Patient Group Direction (PGD)
Supply of Nitrofurantoin for uncomplicated Urinary Tract Infections in females aged 16 years and over but under 65 years

Version Control

This document is only valid on the day it was printed

The current version of this document will be found within the PharmOutcomes module – Community Pharmacy Extended Care (Tier 1) Service 2020

Revision History

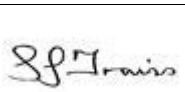
Date of this revision: 01/10/2020

Date of next revision: Jan 2021 (or in response to new local/national guidelines)

Version	Date	Author	Change description
2.1 / 2020	October 2020	Andrew Pickard	New PGD

Authorisation

This document requires authorisation by the following individuals:

Management			
PGD Author	Andrew Pickard, Pharmacy Advisor - NHS England and Improvement Midlands		
Authorisation			
Name and Designation	**Organisation**	**Signature**	**Date**
Dr Jessica Sokolov – Medical Director	NHS England and Improvement Midlands		01/10/2020
Rebecca Woods – Head of Primary Care	NHS England and Improvement Midlands		01/10/2020
Samantha Travis - Pharmacist	NHS England and Improvement Midlands		01/10/2020

CLINICAL CONTENT OF PATIENT GROUP DIRECTION
Supply of Nitrofurantoin for uncomplicated Urinary Tract Infections in females aged 16 years and over but under 65 years

Staff Characteristics	
1. Professional qualifications to be held by staff undertaking PGD	• Community pharmacists accredited by NHS England and Improvement Midlands to provide the Pharmacy Extended Care (Tier1) Service
2. Competencies required to be held by staff undertaking this PGD	• 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 to be 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.
3. Specialist qualifications, training, experience and competence considered relevant to the clinical condition treated under this PGD	• The community pharmacist must be registered with the General Pharmaceutical Council. • The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification – Pharmacy Extended Care (Tier1) Service

Clinical Details	
Indication	Treatment of uncomplicated lower urinary tract infection in females aged 16 years and over but under 65 years of age
Inclusion Criteria	Treat otherwise healthy, non-pregnant women presenting with three or more (≥ 3) of the following symptoms; • Dysuria • Urinary frequency/urgency • Lower abdominal pain • Polyuria • Haematuria Note: Vaginal discharge reduces the likelihood of the woman having a bacterial UTI. **Use dipstick tests to guide treatment decisions in otherwise healthy, non-pregnant women presenting with two or less (≤ 2) symptoms of UTI. The use of dipsticks alone can lead to false-positive results (ie. cases of asymptomatic bacteriuria)**
Exclusion Criteria	• Male • Under 16 years of age • Patients aged 65 years and over • Back or loin pain and pyrexia(fever/chills) – consider pyelonephritis and refer immediately • Elderly patients with confusion suggestive of UTI • Known hypersensitivity to nitrofurantoin • Acute porphyria • Recurrent 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 <45ml/min • Pulmonary disease • Peripheral neuropathy • History of kidney stones/renal colic • Concomitant use of medication that has a clinically significant interaction with nitrofurantoin.

	For a comprehensive list of interactions, please refer to SPC or BNF
Management of excluded clients	• If patient meets exclusion criteria, refer to a Primary Care Clinician. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. • If pyelonephritis is suspected, urgent referral to seek medical advice is required • Record the reason for exclusion and any action taken on PharmOutcomes.
Management of patients requiring referral	If patient declines treatment or advice, ensure the following details are recorded on PharmOutcomes; • The advice given by the clinician • Details of any referral made • The intended actions of the patient (including parent or guardian).

Drug Details	
Name, form & strength of medicine	• Nitrofurantoin MR 100mg capsules • Nitrofurantoin 50mg tablets
Legal classification	Prescription Only Medicine (POM)
Route/Method	Oral
Dosage/Frequency/ Duration of Treatment	First line treatment – • Nitrofurantoin MR 100mg capsules twice daily for 3 days with food Second line treatment - • Nitrofurantoin 50mg tablets four times a day for 3 days with food. Duration of treatment is 3 days for all formulations.
Quantity to supply/administer	• 6 capsules (Nitrofurantoin MR 100mg capsules), or • 12 tablets (Nitrofurantoin 50mg tablets)
Storage	Store in a dry place below 25^{o}C
Cautions	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 45ml/min. 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 http://bnf.org/bnf/ and SPC for full details http://www.medicines.org.uk/emc/**
Side Effects	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. **http://yellowcard.mhra.gov.uk/**

Drug interactions	• Antacids for indigestion (e.g. magnesium trisilicate) decrease absorption of nitrofurantoin • Oral typhoid vaccine can be inactivated by nitrofurantoin • Probenecid and sulfinpyrazone decrease renal excretion • Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine) can lead to increased absorption of nitrofurantoin. • Carbonic anhydrase inhibitors (e.g. acetazolamide) can reduce the anti-bacterial activity of nitrofurantoin • Medicines which make the urine less acidic (e.g. potassium citrate mixture) can reduce anti-bacterial activity. • Quinolones can reduce anti-bacterial activity of nitrofurantoin **Please refer to current BNF http://bnf.org/bnf and SPC www.medicines.org.uk/emc for full details**
Advice to patients	Provide the patient with the manufacturer's Patient Information Leaflet and discuss as necessary. • Take the MR capsules regularly at 12 hourly intervals if possible with food, and complete the course • Tablets should be taken 6 hourly with food to minimise GI reactions • 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 fragranced products • 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. **Please refer to current BNF http://bnf.org/bnf/ or SPC for full details http://www.medicines.org.uk/emc/**

Records and Follow Up	
Follow up	• Seek medical attention immediately if condition deteriorates and/or patient becomes systemically unwell • Advise patient that if rash or other signs of hypersensitivity occur, stop taking the medicine and contact their medical practitioner immediately • Seek medical attention if there is little improvement after 3 days of treatment
Records/audit trail	• 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 patients 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. 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).
Adverse drug reactions	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.

Date last reviewed: August 2020	**Date for next review: January 2021**
Expiry date: 31st March 2021	**Version No: 2.1 / October 2020**

References	• BNF – Current Version • Clinical knowledge summaries – Uncomplicated UTI (lower) women 2019 https://cks.nice.org.uk/urinary-tract-infection-lower-women • Staffordshire and Stoke-on-Trent antimicrobial prescribing guidelines – Managing common infections in Primary Care 2019 http://www.southstaffordshirejointformulary.nhs.uk/docs/apg/ • Microguide – Telford and Wrekin CCG Antimicrobial prescribing guidelines 2018 - https://www.telfordccg.nhs.uk/your-health/medicines-management/prescribing-guidelines/infections • 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
Glossary	BNF – British National Formulary CKS – Clinical Knowledge Summaries SPC – Summary of Product Characteristics PIL – Patient Information Leaflet PGD – Patient Group Direction PMR – Patient Medication Record POM – Prescription Only Medicine MHRA – Medicines and Healthcare Products Regulatory Agency ADR – Adverse Drug Reaction LPC – Local Pharmaceutical Committee

PGD Workgroup

The following individuals have been involved with the production and review of this PGD;

Andrew Pickard MRPharmS	Pharmacy Advisor – NHS England and Improvement Midlands
Dr Gill Hall FRPharmS	Service Development Officer – South Staffordshire LPC
Dr Tania Cork MRPharmS	Chief Operating Officer – North Staffs and Stoke LPC
Susan Bamford MRPharmS	Medicines Optimisation Senior Lead Pharmacist Staffordshire and Stoke on Trent CCGs South East Staffordshire Division
Claire Dearden	Staffordshire and Stoke on Trent CCGs Medicines Optimisation Delivery Manager
Jacqui Seaton MRPharmS	Head of Medicines Management Telford and Wrekin Clinical Commissioning Group
Simon Hay MRPharmS	Service Development Lead – North Staffs and Stoke LPC

Register of practitioners qualified to supply Nitrofurantoin for the treatment of uncomplicated Urinary Tract Infection in females aged over 16 years and under 65 yrs.

Operation of this PGD is the responsibility of the commissioner and service providers.

The practitioner must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Contractors who are commissioned to provide the service will be notified of any amendments, and provided with updated documentation for use by individual practitioners.

NHS England and Improvement authorise this PGD for use by accredited community pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by NHS England and Improvement.

This page must be completed and retained by each individual pharmacist who intends to work in accordance with this PGD.

Professional Responsibility and Declaration

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service
- I am a registered pharmacist with the General Pharmaceutical Council
- I confirm that indemnity insurance is in place to cover my scope of practice
- I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

Name of professional (please print)	Signature	Date of signing

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY