South Sefton Clinical Commissioning Group
Southport and Formby 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 (PGD)

for the supply of

Nitrofurantoin 100mg Modified Release Capsules or Nitrofurantoin 50mg tablets/Capsules

by registered pharmacists for

the treatment of uncomplicated lower urinary tract infections in non-pregnant women

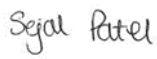
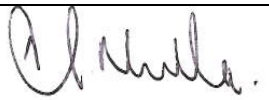
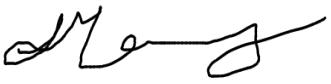
in a community pharmacy setting under the NHS South Sefton CCG and NHS Southport and Formby CCG minor ailment service.

Version number:1.2

Change history

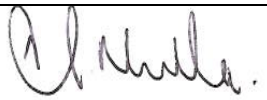
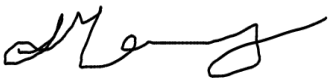
Version number	Change details	Date
1.0	Original document developed by South Sefton CCG medicines management team and Joint Medicines Operation Group (JMOG).	November 2021
1.1	Changes following feedback from clinical prescribing leads and consultant microbiologist. Change to follow up advise to bring into line with NICE Clinical Knowledge Summaries.	December 2021
1.2	Changed “administer and/or supply” to supply in whole document. Included information on off-label use for duration of treatment.	December 2021

PGD development

Name	Job title and organization	Signature	Date
Sejal Patel (Lead author)	Lead Pharmacist, South Sefton CCG		30.12.21
Dr Anna Hunter (Lead doctor)	Prescribing Lead, South Sefton CCG		30.12.21
Dr Hilal Mulla (Lead doctor)	Prescribing Lead, Southport and Formby CCG		30.12.21
Susanne Lynch (Lead pharmacist)	Head of Medicines Management, South Sefton CCG		30.12.21
(Lisa Manning) Representative of other professional group using PGD	Chief Executive Officer, Sefton LPC		30.12.21
Mrs Kay Walsh (Other members of the PGD working group)	Lead Pharmacist, South Sefton CCG		30.12.21
Mrs Janet Fay (Other members of the PGD working group)	Lead Pharmacist, South Sefton CCG		30.12.21
Mrs Jennifer Johnston (Other members of the PGD working group)	Lead Pharmacist, South Sefton CCG		30.12.21
Mrs Helen Roberts (Other members of the PGD working group)	Lead Pharmacist, South Sefton CCG		30.12.21

PGD authorisation

Name	Job title and organisation	Signature	Date
Dr Anna Hunter (Lead doctor)	Prescribing Lead, South Sefton CCG		30.12.21

Dr Hilal Mulla (Lead doctor)	Prescribing Lead, Southport and Formby CCG		30.12.21
Dr Rob Caudwell (Senior doctor)	NHS Southport & Formby CCG Chair		30.12.21
Dr Peter Chamberlain (Senior doctor)	NHS South Sefton CCG Chair		30.12.21
Susanne Lynch (Senior pharmacist)	Head of Medicines Management, South Sefton CCG		30.12.21
(Lisa Manning) Representative of other professional group using PGD	Chief Executive Officer, Sefton LPC		30.12.21
Jane Lunt **Person signing on behalf of <u>CCG</u>**	Interim Chief Nurse, NHS South Sefton CCG and Southport and Formby CCG		05.01.22

PGD adoption by the provider[1]

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

Training and competency of registered Pharmacist

	Requirements of registered Pharmacist working under the PGD
Qualifications and professional registration	• Qualified pharmacist registered with the General Pharmaceutical Council (GPhC)
Initial training	• College of Pharmacy Postgraduate Education (CPPE) e-learning: Women's health: Urogenital conditions • NICE CKS Urinary Tract Infection (lower) –women • NG 109 Urinary tract infection (lower): antimicrobial prescribing • CPPE e-assessment Minor ailments: a clinical approach • Completion of PHE Antimicrobial Stewardship for Community Pharmacy e-learning and e-assessment https://www.e-lfh.org.uk/programmes/antimicrobial-resistance-and-infections/
Competency assessment	• Competent to work under PGDs, including satisfactory completion of training to supply in accordance with this PGD. • CPPE Declaration of Competence for minor ailment service • Staff operating under this PGD are encouraged to review their competency using the NICE competency framework for health professionals using PGDs. • Working as a community pharmacist and accredited to provide Care at the Chemist • Has a clear understanding of the drug to be supplied including side effects and contraindications. • Self-Declaration that training has been completed on PharmOutcomes. *Pharmacists must sign the pharmacy copy of the PGD in every pharmacy where they deliver this service.*

Ongoing training and competency	• Completion of CPPE declaration of competence for minor ailment service at least every 2 years • Commitment to keeping up to date clinical, pharmacological, and pharmaceutical knowledge relevant to the scope of the PGD. • Commitment to continuing professional development and re-validation according to the accreditation requirements of the commissioning organisation. • Commitment to keeping up to date with any changes in practice, national guidance, or policy. • The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification

Clinical condition

Clinical condition or situation to which this PGD applies	Uncomplicated lower urinary tract infection in non-pregnant women

Inclusion criteria	• Non-pregnant women aged between 16-65 years of age
	• Any 2 or 3 key diagnostic signs/symptoms from
	  ○ Dysuria (burning pain when passing urine)
	  ○ New nocturia (passing urine more often than usual at night)
	  ○ Urine cloudy to the naked eye
	• Patient agrees to treatment under this PGD

Exclusion criteria	• Male patients • Allergy or serious adverse effect from nitrofurantoin or to any other components of the preparation • Patients under 16 years of age • Patients over 65 years of age

	• Pregnancy (known or suspected)
	• Breastfeeding
	• Risk of treatment failure due to one or more of the following: Received antibiotic treatment for UTI within 1 month; 2 or more UTI episodes in the last 6 months or 3 or more episodes in the last 12 months; taking antibiotic prophylaxis for recurrent UTI.
	• Previous failed antibiotic treatment for same episode
	• Indwelling catheter or intermittent self-catheterisation
	• Suspected SEPSIS
	  ○ Use the Sepsis Screening and Action Tool
	• New signs/symptoms of pyelonephritis
	  ○ Kidney pain or tender back under ribs
	  ○ New or different myalgia, flu like illness
	  ○ Nausea or vomiting
	  ○ Shaking chills (rigors) or temperature over 37.9°C
	• Genitourinary causes of urinary symptoms
	  ○ Changes to vaginal discharge (75% - 80% with vaginal discharge will not have UTI)
	  ○ Check sexual history to exclude sexually transmitted infections
	  ○ Urethritis – urinary symptoms may be due to urethral inflammation post sexual intercourse, irritant or STIs
	  ○ Genitourinary symptoms of menopause/atrophic vaginitis/vaginal atrophy
	• Frank haematuria
	• Confused or dehydrated
	• Diabetes
	• Known renal impairment

	• Known hepatic impairment • History of renal stones / renal colic, known abnormality of the urinary tract e.g., vesicoureteric reflux, reflux nephropathy, neurogenic bladder, urinary obstruction, stent, recent instrumentation • Known haematological abnormalities, anaemeia, blood dyscrasias, known porphyria, vitamin B (particularly folate) deficiency, G6PD deficiency, electrolyte imbalance • Known or susceptibility to peripheral neuropathy, or known neurological disorder • Known pulmonary disease • Concomitant use of medication that has a clinically significant interaction with nitrofurantoin (for a comprehensive list of interactions refer to SPC and BNF) • Immunosuppressed • Persistent symptoms • Decline to provide consent or non-capacity to consent.

Cautions (including any relevant action to be taken)	Refer to summary of product characteristics (https://www.medicines.org.uk/emc/) for full details of contraindications and cautions Interaction 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. Typhoid Vaccine (oral): Antibacterials inactivate oral typhoid vaccine.
Arrangements for referral for medical advice	• A referral to another healthcare provider (e.g., GP/Out of Hours Service/A&E) will be made following pathways as set out in the CPCS. The urgency with which a referral needs to be made is based on the presenting symptoms.
Action to be taken if patient excluded	• For all patients – share self- care and safety netting advise using TARGET UTI leaflet https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/amr/target-antibiotics- toolkit/leaflets-to-share-with-patients.aspx • If pyelonephritis/SEPSIS is suspected, urgent referral to seek medical advice is required • Patients excluded from treatment should be referred to a medical practitioner as appropriate. The urgency with which a referral needs to be made is based on the presenting symptoms. • Record the reason for exclusion and any action taken on PharmOutcomes.

Action to be taken if patient declines treatment	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

Details of the medicine

Name, form and strength of medicine	• Nitrofurantoin 100mg modified release capsules (first line) • Nitrofurantoin 50mg tablets/capsules
Legal category	Prescription only medicine (POM)
Indicate any off-label use (if relevant)	Duration of treatment for lower UTI differs from the SPC but is in line with BNF and national clinical guidelines.
Route/method of administration	Oral
Dose and frequency	Nitrofurantoin 100mg MR capsules twice daily for three days (with food) OR Nitrofurantoin 50mg tablets/capsules four times a day for three days (with food)
Quantity to be supplied	Supply • 6 x 100mg MR capsules **OR** • 12 x 50mg tablets/capsules
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 in this way until such symptoms go away. Discoloration of the urine to yellow or brown is common. *Refer to British national Formulary (BNF)/ Summary of product characteristics (SmPC) for full details of adverse effects.* **Frequency not known** Agranulocytosis; alopecia; anaemia; angioedema; aplastic anaemia; appetite decreased; arthralgia; asthenia; chest pain; chills; circulatory collapse; confusion; cough; cyanosis; depression; diarrhoea; dizziness; drowsiness; dyspnoea; 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, address, and date of birth • Name of registered GP • Date and time of supply • Treatment supplied • Quantity supplied • Batch number and expiry date • Name of person supplying the medicine Information must be sent to the GP by PharmOutcomes for entry into the patient's 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	• Provide the patient with the manufacturer's Patient Information Leaflet • Advise patient to take at regular intervals and to complete the 3- day course even if the original infection appears better • Inform patient of possible side effects and their management and who to contact should they become troublesome. • Share self- care and safety netting advise using TARGET UTI leaflet. • The activity of nitrofurantoin is reduced with increasing pH; avoid alkalinising agents

	e.g., potassium citrate. Not recommended OTC. • Nitrofurantoin may colour the urine 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 • If the condition becomes recurrent, contact GP for further investigation • 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 enzyme inducing antibiotics e.g. rifampicin or rifabutin) affect these contraceptives. This is the latest guidance from the Faculty of Sexual & Reproductive Healthcare • Paracetamol and ibuprofen may relieve dysuric pain and discomfort. • Advise patient to stop taking immediately and seek medical advice if they develop pulmonary, hepatic, haematological or neurological reactions e.g., breathing difficulties, abdominal pain, discomfort, bruising and bleeding.
Follow-up advice to be given to patient or carer	• Advise patient to seek urgent medical review if symptoms worsen rapidly or significantly at any time or fail to improve within 48 hours of starting antibiotics. • Advise patient to seek medical attention immediately if patient becomes systemically unwell • Advise patient that if rash or other signs of hypersensitivity occur, stop taking the medicine and contact their medical practitioner/seek medical advice immediately

Appendices

Appendix A Key references

1. Public Health England Diagnosis of urinary tract infections https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/927195/UTI_diagnostic_flowchart_NICE-October_2020-FINAL.pdf [Accessed November 2021]
2. Summary of Product Characteristics (nitrofurantoin 100mg MR capsules) https://www.medicines.org.uk/emc/product/429 [Accessed November 2021]
3. Summary of Product Characteristics (nitrofurantoin 50mg tablets) https://www.medicines.org.uk/emc/product/3601 [Accessed November 2021]
4. Royal College of General Practitioners TARGET antibiotics toolkit hub https://elearning.rcgp.org.uk/course/view.php?id=553 [Accessed November 2021]
5. British National Formulary (BNF) https://bnf.nice.org.uk/drug/nitrofurantoin.html#sideEffects [Accessed November 2021]
6. National Institute for Health and Care Excellence (NICE) Urinary tract infection (lower) antimicrobial prescribing https://www.nice.org.uk/guidance/ng109 [Accessed November 2021]
7. National Institute for Health and Care Excellence (NICE) Patient Group Directions Medicines practice guidelines https://www.nice.org.uk/guidance/mpg2 [Accessed December 2021]
8. Clinical Knowledge Summaries urinary tract infections (lower) women https://cks.nice.org.uk/topics/urinary-tract-infection-lower-women/ [Accessed November 2021]

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