



Patient Group Direction

Supply of Nitrofurantoin Capsules MR 100mg / Tablets 50mg

PGD No 559 Version – 1.0

The purpose of the PGD is to allow management of acute uncomplicated urinary tract infection (UTI) in non-pregnant females between 16 and 65 years of age by registered pharmacists within Community Pharmacies.

This PGD authorises pharmacists delivering the NHS Pharmacy First Service Level Agreement to supply nitrofurantoin to non-pregnant females aged 16-65 years (inclusive of age 65 years) presenting with symptoms of an acute uncomplicated urinary tract infection (UTI) who meet the criteria for inclusion under the terms of the document

Change History - None

PGD Nitrofurantoin MR Capsules 100mg / tablets 50mg

Authorisation

This specimen Patient Group Direction (PGD) has been produced by the Scottish Antimicrobial Prescribing Group and the Primary Care Community Pharmacy Group to assist NHS Boards provide uniform services under the 'NHS Pharmacy First Service' banner across NHSScotland. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply nitrofurantoin capsules or tablets under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been reviewed for NHS Forth Valley by

Doctor	David Herron	Signature	Signed by David Herron
Pharmacist	Kirstin Cassells	Signature	Signed by Kirstin Cassells
Microbiologist	Robert Weir	Signature	Signed by Robert Weir

Approved on behalf of NHS Forth Valley by

Medical Director	Andrew Murray	Signature	Signed by Andrew Murray
Director of Pharmacy/Senior Pharmacist	Scott Mitchell	Signature	Signed by Scott Mitchell
Director of Nursing	Angela Wallace	Signature	Signed by Angela Wallace

Date Approved 30th July 2020

Effective from	<u>30th July 2020</u>	Review Date	<u>1st April 2022</u>
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Clinical Situation

Indication	Acute uncomplicated urinary tract infection (UTI) in non-pregnant females between 16 and 65 years of age (inclusive)
Inclusion Criteria	<p>Non-pregnant females, assigned as female at birth who have not had any reassignment procedures, aged between 16 and 65 years presenting with three or more of the following symptoms</p> <ul style="list-style-type: none"> • Dysuria • Frequency • Urgency • Suprapubic tenderness • or BOTH dysuria and frequency are present. <p>Diagnosis based on three symptoms or two symptoms (dysuria and frequency) should be supported with a urine dipstick test which is positive for nitrites if this is available.</p> <p>A renal function assessment should be considered prior to supplying nitrofurantoin,</p>
Exclusion Criteria	<ul style="list-style-type: none"> • Patients assigned as male at birth • Females under 16 years or over 65 years • Allergy or serious adverse effect from nitrofurantoin or to any other components of the preparation • Symptoms are suggestive of upper urinary tract infection (fever and chills, rigors, nausea, vomiting, diarrhoea, loin pain, flank tenderness, back pain of acute onset or systemically unwell). • Frank haematuria • Confused or dehydrated • Indwelling catheter • Pregnancy (known or suspected) • Breastfeeding • Diabetes • Known moderate to severe renal impairment, abnormality of the urinary tract or stent in urinary tract. • History of renal stones / renal colic, abnormal urinary tract eg vesicoureteric reflux, reflux nephropathy, neurogenic bladder, urinary obstruction, stent, recent instrumentation. • Known severe hepatic insufficiency • Known haematological abnormalities, blood dyscrasias, known porphyria, vitamin B (particularly folate) deficiency, G6PD deficiency, electrolyte imbalance • Known or susceptibility to peripheral neuropathy, or known neurological disorder • Immunosuppressed • Current treatment with warfarin • Known interstitial lung disease or poorly controlled respiratory disease • Taking any medication which interacts with nitrofurantoin– refer to BNF for full list of interactions. Eg antacids (in particular magnesium trisilicate), quinolone antibacterials and sulfinpyrazone • Risk of treatment failure due to one or more of the following:

	<p>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.</p> <ul style="list-style-type: none"> • Decline to provide consent or non-capacity to consent. • Symptoms of UTI lasting longer than 7 days • Presence of vaginal discharge or itch
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	<ul style="list-style-type: none"> • Recent hospital in-patient stay (in the previous three months). • Known previous nitrofurantoin-resistant isolates or multi-drug-resistant isolates or recent travel to a country with known increased incidence of antimicrobial resistance • Any doubt as to inclusion/exclusion criteria being met.
Action if Excluded	Refer to GP Practice/Out-of-hours service and document in Patient Medication Record (PMR) or Pharmacy Care Record (PCR).
Action if Patient Declines	<p>Note that self-care may be considered as an option depending on symptom severity.</p> <p>If patient declines treatment, advise on self-care to relieve symptoms and advise to see their GP if symptoms fail to resolve within 3 days or if symptoms worsen.</p> <p>The reason for declining treatment and advice given must be documented.</p> <p>Ensure patient is aware of risks and consequences of declining treatment.</p> <p>Record outcome in Patient Medication Record (PMR) or Pharmacy Care Record (PCR) if appropriate.</p>

Depending on availability either of the 2 treatment choices can be used

Description of Treatment

Name of Medicine	Nitrofurantoin
Form/Strength	100mg MR capsules
Route of administration	Oral
Dosage	100mg
Frequency	Twice a day (12hourly) (with or just after food)
Duration of treatment	3 days
Quantity to supply/administer	6 x 100mg MR capsules
▼ additional monitoring	No
Legal Category	POM (Prescription Only Medicine)
Is the use outwith the SPC	No
Storage requirements	As per manufacturer's instructions Store below 25°C in a cool dry place Ensure capsules are within expiry date
Additional information	None

Description of Treatment

Name of Medicine	Nitrofurantoin
Form/Strength	50mg tablets
Route of administration	Oral
Dosage	50mg
Frequency	Four times a day (with or just after food)
Duration of treatment	3 days
Quantity to supply/administer	12x 50mg tablets
▼ additional monitoring	No
Legal Category	POM (Prescription Only Medicine)
Is the use outwith the SPC	No
Storage requirements	As per manufacturer's instructions Store below 25°C in a cool dry place Ensure tablets are within expiry date
Additional information	None

<p>Warnings including possible adverse reactions and management of these</p>	<p>For a full list of side effects – refer to the marketing authorisation holder’s Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on www.medicines.org.uk</p>
<p>Reporting procedure for adverse reactions</p>	<p>Pharmacists should document and report all adverse incidents through their own internal governance systems.</p> <p>All adverse reactions (actual and suspected) will be reported to the appropriate medical practitioner and recorded patient’s medical record. Pharmacists should record in their PMR and send an SBAR to the GP as appropriate.</p> <p>Where appropriate, use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/</p>
<p>Advice to Patient/carer including written information</p>	<ul style="list-style-type: none"> • Advise patient about the importance of hydration in relieving symptoms. • Provide a cystitis/UTI patient information leaflet and discuss contents with patients. https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/amr/target-antibiotics-toolkit/-/media/85AAD1D4DDEF455A85E0416C3BB714AE.ashx. The patient information leaflet contained in the medicine should be made accessible to the patient. Where this is unsuitable, sufficient information should be given to the patient in a language that they can understand. • Inform patient of possible side effects and their management and who to contact should they become troublesome. • Explain the benefits and risks of taking antibiotics for this condition. • Urinary alkalinising agents should be avoided with nitrofurantoin as these reduce the antibacterial activity of nitrofurantoin • Avoid concomitant administration of magnesium trisilicate as this may reduce nitrofurantoin absorption. • Nitrofurantoin may colour the urine yellow or brown. This is harmless • If on combined oral contraception, no additional contraceptive precautions are required unless vomiting or diarrhoea occur. (See reference section for Faculty of Reproductive and Sexual Healthcare Guidance) • Advise patient of self-management strategies including maintaining a good fluid intake, wearing loose fitting underwear/clothing, wearing cotton underwear and avoidance of vaginal deodorants. • Advise patient on ways to prevent re-infection – e.g. double voiding, voiding after sexual intercourse. • Paracetamol and ibuprofen may relieve dysuric pain and discomfort. • Ensure patient is aware that if symptoms worsen, they experience significant flank pain, become systemically unwell, or develop a fever, then they should seek medical advice that day.

	<ul style="list-style-type: none"> Advise patient to seek further medical advice, if symptoms do not resolve after 3 days, if symptoms return or drug side effects are severe. Advise patient to discontinue treatment if rash develops and seek medical advice. Advise patient to stop taking immediately and seek medical advice if develops pulmonary, hepatic, haematological or neurological reactions e.g. breathing difficulties, abdominal pain discomfort, bruising and bleeding and seek advice from GP, OOH or NHS 24. Advise patient that their GP will be informed the next working day that antibiotics have been supplied. Advise patient that if they require to seek further advice from the Out-of-hours service they should make staff aware of their nitrofurantoin treatment. <p>Information on medicines can be found at https://www.medicines.org.uk/emc/browse-medicines or https://www.gov.uk/pil-spc</p>
Monitoring	Not applicable
Follow-up	Not applicable
Additional Facilities	<p>The following should be available where the medication is supplied:</p> <ul style="list-style-type: none"> An acceptable level of privacy to respect patient's right to confidentiality and safety. Access to medical support (this may be via the telephone). Approved equipment for the disposal of used materials. Clean and tidy work areas, including access to hand washing facilities. Access to current BNF (online version preferred).

Characteristics of staff authorised under the PGD

Professional qualifications	<p>Registered pharmacist with current General Pharmaceutical Council (GPhC) registration.</p> <p><i>Under PGD legislation there can be no delegation. Supply of the medication has to be by the same practitioner who has assessed the patient under this PGD.</i></p>
Specialist competencies or qualifications	<p>Has successfully completed NES Pharmacy e-learning module on "Pharmacy First".</p> <p>Able to assess the person's capacity to understand the nature and purpose of the medication in order to give or refuse consent.</p> <p>Must be familiar with the relevant nitrofurantoin Summary of Product Characteristics (SPC).</p>
Continuing education and training	<p>Has read current guidance on the management of urinary tract infections e.g. PHE/NICE, SIGN, SAPG https://www.sapg.scot/quality-improvement/primary-care/urinary-tract-infections/</p> <p>Aware of local treatment recommendations.</p> <p>Attends approved training and training updates as appropriate.</p> <p>Undertakes CPD when PGD or NES Pharmacy module updates.</p>

Audit Trail

Record/Audit Trail	<p>All records must be clear, legible and in an easily retrieval format. Pharmacists must record in Patient Medication Record (PMR) or Pharmacy Care Record (PCR).</p> <p>The following records should be kept (paper or computer based) and are included in the patient assessment form:</p> <ul style="list-style-type: none"> • Patient's name/parent/guardian/person with parental responsibility, address, date of birth and consent given • Patient's CHI number • Contact details of GP (if registered) • Presenting complaint and diagnosis • Details of medicine supplied • The signature and printed name of the healthcare professional who supplied the medicine. • Advice given to patient (including side effects) • The patient group direction title and/or number • Whether the patient met the inclusion criteria and whether the exclusion criteria were assessed • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record • Referral arrangements (including self-care) <p><i>The patient's GP, where known, should be provided with a copy of the client assessment form for the supply of nitrofurantoin on the same, or next available working day.</i></p> <p>These records should be retained in accordance with local/national guidance. For young people older than 16 years, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment. For 17 years and over, retain for 6 years after date of supply. Or for 3 years after death, where this is greater than above.</p> <p>All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each service. A designated person within each service will be responsible for auditing completion of drug forms and collation of data</p>
Additional references	<p>British National Formulary (BNF) current edition Nitrofurantoin SPC PHE/NICE. Managing common infections: guidance for primary care PHE Urinary tract infection: diagnostic tools for primary care RCGP TARGET Antibiotic toolkit HPS Scottish UTI Network Faculty of Sexual and Reproductive Health - Jan 2019</p> <p>https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/fsrh-guidance-drug-interactions-hormonal-contraception-jan-2019.pdf</p>

PATIENT GROUP DIRECTION FOR THE SUPPLY OF NITROFURANTOIN BY COMMUNITY PHARMACISTS UNDER THE “NHS PHARMACY FIRST SERVICE”

Individual Authorisation

PGD does not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals.

Note to Authorising Authority: authorised staff should be provided with access to the clinical content of the PGD and a copy of the document showing their authorisation.

I have read and understood the Patient Group Direction authorised by each of the individual NHS Boards that I wish to operate in and agree to provide Nitrofurantoin MR capsules or tablets

Name of Pharmacist _____

GPhC Registration Number _____

Normal Pharmacy Location

(Only one Pharmacy name and contractor code is required for each Health Board (HB) area where appropriate. If you work in more than 3 HB areas please use additional forms.)

Name & Contractor code HB (1) _____

Name & Contractor code HB (2) _____

Name & Contractor code HB (3) _____

Please indicate your position within the pharmacy by ticking one of the following:

Locum Employee Manager Owner

Signature _____ Date _____

Please tick and send to each Health Board you work in. Fax numbers, email and postal addresses are given overleaf.

Ayrshire & Arran Grampian Orkney

Borders Gr Glasgow & Clyde Shetland

Dumfries & Galloway Highland Tayside

Fife Lanarkshire Western Isles

Forth Valley Lothian

NHS Board	Address	Fax Number
Ayrshire & Arran	Mr Allan Thomas, NHS Ayrshire & Arran, Eglington House, Ailsa Hospital, Dalmellington Road, Ayr, KA6 6AB Angela.oumoussa@aapct.scot.nhs.uk	Please e-mail or post
Borders	Adrian Mackenzie, Lead Pharmacist Pharmacy Department, Borders General Hospital, Melrose, TD6 9BS communitypharmacy.team@borders.scot.nhs.uk	Please e-mail or post
Dumfries & Galloway	NHS Dumfries & Galloway, Primary Care Development, Ground Floor North, Mountainhall Treatment Centre, Bankend Rd, Dumfries, DG1 4TG dumf-uhb.pcd@nhs.net	Please e-mail or post
Fife	PGD Administrator, Pharmacy Services, NHS Fife, Pentland House, Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UW Fife-uhb.pgd@nhs.net	Please e-mail or post
Forth Valley	Community Pharmacy Development Team, Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR FV-UHB.communitypharmacysupport@nhs.net	Please email or post
Grampian	Pharmaceutical Care Services Team NHS Grampian, Pharmacy & Medicines Directorate, Westholme, Woodend, Queens Road, Aberdeen, AB15 6LS nhsq.pharmaceuticalcareservices@nhs.net	Please e-mail or post
Greater Glasgow & Clyde	Janine Glen, Contracts Manager, Community Pharmacy, NHS Greater Glasgow & Clyde, Clarkston Court, 56 Busby Road, Glasgow G76 7AT GG-UHB.cpdevteam@nhs.net	0141 201 6044 Or email
Highland	Community Pharmaceutical Services, NHS Highland, Assynt House, Beechwood Park, Inverness. IV2 3BW high-uhb.cpsoffice@nhs.net	Please e-mail or post
Lanarkshire	Pharmacy/Prescribing Admin Team, NHS Lanarkshire Headquarters, Kirklands, Fallside Road, Bothwell, G71 8BB	01698 858271
Lothian	Bob Taylor, Primary Care Contractor Organisation, 2 ND Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG CommunityPharmacy.Contract@nhslothian.scot.nhs.uk	Please e-mail or post
Orkney	Sylvia Robertson, Primary Care Pharmacist, NHS Orkney, Balfour Hospital, New Scapa Road, Kirkwall, Orkney KW15 1BH	01856 888 061
Shetland	Mary McFarlane, Principle Pharmacist, NHS Shetland, Gilbert Bain Hospital, Lerwick, Shetland, ZE1 0TB	01595 743356
Tayside	Diane Robertson Pharmacy Department, East Day Home, Kings Cross Hospital, Clepington Road, Dundee, DD3 8AE	No fax, please post
Western Isles	Stephan Smit, Primary Care Dept, The Health Centre, Springfield Road, Stornoway, Isle of Lewis, HS1 2PS	No fax, please post