NHS
Liverpool
Clinical Commissioning Group

This Patient Group Direction (PGD) must only be used by registered pharmacists 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 or nitrofurantoin 50mg Capsules / Tablets

by registered pharmacists for the

Treatment of Uncomplicated Urinary Tract Infection in non-pregnant women

under the Liverpool Clinical Commissioning Group Minor Ailments Service

Version number: 1.1

Valid from: March 2021
Review date: March 2022
Expiry date: March 2023

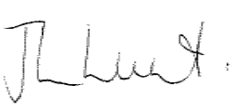
Change history

Version number	Change details	Date
1.0	Original document developed with the Liverpool Medicines Optimisation Group (MOC)	November 2020
1.1	Amendments following LMC consultation and review by Clinical Effectiveness Committee	January 2021

PGD development

Name	Job title and organisation
Lead author	Peter Johnstone Head of Medicines Optimisation Liverpool CCG
Lead doctor	Dr Fiona Ogden-Forde Clinical lead for Prescribing Liverpool CCG
Lead pharmacist	Peter Johnstone Head of Medicines Optimisation Liverpool CCG
Representative of other professional group using PGD	Matt Harvey Pharmacist Chair of Liverpool Pharmaceutical Committee
Other members of the PGD working group: Members of Liverpool Medicines Optimisation Committee (November 2020)	

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Fiona Ogden-Forde Clinical lead for Prescribing Liverpool CCG		5th March 2021
Senior pharmacist	Peter Johnstone Head of Medicines Optimisation Liverpool CCG		5th March 2021
Person signing of behalf of CCG	Jane Lunt Head of Quality / Chief Nurse Liverpool CCG		17th March 2021

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Training and competency of registered pharmacist

	Requirements of registered pharmacists working under the PGD
Qualifications and professional registration	Qualified pharmacist registered with the General Pharmaceutical Council (GPhC)
Initial training	Competent to work under Patient Group Directions, including satisfactory completion of training to administer/supply in accordance with this Patient Group Direction. Working as a community pharmacist and accredited to provide the Minor Ailments Service.
Competency assessment	CPPE Declaration of Competence Documents (DoCs)
Ongoing training and competency	Commitment to continuing updating and re-validation according to the accreditation requirements of the commissioning organisation. Commitment to keep up-to-date with clinical developments in this area or changes to the recommendations for the medicine listed, as part of their Continual Professional Development.

Clinical condition

Clinical condition or situation to which this PGD applies	Uncomplicated Urinary Tract Infection in Non-Pregnant Women (aged between 18 and 65 years of age)
Inclusion criteria	Non-pregnant women aged 18 to 65 years of age with the following: Severe symptoms or the presence of three or more of the following symptoms: o Dysuria o New nocturia o Urine cloudy to the naked eye o Urinary frequency o Urgency o Suprapubic tenderness Dipstick testing is not required for patients with two or more symptoms (RCGP) Vaginal discharge reduces the likelihood of a woman having a bacterial UTI. 80% of cases do not have a UTI. *Patient agrees to treatment under this PGD.*
Exclusion criteria	• Males • Suspected sepsis / pyelonephritis • Vaginal discharge or irritation • Known hypersensitivity/allergy to nitrofurantoin or any excipient in the product • Treatment with nitrofurantoin in the last three months any additional risk factors for resistance to nitrofurantoin • More than two episodes of UTI treated with antibiotics within the last 6 months or 3 or more in last 12 months (NICE) • Patients under 18 years of age • Patients over 65 years of age • Pregnant or breastfeeding • Known renal impairment (eGFR <45ml/min if available on SCR, or reported by patient) • Diabetes Mellitus • Hepatic impairment, including acute porphyria • Peripheral neuropathy • Neurological disorders • Significant immunosuppression (due to disease or treatment) • Known blood dyscrasias including G6PD deficiency

	• Haematuria • Anaemia • Electrolyte imbalance • Vitamin B (particularly folate) deficiency • Fever or systemically unwell. (as could indicate more severe illness or sepsis) • Previous failed antibiotic treatment (for same episode) • Persistent symptoms • Current prophylactic treatment with any antibiotic agent • Abnormalities or pathology of genito-urinary tract • Patients with indwelling catheters or Intermittent self catheterisation • Significant loin pain • Confused or dehydrated • Patients taking any interacting medication (see current BNF or SPC)
Cautions (including any relevant action to be taken)	Refer to Summary of Product Characteristics http://www.medicines.org.uk/emc/ Nitrofurantoin can interfere with some tests for glucose in the urine. Individuals currently taking any of the following drugs (or any other interacting drugs as per BNF): • Probenecid (decreased renal excretion of nitrofurantoin) • Sulphinpyrazone (decreased renal excretion of nitrofurantoin) • Carbonic anhydrase inhibitors (i.e. acetazolamide) (decreased anti-bacterial activity) • Quinolone antibiotics (e.g. ciprofloxacin) (anti-bacterial antagonism) • Magnesium trisilicate (reduce absorption) • Oral typhoid vaccine: avoid nitrofurantoin for 3 days (before and after)

Action to be taken if patient excluded	• Patients who do not meet the inclusion criteria for number or severity of symptoms should be advised that cystitis is self-limiting and will resolve without antibiotics. Give self-care and safety netting advice as per the TARGET UTI leaflet available at: https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/amr/target-antibiotics-toolkit/leaflets-to-share-with-patients.aspx • Patients who meet the inclusion criteria for severity and number of symptoms, but are not suitable for nitrofurantoin treatment, may be treated under the Trimethoprim PGD, if appropriate. • Refer to GP practice, if appropriate • Clearly record the decision on the patient's consultation proforma including any advice given and action taken.
Action to be taken if patient declines treatment	Record decision on the patient's consultation proforma including any advice given and action taken. Refer to GP as appropriate.

Details of the medicine

Name, form and strength of medicine Include ▼ for black triangle medicines	Nitrofurantoin 100mg MR capsules, nitrofurantoin 50mg capsules or tablets The most cost-effective preparation should be supplied where possible, but any patient factors should also be considered (such as compliance with QDS regimen).
Legal category	*POM*
Indicate any off-label use (if relevant)	*N/A*
Route/method of administration	Oral
Dose and frequency	*Nitrofurantoin 100mg MR BD for three days* Or *Nitrofurantoin 50mg QDS for three days*
Quantity to be administered and/or supplied	Supply 6 nitrofurantoin 100mg MR capsules or 12 nitrofurantoin 50mg capsules or tablets per episode

Maximum or minimum treatment period	Maximum treatment period of three days.
Adverse effects	Nitrofurantoin may cause dizziness and drowsiness. Patients should be advised not to drive or operate machinery if affected until symptoms stop. Discolouration of the urine to yellow or brown is common. The following side effects have occasionally been reported: • Nausea • Vomiting • Pruritis • Skin rashes • Abdominal pain and diarrhoea Severe adverse reactions are rare but there have been reports of the following effects: • Acute pulmonary reactions. Patients should discontinue treatment if they experience cough, chest pain or dyspnoea. • Neurological effects including peripheral neuropathy. • Severe allergic skin reactions including erythema multiforme. • Haematological effects. Refer to SPC or current BNF for full details.
Records to be kept	The following will be recorded in the patient's consultation proforma: • Advice given to patient • Patients name, address, date of birth and GP (if registered). • Date and time of supply • The batch number and expiry date • Name of person supplying the medicine

Patient information

Verbal/written advice to be given to patient	• Discuss side effects and administration with the patient and provide a manufacturers patient information leaflet. • Advise patient that nitrofurantoin can colour the urine yellow or brown. • Always complete the course. • Advise the patient to take nitrofurantoin with food. • Advise patient on self-care regarding adequate fluid intake and other self-management strategies such as wearing loose fitting clothes/underwear, wearing cotton underwear and avoidance of vaginal douches/deodorants. • Paracetamol or ibuprofen may be useful to relieve pain/discomfort. • Consult your GP if symptoms do not settle after 3 days. **This instruction must be included on the label.** • Risk of possible STDs should be raised if appropriate. Consider encouraging self testing for chlamydia through "Love is infectious" site https://www.merseycare.nhs.uk/our-services/physical-health-services/sexual-health/love-is-infectious/ • Advise patient on oral vitamin K antagonists that antibiotic treatment may affect their INR and to inform the anticoagulant clinic. • **If symptoms worsen during treatment, the patient experiences significant flank pain, becomes systemically unwell or develops a fever then the patient should seek further medical advice. Consider the risk of sepsis.**
Follow-up advice to be given to patient or carer	Contact GP if no improvement of symptoms after 3 days or sooner if symptoms worsen.

Appendices

Appendix A Key references

1. Clinical Knowledge Summaries Guideline. Urinary tract infection (lower) - women. (Accessed November 2020)
2. Summary of Product Characteristics (nitrofurantoin MR Capsules) https://www.medicines.org.uk/emc/medicine/22543 (Accessed November 2020) and Summary of Product Characteristics (nitrofurantoin 50mg capsules) https://www.medicines.org.uk/emc/medicine/22563 (Accessed November 2020) and Summary of Product Characteristics (nitrofurantoin 50mg tablets) https://www.medicines.org.uk/emc/medicine/29700 (Accessed November 2020)
3. Urinary tract infection: diagnosis guide for primary care (Accessed November 2020)
4. PHE diagnostic flowchart https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/927195/UTI_diagnostic_flowchart_NICE-October_2020-FINAL.pdf
5. https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/amr/target-antibiotics-toolkit/-/media/320CDA7F59884C6689A0109CBCEAFE70.ashx

Appendix B Health professionals' agreement to practise

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD.

Name of pharmacist	Signature	Senior representative authorising pharmacist	Date
