the following details are recorded on PharmOutcomes:

- The safety netting advice given by the pharmacist
- The intended actions of the patient (including parent or guardian)

2. Description of Treatment

Name, strength & formulation of drug

- Nitrofurantoin MR 100mg capsules
- Nitrofurantoin 50mg tablets

Legal Status:

Prescription Only Medicine (POM)

Dosage/Dose range:

First line treatment –

- Nitrofurantoin MR 100mg capsules twice daily for 3 days with food

Second line treatment – (only if above is not available)

- Nitrofurantoin 50mg tablets four times a day for 3 days with food

Duration of treatment is 3 days for all formulations

Route/Method:

Oral

Frequency of Administration:

Single course of 3 days treatment for each discrete infection

Maximum dose:

200mg daily in divided doses

Follow up treatment:

- Seek medical attention immediately if condition deteriorates and/or patient becomes systemically unwell
- Advise patient that if rash, other signs of hypersensitivity or other side effects occur, stop taking the medicine and contact their medical practitioner immediately
- Seek medical attention if there is little improvement after 3 days of treatment

3. Further Aspects of Treatment:

Relevant Warnings & Potential Adverse Effects

Relevant Warnings:

Potential Adverse Effects/ Reactions: - Nitrofurantoin may cause dizziness and drowsiness. Patients should be advised not to drive or operate machinery if affected until such symptoms stop. Discolouration of the urine to yellow or brown is common.
The following side effects have occasionally been reported. These are generally mild and reversible when nitrofurantoin is withdrawn.

- Nausea
- Vomiting
- Pruritus
- Skin rashes
- Abdominal pain and diarrhoea

Severe adverse reactions are rare, but there have been reports of the following effects:

- Acute pulmonary reactions
- Neurological effects including peripheral neuropathy
- Severe allergic skin reactions including erythema multiforme
- Haematological effects (generally reversible on cessation of treatment)

Please refer to SPC for uncommon and rare side effects Use the Yellow Card System to report adverse drug reactions directly to the MHRA. Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)

See Manufacturers SPC for full details of all potential adverse reactions
https://www.medicines.org.uk/emc/product/429/smpc
https://www.medicines.org.uk/emc/product/3601/smpc

Identification and Management of Adverse Reactions

See manufacturers Summary of Product Characteristics for details of all potential adverse reactions.

Reporting Procedure of Adverse Effects

All serious adverse reactions must be reported to MHRA via the yellow card system www.yellowcard.gov.uk.
A client presenting with a suspected serious ADR should be referred to their medical practitioner.

Advice to Patient / Carer (written)

Provide the patient with the manufacturer's Patient Information Leaflet and discuss as necessary.

- Take the MR capsules regularly at 12 hourly intervals with food and complete the course
- Tablets should be taken 6 hourly with food to minimise GI reactions
- Advise patients that discoloration of urine may occur
- Drink plenty of fluids but avoid caffeine containing and alcoholic drinks
- Try to empty the bladder when urinating
- Passing water following intercourse may also prevent recurrent attacks
- Attacks may be precipitated by the use of fragrancedproducts
- If symptoms have not improved after 3 days, advise patient to contact their Primary Care

Clinician.
• If the condition becomes recurrent, contact Primary Care Clinician for further investigation
• Advise that in 50% of cases, symptoms clear up within 3 days without treatment
• Paracetamol or ibuprofen can be taken to alleviate symptomatic pain or discomfort
• Cranberry juice and urine alkalization products are not proven to be effective.
• It is no longer necessary to use an extra method of contraception with the pill, patch or vaginal ring when taking nitrofurantoin unless the patient experiences diarrhoea and vomiting.
This change in advice comes because to date there is no evidence to prove that antibiotics (other than rifampicin or rifabutin) affect these contraceptives. This is the latest guidance from the Faculty of Sexual & Reproductive Healthcare.
• Provide TARGET leaflet – Urinary Tract Infection TYI-UTI leaflet for women under 65 years

Arrangements for Referral to Medical Advice

- Please follow standard processes for an onward referral for medical advice.

Records

• In discussion with the client enter consultation details onto the relevant module within PharmOutcomes at the time of the consultation. All consultations must be entered onto PharmOutcomes on the day that the consultation takes place.
• Details of the supply must also be made in the patients (PMR) record.
• All supplies of nitrofurantoin must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended. In addition to the above, the label must also state the words "Supplied under a PGD" to help with audit purposes.
• Electronic patient records should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old.
• If the client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes and any specific advice that has been given.
• In every case when a supply of nitrofurantoin is made in accordance with this PGD, the pharmacist must inform the patient's GP of the supply within two working days. This will be done through secure nhs.net email accounts via PharmOutcomes once the consultation data has been recorded within the specified module or via automatic MESH messaging. Where no nhs.net account is available to PharmOutcomes, the pharmacist will be informed by the system and must make alternative arrangements to send the information (within two working days).

Additional Facilities

N/A

Special Considerations / Additional Information

N/A

Reference

- SIGN 160 – Management of suspected urinary tract infection in women sign-160-qrg-uti_web-version.pdf
- BNF – Current Version
- Clinical knowledge summaries – Uncomplicated UTI (lower) women October 2020 https://cks.nice.org.uk/topics/urinary-tract-infection-lower-women/management/
- Electronic Medicines Compendium - SPC Nitrofurantoin MR caps and tablets https://www.medicines.org.uk/emc/product/429/smpc https://www.medicines.org.uk/emc/product/3601/smpc

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Occupational Therapists	Dieticians
Radiographers	Dental Hygienists	Midwives
Nurses	Speech and Language Therapists	Dental Therapists
Orthoptists	Chiropodists / Podiatrists	Ambulance Paramedics
Optometrists	Prosthetists and Orthotists	Physiotherapists
State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State or issued with his approval.		

Qualifications required (professional registration applies to specific professions)

Pharmacists using this PGD must be currently registered with their relevant professional body General Pharmaceutical Council (GPhC)

Additional requirements (applies to all staff)

Community pharmacists self-declaring competence to provide the Pharmacy UTI PGD Service via the PharmOutcomes module enrolment.

Continued training requirements (applies to all staff)

- Has a clear understanding of the legal requirements to operate a PGD.
- Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken) and the treatment itself.
- Has a clear understanding of the drug tobe administered including side effects and contraindications.
- All clinicians operating within the PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills.

Management & Monitoring of Patient Group Direction
PGD-03

Nitrofurantoin
Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring, and authorising the use of this Patient Group Direction by the named healthcare professional.

This page is to be retained by the individual healthcare professional/practitioner.

This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.

By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).

Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines, or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:

is authorised to administer

Nitrofurantoin

……under this Patient Group Direction (PGD-03)

Signature of Healthcare Professional:

Date signed:

State profession:

Authorisation to use this PGD by: -

This above-named healthcare professional has been authorised to work under this PGD by:

Name of Manager/Clinical Lead: -	Signature of Manager/Clinical Lead: -	Date signed:

PGD Valid from: 12/06/2023	Review Date:	Expiry Date:

Management & Monitoring of Patient Group Direction *PGD-03*

Nitrofurantoin

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD. The following healthcare professionals are authorised to administer

Nitrofurantoin under the Patient Group Direction (*PGD-03*)

PGD Valid from date: 12/06/2023 PGD Expiry Date:

Healthcare Professional			Authorised by:		
Name	Signature	Date	Name	Signature	Date

PGD Valid from: 12/06/2023	Review Date:	Expiry Date: