NHS
Frimley
Clinical Commissioning Group

This Patient Group Direction (PGD) must only be used by registered pharmacist who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the supply of

Nitrofurantoin 100mg MR Capsules and 50mg tablets

by registered, trained and authorised community pharmacists and locum pharmacists

For the

Treatment of uncomplicated urinary tract infections (UTI) in non-pregnant women in Frimley CCG

Version number: 1

Reference Number:FCCG001

Valid from: May 2022

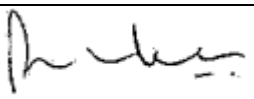
Review date: January 2024

Expiry date: May 2024

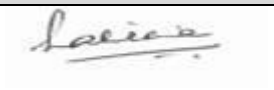
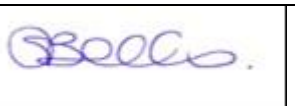
Change history

Version number	Change details	Date
1	**Created**	**December 2021**

PGD development

Name	Job title and organisation	Signature	Date
Lead doctor (or dentist)	Dr J Platt, CCG GP Prescribing Lead Frimley CCG		3/4/2022
Lead pharmacist	Melody Chapman Medicines Optimisation Pharmacist Frimley CCG		3/4/2022
Representative of other professional group using PGD	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx		xxxxxxxx
Other members of the PGD working group	Dr Kumari Consultant Microbiologist Wexham Park Hospital		27.5.22

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor (or dentist)	Dr L Iyer Executive Medical Director Frimley CCG		06/04/22
Senior pharmacist	Yousaf Ahmad, ICS Chief Pharmacist and Director of Medicines Optimisation Frimley CCG		06/04/22
Senior representative of professional group using the PGD	Sarah Bellars Executive Director of Quality and Nursing Director of Infection, Prevention and Control (DIPC) Frimley CCG		06/04/22

PGD adoption by the provider

Name	Job title and organisation	Signature	Date

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Pharmacist currently registered with General Pharmaceutical Council https://www.pharmacyregulation.org/registers/pharmacist
Initial training	Undertaken recognised PGD training. **Centre for Pharmacy Postgraduate Education (CPPE) distance learning:** • CPPE distance learning pack 'Common clinical conditions and minor ailment: distance learning' (8hrs) https://www.cppe.ac.uk/programmes/l?t=RespMin-P-03&evid=45133 • CPPE learning assessment 'Minor Ailments; a clinical approach (2020) https://www.cppe.ac.uk/programmes/l/minor2-a-10 **NICE Guidance:** • NICE CKS Urinary Tract Infection (lower) –women https://cks.nice.org.uk/urinary-tract-infection-lower-women **SCAN (South Central Antimicrobial Network) Guidance:** • Uncomplicated Urinary Tract Infection in non-pregnant women SCAN Guidelines (microguide.global)
Competency assessment	**Completion of education in both the legal and professional aspects of PGD administration and the supply of medicines using:** ○ GPhC Standards For Pharmacy Professionals ○ Legal framework of PGD's https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017.pdf ○ Medicine, Ethics and Practice: Royal Pharmaceutical Society (RPS) https://www.rpharms.com/publications/the-mep **CPPE Declaration of competence:** • Minor ailments – this includes Consultation skills, Common Clinical Conditions and Minor Ailments https://www.cppe.ac.uk/services/declaration-of-competence#navTop **Self-Declaration that this training has been completed on PharmOutcomes**. The Pharmacist must complete electronic declaration (enrolment) via PharmOutcomes, by clicking on Nitrofurantoin PGD tab.
Ongoing training and competency	• The Pharmacist is responsible for keeping him/herself aware of any changes to the recommendations for the medicine listed.

	• It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of their own individual scope of practice. • The pharmacist is required to complete the required training and competency declaration every time a new contract is signed as this may change slightly in line with current evidence.

Clinical Condition

Clinical condition or situation to which this PGD applies	Treatment of otherwise healthy non-pregnant women presenting with uncomplicated urinary tract infection.
Inclusion criteria	**Eligibility criteria:** • Female • Aged 16-64 years old • No complications e.g. catheter **Present in the pharmacy (or contactable by telephone)** **Must present with 2 or more of the following key symptoms:** 1) Dysuria (burning pain when passing urine) 2) Urine Cloudiness (visible cloudy colour) 3) Nocturia of recent onset (needing to pass urine more than usual at night) Please note if the patient thinks their symptoms are mild, she should be advised that immediate antibiotics may not be necessary, as per PHE guidance. Instead, give self-care advice including patient information leaflet e.g. the RCGP Target Antibiotic Toolkit leaflet: Treating Your Infection – Urinary Tract Infection Leaflet, with advice to return if symptoms return or no improvement in 48 hours or symptoms worsen at any time. Other symptoms • Increased urinary frequency and urgency of recent onset • Suprapubic pain • No signs of a complicated UTI: haematuria or symptoms of pyelonephritis i.e. fever, flank pain, chills, nausea/ vomiting, rigors, loin or abdominal pains/ tenderness and headache Patients must consent to sharing their details and the consultation with their registered GP. The consent can be verbal and will be recorded on PharmOutcomes as part of the consultation process.
Exclusion criteria	**Not meeting eligibility criteria:** • Male • Aged under 16 years /aged over 65 years • Any complications • Pregnant/possible pregnancy or breast feeding • Living in residential care facility • Refused / not consented to treatment. **Signs of a complicated UTI:** • Symptoms of pyelonephritis i.e. fever, flank pain, chills, nausea/ vomiting, rigors, loin or abdominal pains/ tenderness

	and headache • Unresolving urinary symptoms • Vaginal discharge or itch • Haematuria (unless menstruating) • Urological abnormalities or who have had surgery involving the lower urinary tract • Indwelling catheter • Known renal impairment or acute kidney injury **Increased risk of Nitrofurantoin antibiotic resistance:** • Current prophylactic use of nitrofurantoin • Currently taking a prescribed antibiotic • Recurrent UTI - a frequency of 2 or more UTIs in the last 6 months or 3 or more UTIs in the last 12 months. **Sensitivity:** • Known hypersensitivity to nitrofurantoin or to any ingredient of the nitrofurantoin product being supplied **Medical risks:** • Immunocompromised patients or patients taking immunosuppressant medicines or Disease Modifying Antirheumatic Drugs) DMARDs - seek urgent medical attention for full blood count and liver function tests • Hepatic impairment • Renal impairment or acute kidney injury • G6PD deficiency • Acute porphyrias **Drug Interactions:** **Refer to BNF interactions for full list:** **https://bnf.nice.org.uk/interaction/nitrofurantoin-2.html** Patients who are currently taking any of the following are at risk of a severe interaction: ○ Dapsone ○ Prilocane Risk of neurotoxicity with: ○ Phenytoin ○ Amiodarone ○ Cytotoxics Treat as complex patients and refer to GP.

Cautions (including any relevant action to be taken)	• Interaction with other medicinal products and other forms of interaction
	  ○ Increased absorption with food or agents delaying gastric emptying.
	  ○ Decreased absorption with magnesium trisilicate – avoid co-administration
	  ○ Decreased renal excretion of nitrofurantoin by probenecid and sulphinpyrazene.
	  ○ Decreased anti-bacterial activity by carbonic anhydrase inhibitors and urine alkalisation –don't sell OTC.
	  ○ Anti-bacterial antagonism by quinolone anti-infectives.
	  ○ Interference with some tests for glucose in urine.
	  ○ Typhoid Vaccine (oral): Antibacterials inactivate oral typhoid vaccine.
	Complex patients – refer to GP if in doubt
	• Nitrofurantoin should be used with caution in patients with pulmonary disease, hepatic dysfunction, neurological disorders, and tendency to allergies. Complex patient – refer to GP.
	• Discontinue treatment with nitrofurantoin if otherwise unexplained pulmonary, hepatic, haematological or neurological syndromes occur
	• Peripheral neuropathy and susceptibility to peripheral neuropathy, which may become severe or irreversible, has occurred and may be life threatening. Therefore, treatment should be stopped at the first signs of neural involvement (paraesthesiae).
	• Nitrofurantoin should be used in caution with patients with anaemia, diabetes mellitus, electrolyte imbalance, debilitating conditions and vitamin B (particularly folate) deficiency.
	• Acute, subacute and chronic pulmonary reactions have been observed in patients treated with nitrofurantoin. If these reactions occur, nitrofurantoin should be discontinued immediately.
	• Chronic pulmonary reactions (including pulmonary fibrosis and diffuse interstitial pneumonitis) can develop insidiously and may occur commonly in elderly patients. Close monitoring of pulmonary conditions of patients receiving long-term therapy is warranted (especially in the elderly).
	• Patients should be monitored closely for signs of hepatitis (particularly in long-term use). Urine may be coloured yellow or brown after taking nitrofurantoin. Patients on nitrofurantoin are susceptible to false positive urinary glucose (if tested for reducing substances).

Arrangements for referral for medical advice	• Contact details of services available to be provided to patient, with hours of opening. • Pharmacist to provide summary of assessment via PharmOutcomes. • PharmOutcomes message to GP.
Action to be	• For complex UTI refer patient to GP.

taken if patient excluded	• For mild symptoms, provide advice to return if symptoms return or no improvement in 48 hours or symptoms worsen at any time. • If suspect pyelonephritis or sepsis call 111 for advice. • Immunocompromised patients or patients taking immunosuppressant medicines or Disease Modifying Antirheumatic Drugs) DMARDs - seek urgent medical attention via 111 for full blood count.
Action to be taken if patient declines treatment	Record refusal and state reason for refusal, any action taken or advice given.

Details of the medicine

Name, form and strength of medicine	• Nitrofurantoin 100mg capsules MR • Nitrofurantoin 50mg tablets
Legal category	POM
Indicate any off-label use (if relevant)	N/A
Route/method of administration	Oral
Dose and frequency	• One 100mg MR capsule to be taken TWICE a day (12 hourly) for 3 days (with food or milk). • If national supply problem with 100mg MR capsules the 50mg tablets may be supplied, however twice daily administration is preferable due to reduced frequency of administration and adherence to dosing regimen. One 50mg tablet four times a day for 3 days with food or milk.
Quantity to be administered and/or supplied	• 6 capsules • 12 tablets
Maximum or minimum treatment period	• 3 days
Adverse effects	***For full list of Adverse Drug reactions (ADRs) see British National Formulary (BNF)/ Summary of Product Characteristics (SmPC)*** Nitrofurantoin may cause dizziness and drowsiness and the patient should not drive or operate machinery if affected this way. **BNF https://bnf.nice.org.uk/drug/nitrofurantoin.html** **Frequency not known** Agranulocytosis; alopecia; anaemia; angioedema; aplastic anaemia; appetite decreased; arthralgia; asthenia; chest pain; chills; circulatory collapse; confusion; cough; cyanosis; depression; diarrhea; dizziness; drowsiness; dyspnea; eosinophilia; euphoric mood; fever; granulocytopenia; haemolytic anaemia; headache; hepatic disorders; idiopathic intracranial hypertension; increased risk of infection; leucopenia; lupus-like syndrome; nausea; nerve disorders; nystagmus; pancreatitis; psychotic disorder; pulmonary hypersensitivity; pulmonary reaction (possible association with lupus erythematosus-like syndrome); respiratory disorders; skin reactions; Stevens-Johnson syndrome; thrombocytopenia; urine discolouration;

	vertigo; vomiting
Records to be kept	The following will be recorded on PharmOutcomes: • Patient name, age, gender • Name of registered GP • The condition to be treated • Treatment recommended • Quantity supplied • Batch number and expiry date • Name of manufacturer • Duration of treatment • Date of supply • Name of the individual assessing the patient and making the supply *Information must be sent to the GP by PharmOutcomes for entry into the patients records* Document any allergies and other adverse drug reactions clearly in the pharmacy patient records and inform GP and other relevant practitioners for further reporting and action if needed.

Patient information

Written/Verbal information to be given to patient or carer	• Highlight the patient information leaflet included in the box • Advise patient to take at regular intervals and to complete the 3-day course even if the original infection appears better • Take whole with a full glass of water and take with food or milk • The activity of nitrofurantoin is reduced with increasing pH; avoid alkalinising agents e.g. potassium citrate. Not recommended OTC. • Nitrofurantoin may make your urine become coloured dark yellow or brown. This is quite normal and not a reason to stop taking the medicine. • Advise patient that if they experience any unacceptable side effects they should see their GP for further advice • Advise patient that if a rash appears to stop the medicine and seek medical advice • Antibiotics and oral contraceptives: World Health Organisation (WHO) no longer advise that additional precautions are required when using combined hormonal contraceptives with antibiotics that are not enzyme inducers for a duration of less than 3 weeks. This is supported by the Faculty of Sexual and Reproductive Healthcare. https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • Advice should be provided around the usual precautions if nausea and vomiting should arise from taking the antibiotics • Advise patient to seek advise from GP if symptoms do not resolve after completion of course and to take an early morning urine sample with them to the appointment. • Provide advice on ways to reduce recurrence of further episodes – Voiding after intercourse, maintaining adequate fluid intake. • Give the patient any available literature available on cystitis management **Self-care:** • Advise people with lower UTI about using paracetamol for pain, or if preferred and suitable ibuprofen. • Advise people with lower UTI about drinking enough

	fluids to avoid dehydration. • Be aware that no evidence was found on cranberry products or urine alkalinising agents to treat lower UTI.
Follow-up advice to be given to patient or carer	• Routine follow up is not necessary • Advise to call 111 if complex patient/concerns • Advise to seek advice from GP if symptoms don't resolve • Refer to NHS Choices for more information: https://www.nhs.uk/conditions/cystitis/ • eMC nitrofurantoin Patient Information Leaflet • Give TARGET UTI leaflet: Urinary tract infection resource suite: Patient facing materials (rcgp.org.uk)

Appendices

Appendix A Key references

1) BNF On-Line: https://bnf.nice.org.uk/drug/nitrofurantoin.html Date accessed 16.12.21

2) NICE CKS Urinary Tract Infection (lower) –women https://cks.nice.org.uk/urinary-tract-infection-lower-women. Date accessed 16.12.21

3) NICE Guidance: Urinary tract infection(lower):antimicrobial prescribing [NG109] Published date: October 2018 https://www.nice.org.uk/guidance/ng109 Date accessed 16.12.21

4) SCAN – South Central Antimicrobial Network Guidelines for Antibiotic Prescribing in the Community SCAN Guidelines (microguide.global) <When registering for access, please choose GetGuide South Central Antimicrobial Network.>Date accessed 16.12.21

5) e MC Summary of Product Characteristics (SmPC) Nitrofurantoin 100mg MR capsules https://www.medicines.org.uk/emc/product/429 Date accessed 16.12.21

6) eMC Patient Information Nitrofurantoin 50mg tablets https://www.medicines.org.uk/emc/product/3601/smpc#gref Date accessed 16.12.21

7) Faculty of Sexual and Reproductive Health Clinical Guidance. Clinical Effectiveness Unit Drug Interactions with Hormonal Contraception J- Updated 2017 Reviewed January 2019: https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ Date accessed 16.12.21

Appendix B Health professionals' agreement to practise

The Community Pharmacists named below based at ……..Pharmacy are authorised to supply nitrofurantoin 100mg M/R capsules and nitrofurantoin 50mg tablets in the management of uncomplicated UTI as specified under this Patient Group Direction.

I have read and understood the Patient Group Direction and will provide the service only in accordance with this PGD.

Name of health professional (please print)	Signature	Senior representative authorising health professional	Authorising Signature	Date

Note to Authorising Manager:

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so.

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation

Reference Number:FCCG001

Valid from: May 2022

Review date: January 2024

Expiry date: May 2024