PATIENT GROUP DIRECTION (PGD)

Supply/Administration of nitrofurantoin
For the treatment of lower UTI

Documentation details

Reference no:	CommPharm Nitrofurantoin UTI PGD
Version no:	V1.2
Valid from:	December 2021
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Expiry date:	December 2023

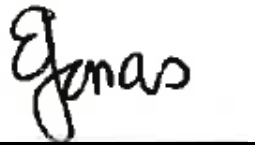
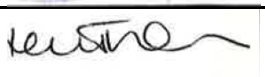
Change history

Version number	Change details	Date
1.0	Written by Elizabeth Jonas and checked by Helen Wilkinson & Michelle Jones	November 2021
1.1	Written by BNSSG CCG, adapted for BSW CCG and checked by Marco Yeung and Paul Clarke	December 2021
1.2	Removed Haematuria from the caution section. Updated UTI leaflet link	January 2022

Glossary

Abbreviation	Definition

1. PGD template development

Developed by:	Name	Signature	Date
Pharmacist	Elizabeth Jonas, Senior Medicines Optimisation Pharmacist, BNSSG CCG		11.02.2020
Doctor	Dr Shaba Nabi, GP Prescribing lead, BNSSG CCG		13.02.2020
Registered Professional representing users of the PGD	Helen Wilkinson, Principal Medicines Optimisation Pharmacist, BNSSG CCG		12.02.2020

PGD Working Group Membership

Name	Designation
Helen Wilkinson	Principal Medicines Optimisation Pharmacist, BNSSG CCG
Elizabeth Jonas	Senior Medicines Optimisation Pharmacist, BNSSG CCG
Michelle Jones	Senior Medicines Optimisation Pharmacist , BNSSG CCG
Judith Poulton	Pharmacist, Avon Local Pharmaceutical Committee
Dr Shaba Nabi	GP Prescribing Lead, BNSSG CCG
Richard Brown	Pharmacist, Avon Local Pharmaceutical Committee

2. Organisational authorisations *(may require amendment depending on how the service using the PGD is being commissioned/the organisation who is responsible for authorising the PGD – not all fields may be applicable)*

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Bath and North East Somerset, Swindon and Wiltshire CCG authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Community Pharmacies contracted to provide the BSW CCG Community Pharmacy PGD Service for Minor Ailments
Limitations to authorisation
None

Organisational approval (legal requirement)

Senior Doctor			
Role	**Name**	**Sign**	**Date**
Medical Director BSW CCG	Dr Ruth Grabham		**08.12.21**

Senior Pharmacist			
Role	**Name**	**Sign**	**Date**
Associate Director (Medicines Optimisation), BSW CCG	Paul Clarke		**02.12.21**

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director (Medicines Optimisation), BSW CCG	Nadine Fox		**02.12.21**

Local enquiries regarding the use of this PGD may be directed to bswccg.prescribing@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets/templates may be used where appropriate in accordance with local policy.

3. Characteristics of staff

Qualifications and professional registration	• Pharmacists registered with the General Pharmaceutical Council (GPhC)
Initial training	• must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • Has undertaken appropriate training and declared themselves assessed competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must have access to the Patient Group Direction and associated online resource • should fulfil any additional requirements defined by local policy ***The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the declaration of competence to undertake clinical assessment of patient leading to diagnosis of the conditions listed.***
Competency assessment	*Complete the self-declaration for this PGD on PharmOutcomes* *Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions* ***Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.***
Ongoing training and competency	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to this PGD and should be aware of any change to the recommendations for the medicines listed. It is the responsibility of the individual to keep up-to-date with Continued Professional Development (CPD).
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	**Treatment of acute uncomplicated urinary tract infections, in non-pregnant females aged between 16 and 64 years old** **Nitrofurantoin is second line for patients when there are high risk factors for increased resistance** (risk factors for increased resistance include: care home resident, hospitalisation >7 days in the last 6 months, un-resolving urinary symptoms, recent travel to a country with increased antimicrobial resistance (outside northern Europe and Australasia) especially health related, previous known UTI resistance to trimethoprim, cephalosporins or quinolones)

Criteria for inclusion	• Female adults with an uncomplicated urinary tract infection
	• Aged between 16 and 64 years (inclusive)
	• Valid informed consent
	
	• Two or three of the three key diagnosis signs / symptoms
	  - Dysuria
	  - New nocturia
	  - Urine cloudy to the naked eye
	
	• Second line treatment when there are risk factors for increased resistance.

Criteria for exclusion	• No valid informed consent
	• Age under 16 years
	• Patients aged 65 years or over
	• Male patients
	• **Red flags**
	  - Signs of sepsis
	  - Patient with symptoms of pyelonephritis (signs include kidney pain/ tenderness in the back under the ribs, new/different myalgia, flu like illness, shaking chills (rigors) or temperature 37.9oC or above, nausea/vomiting)
	  - Visible haematuria (blood in urine)
	• Pregnancy
	• Breast-feeding
	• Patients who are immuno-compromised
	• Patient with vaginal and/ or urethral causes of urinary symptoms:
	  - Vaginal discharge (80% do not have a UTI),
	  - Urethritis
	  - Sexually transmitted infections
	  - Genitourinary syndrome of menopause
	  - Thrush
	• Patients with known renal impairment
	• Have any urological abnormalities (for example renal calculus, vesicoureteric reflux, reflux nephropathy, neurogenic bladder, urinary obstruction or recent instrumentation) or who have had surgery involving the lower urinary tract, urinary catheter
	• Presenting with a recent UTI treated with antibiotics in the last two weeks
	• Women with drug induced cystitis (allopurinol, danazol,

	cyclophosphamide, tiaprofenic acid and possibly other NSAIDs) • Acute porphyria • Patients with only one of the key diagnosis signs/ symptoms (dysuria, new nocturia, urine cloudy to the naked eye) – refer to GP practice or out of hours for a urine dipstick to be performed to aid diagnosis • Patients with none of the key diagnosis signs/ symptoms (dysuria, new nocturia, urine cloudy to the naked eye). Review if there are any other urinary symptoms: - Urgency - Frequency - Visible haematuria - Suprapubic tenderness If there are refer to GP practice or out of hours for a urine dipstick to be performed to aid diagnosis. If not reassure UTI unlikely. • Hypersensitivity to nitrofurantoin, other nitrofurans or any of the excipients • Patients with G6PD deficiency • Patients taking prophylactic nitrofurantoin
Cautions including any relevant action to be taken	• For women under 65 years with mild symptoms who have normal immunity, normal renal function, and a normal renal tract, treatment can be delayed if she wishes to see if symptoms will resolve without treatment • Consider referral to prescriber where appropriate. • Since pre-existing conditions may mask adverse reactions, Nitrofurantoin should be used with caution in patients with pulmonary disease, hepatic dysfunction, neurological disorders, and allergic diathesis. • Nitrofurantoin should be used in caution with patients with anaemia, electrolyte imbalance, debilitating conditions and vitamin B (particularly folate) deficiency. • Diabetic patients – UTI could be a symptom of poor control and so current medication and diabetic control should be discussed/ reviewed. • If there are any concerns that a young person is being abused or exploited, the UTI can still be treated, and the appropriate Safeguarding SOP followed.
Action to be taken if the patient is excluded	• Record reasons for exclusion and any action(s) taken in patient notes • Document advice given and the decision reached • Advise patient on alternative treatment. • Refer to a GP if appropriate
Action to be taken if the patient or carer declines treatment	• Record reasons for decline and any action(s) taken in patient notes • Advise patient on alternative treatment. • Document advice given and the decision reached • Refer to a prescriber if appropriate
Arrangements for referral for medical advice	• Clinical information should be sent to the patient's GP in accordance with local protocols

5. Description of treatment

Name, strength & formulation of drug	NITROFURANTOIN 100mg Modified Release Capsules
Legal category	Prescription-only medicine (POM)
Route / method of administration	ORAL
Dose and frequency of administration	100mg twice a day
Duration of treatment	THREE days
Quantity to be supplied	6 x Nitrofurantoin MR capsules
Storage	Do not store above 25°C.
Drug interactions	○ Nitrofurantoin is predicted to increase the risk of methaemoglobinaemia when given with topical anaesthetics prilocaine and dapsone. Use with caution or avoid. ○ Oral magnesium salts (as magnesium trisilicate) reduce absorption of nitrofurantoin ***A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk***
Identification & management of adverse reactions	• Rare: Agranulocytosis; aplastic anaemia; arthralgia; benign intracranial hypertension; blood disorders; cholestatic jaundice; erythema multiforme; exfoliative dermatitis; hepatitis; pancreatitis; thrombocytopenia; transient alopecia • Frequency unknown: Acute pulmonary reactions; anaphylaxis; angioedema; anorexia; chronic pulmonary reactions (pulmonary fibrosis reported; possible association with lupus erythematosus-like syndrome); diarrhoea; hypersensitivity reactions; nausea; peripheral neuropathy; pruritus; rash; sialadenitis; urticaria; vomiting Use the Yellow Card System to report unexpected adverse drug reactions directly to the CSM. Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF or via www.yellowcard.gov.uk **A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk**
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: ***https://yellowcard.mhra.gov.uk*** • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy. • If anaphylaxis management may be required include this information here (e.g. adrenaline to be held/resuscitation team

	details)
Written information to be given to patient or carer	• Give marketing authorisation holder's patient information leaflet (PIL) provided with the product. • Provide copy of TARGET UTI leaflet https://elearning.rcgp.org.uk/mod/book/view.php?id=12647&chapterid=441
Patient advice / follow up treatment	• Take the antibiotics at regular intervals and complete the course supplied • Advise patient to refer to their GP practice or contact NHS if: - they have shivering, chills and muscle pain - feel confused or are very drowsy - have not passed urine all day - are vomiting - see blood in their urine - their temperature is above 38ºc or less than 36ºC - have kidney pain in their back just under the ribs - symptoms get worse - symptoms are not starting to improve within 48 hours of taking antibiotics. • Discuss side effects and advise to come back if side effects occur • Advise on self-care including drinking enough fluids to stop you feeling thirsty – aiming for 6 to 8 glasses per day and 'over the counter' analgesia. If the patient has recurrent UTIs (three or more episodes of acute UTI in the last 12 months or two episodes within six months) discuss with them options to prevent UTIs – see the target UTI leaflet and recurrent UTI guidelines https://prescribing.bswccg.nhs.uk/wpdm-package/wiltshire-swindon-banes-primary-care-antibiotic-guidance-jan-2019-nice-update
Records	Record: • that valid informed consent was given • name/signature of individual, address, date of birth and GP with whom the individual is registered (if relevant) • History, examination, investigations, diagnosis • Drug history including any allergies • name of registered health professional • name and brand of medication supplied/administered • date and time of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) • Referral arrangements (including self-care) • Add patient name and date of supply to the pack before issuing. Liquid dose forms must include the expiry date of reconstituted suspension. ***Records should be signed and dated (or a password controlled e-records).*** ***All records should be clear, legible and contemporaneous.***

	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	• Summary of Product Characteristics for nitrofurantoin (available at www.emc.medicines.org.uk • British National Formulary (available online at www.medicinescomplete.com) • BSW Antimicrobial Prescribing Guidelines available https://prescribing.bswccg.nhs.uk/wpdm-package/wiltshire-swindon-banes-primary-care-antibiotic-guidance-jan-2019-nice-update • NICE Clinical Knowledge Summaries (available at https://cks.nice.org.uk/urinary-tract-infection-lower-women) • Public Health England Urinary trat infection: diagnostic tool for primary care(available at https://www.gov.uk/government/publications/urinary-tract-infection-diagnosis)

7. Registered health professional authorisation sheet

CommPharm Nitrofurantoin UTI Vs 1.0 **Valid from:** December 2021 **Expiry:** December 2023

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager (if applicable)

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of INSERT NAME OF ORGANISATION for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD