

# PATIENT GROUP DIRECTIONS\*

**The Supply of Nitrofurantoin 100mg Modified Release Capsules  
for the treatment of uncomplicated lower urinary tract infection in women  
by Community Pharmacists participating in the  
NHS Cheshire Clinical Commissioning Group  
Pharmacy First Minor Ailments Service**

Version 5

Date of introduction June 2021

(It is intended that this document will be updated in 2 years  
subject to no amendments in the interim period )

Review Date May 2023

**\*HSC 2000/026 Patient Group Directions (England Only)**

**Version Control:**

Nitrofurantoin 100mg Modified Release Capsules for the treatment of uncomplicated lower urinary tract infection in women

Version	Date of introduction	Author	Status	Comment
V1	November 2015	PGD Development and review group	Approved	To offer nitrofurantoin MR first line to bring community pharmacy service in line with Management of Infection Guidelines.
V2	April 2016	PGD Development and review group	Draft	Awaiting development group comment
V2	April 2016	PGD Development and review group	Approved	Approved with minor amendments recommended by the PGD subgroup
V3	April 2017	PGD Development and review group	Approved	Approved by PGD subgroup on 8 Mar 2017
V4	April 2019	PGD Development and review group	Approved	Addition of NHS West Cheshire CCG. Updated Patient information leaflet. Approved by PGD subgroup on 12 December 2018.
V5	April 2021	PGD Development and review group	Draft	Updated inclusion criteria; updated TARGET leaflet; updated steering group and CCG signatories
V5	April 2021	PGD Development and review group	Draft	Pulmonary and neurological conditions added to exclusion criteria
V5	June 2021	PGD subgroup	Approved	Approved by PGD subgroup on 17 Jun 2021

Patient Group Direction:	Nitrofurantoin 100mg modified release capsules for the treatment of uncomplicated lower urinary tract infection in women.
Clinical Department/Service:	Community Pharmacists participating in the Pharmacy First Minor Ailments Service commissioned by NHS Cheshire Clinical Commissioning Group

### 1. Clinical Condition

1.1	Define situation/condition	<ul style="list-style-type: none"> <li>Uncomplicated lower urinary tract infection in women.</li> </ul>
1.2	Criteria for inclusion	<ul style="list-style-type: none"> <li>Treatment should only be provided when there are severe symptoms or <math>\geq 2</math> symptoms from the following list: <ul style="list-style-type: none"> <li><i>Dysuria — discomfort, pain, burning, tingling or stinging associated with urination.</i></li> <li><i>Nocturia — passing urine more often than usual at night.</i></li> <li><i>Changes in urine appearance or consistency; Urine may appear cloudy to the naked eye, or change colour or odour.</i></li> </ul> </li> <li>Patient agrees to treatment under this PGD</li> </ul>
1.3	Criteria for exclusion	<ul style="list-style-type: none"> <li>Known hypersensitivity / allergy to nitrofurantoin or any excipient in the product.</li> <li>Treatment either via the pharmacy service or GP within the previous three months.</li> <li>Patients under 18 years of age.</li> <li>Patients over 65 years of age.</li> <li>Haematuria.</li> <li>Known renal impairment.</li> <li>Known hepatic impairment.</li> <li>Known neurological disorders.</li> <li>Known pulmonary disease.</li> <li>Pregnant or breast feeding.</li> <li>Known blood dyscrasias.</li> <li>Peripheral neuropathy.</li> <li>Vaginal itch or unusual discharge.</li> <li>Fever or systemically unwell</li> </ul>

		<ul style="list-style-type: none"> <li>• Loin pain.</li> <li>• Confused or dehydrated.</li> <li>• Patient already taking prophylactic nitrofurantoin.</li> <li>• Patient recently received oral typhoid vaccine (oral antibacterials inactivate oral typhoid vaccine).</li> <li>• Patients taking medicines that may interact e.g. nalidixic acid or sulfapyrazone or medicines containing magnesium salts e.g. magnesium trisilicate (<b>See BNF or SPC for full list</b>)</li> <li>• Patients who are anaemic, have diabetes or vitamin B (particularly folate) deficiency.</li> <li>• Porphyria.</li> <li>• G6PD Deficiency (see BNF)</li> </ul>
1.4	Cautions/additional information	Refer to of Product characteristics. ( <a href="http://emc.medicines.org.uk/">http://emc.medicines.org.uk/</a> )
1.5	Action if patient excluded	<ul style="list-style-type: none"> <li>• Patients who do not meet the inclusion criteria for number or severity of symptoms should be advised that cystitis is usually self-limiting and will resolve without antibiotics. Give self care and safety netting advice as contained in the TARGET UTI leaflet at the end of the PGD.</li> <li>• Patients who meet the inclusion criteria for severity or number of symptoms but who are excluded from treatment with nitrofurantoin may be considered for treatment with either pivmecillinam (second line option) or trimethoprim (third line option).</li> <li>• Patients who are excluded from treatment because of signs or symptoms of systemic disease or more serious urinary tract conditions should be referred to GP practice or out of hours via NHS 111 as appropriate. The patient should be provided with a referral note to hand to the GP indicating the reasons for the referral.</li> <li>• Clearly record the decision on the patient's consultation proforma, advice given and any action taken.</li> </ul>
1.6	Action if patient declines	Clearly record the decision on the patient's consultation proforma, including any advice given and any action taken, refer to GP or out of hours via NHS 111 as appropriate.

## 2. Characteristics of staff

2.1	Class of Health Professional for whom PGD is applicable (professional)	Qualified Pharmacist registered with the General Pharmaceutical Council (GPhC)
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	qualification and training)	
2.2	Additional requirements	<ul style="list-style-type: none"> <li>Competent to work under Patient Group Directions, including satisfactory completion of training to administer /supply in accordance with this patient group direction</li> <li>Working as a community pharmacist and accredited to provide the Minor Ailments Service.</li> </ul>
2.3	Continued training requirements	<ul style="list-style-type: none"> <li>Commitment to continuing updating and re-validation according to the accreditation requirements of the commissioning organisation.</li> <li>Commitment to keep up to date with clinical developments or changes to the recommendations for the medicine listed, as part of their Continual Professional Development.</li> </ul>

### 3. Description of Treatment

3.1	Generic name of medicine and form	Nitrofurantoin 100mg modified release (MR) capsules.
3.2	Legal status	POM
3.3	Storage	Room temperature not above 25°C.
3.4	Licensed or unlicensed	Licensed
3.5	Dose(s)	100mg MR twice a day
3.6	Route/Method of Administration	Oral
3.7	Frequency of administration	As detailed above (3.5).
3.8	Total dose and number of times treatment can be administered over what time	100mg MR twice a day. Treatment to be continued for three days Supply 6 capsules.
3.9	Side effects of drugs (including potential Adverse Drug Reaction)	<ul style="list-style-type: none"> <li>Gastrointestinal disturbances including nausea, vomiting and diarrhoea.</li> <li>Acute pulmonary reactions commonly manifested as fever, chills, cough, chest pain. Discontinue treatment.</li> <li>Peripheral neuropathy: Treatment should be stopped at the first signs of neural involvement (paraesthesiae).</li> <li>Hypersensitivity reactions including rashes pruritus and urticaria, angioedema, anaphylaxis, sialadenitis.</li> <li>Rarely, cholestatic jaundice, hepatitis, exfoliative dermatitis.</li> </ul>







		<ul style="list-style-type: none"> <li>Refer to SPC and current BNF for full details.</li> </ul>
3.10	Advice/management of adverse reactions/events	Seek advice from GP practice or out of hours via NHS 111 as appropriate.
3.11	Procedure for reporting Adverse Drug Reactions (ADR's)	<ul style="list-style-type: none"> <li>Report serious suspected adverse drug reactions (or all suspected ADRs if the medicine is black triangle) to the Medicines Health and Regulatory Agency using either the yellow cards or via <a href="http://www.yellowcard.gov.uk">www.yellowcard.gov.uk</a></li> <li>Record any adverse drug reaction in the patient's consultation record and PMR.</li> <li>Notify patient's GP practice.</li> </ul>
3.12	Information on follow up treatment	Contact GP practice or out of hours via NHS 111 if symptoms worsen rapidly or significantly at any time, do not start to improve within 48 hours of taking the antibiotic, or the person becomes systemically unwell.
3.13	Written/verbal advice for patient/carer before/after treatment.	<ul style="list-style-type: none"> <li>Discuss side effects and administration with the patient and provide a manufacturers patient information leaflet.</li> <li>Always complete the full course.</li> <li>Take with food, swallow whole.</li> <li>Encourage women to maintain hydration by drinking water.</li> <li>Paracetamol or Ibuprofen may be useful to relieve pain/discomfort.</li> <li>If symptoms do not start to improve within 48 hours of taking the antibiotic consult your GP. <b><i>This instruction must be printed on the label.</i></b></li> <li>If condition recurs within 3 months consult your GP.</li> <li>Risk of possible STDs should be raised if appropriate. Sexually active young women with urinary symptoms advise or offer Chlamydia screening.</li> <li>May colour urine yellow or brown.</li> <li>Consult your GP practice if you notice blood in your urine.</li> <li>May cause dizziness or drowsiness advise patient not to drive or operate machinery if affected.</li> </ul>
3.14	Specify method of recording supply/ administration, names of health professional,	<p>The following will be recorded in the patient's consultation proforma:</p> <ul style="list-style-type: none"> <li>Quantity supplied.</li> </ul>

	patient identifiers, sufficient to enable audit trail.	<ul style="list-style-type: none"> <li>• Advice given to patient.</li> <li>• Date of supply.</li> <li>• The signature of the person supplying the medicine.</li> </ul>
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#### 4. Development of the PGD

##### Multidisciplinary Group:

The group who have been involved in the development of this PGD included the following people:

Name	Designation	Signature	Date
Janet Kenyon	Assistant Director of Medicines Strategy and Optimisation NHS Cheshire Clinical Commissioning Group		8.6.2021
Dr Graham Duce	GP Prescribing Lead NHS Cheshire Clinical Commissioning Group.		17.6.2021
Dr Andrew Dunbavand	GP Prescribing Lead NHS Cheshire Clinical Commissioning Group.		08.7.2021
Suzanne Austin	Pharmacy Local Professional Network Chair.		17.6.2021
Susan Nixon	Minor Ailments Co-ordinator NHS Cheshire Clinical Commissioning Group.		17.6.2021
Dr Ildiko Kustos	Consultant Medical Microbiologist Countess of Chester Hospital NHS Foundation Trust		15.7.2021

#### 5. References

- SPC for contraindications and cautions (<http://emc.medicines.org.uk/>)
- BNF 79 March 2020 – September 2020
- RCGP Target leaflet



**Responsible Organisation:**

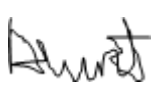
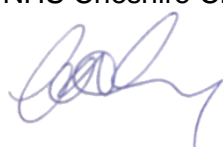
NHS Cheshire Clinical Commissioning Group

**Responsibilities of each Organisation:**

Each organisation is required to:

1. Approve the contents of this documentation (in the knowledge that it has been prepared by a multidisciplinary group as above).
2. Ensure that every PGD is approved and signed by a nominated Senior Pharmacist and Senior Doctor.
3. Ensure that the PGD is approved and signed by a senior member of staff, representative of the staff to whom the PGD relates e.g. nurses, chiropodists etc.
4. Ensure that the PGD is approved and signed by the Clinical Governance Lead for the Organisation.
5. Ensure that individual health professionals working under the direction sign appropriate documentation.

**PATIENT GROUP DIRECTION for the Supply of nitrofurantoin 100mg MR capsules for the treatment of uncomplicated lower urinary tract infection in women**

Organisation (s)	NHS Cheshire Clinical Commissioning Group
<b><u>Approved by</u></b>  <b>Patient Group Direction Subgroup Chair</b>  Name  Position   Signature  Date	Andrea Lunt  Assistant Director of Medicines Strategy and Optimisation & Lead Pharmacist for PGD subgroup NHS Cheshire Clinical Commissioning Group.   20.09.2021
<b>Clinical Governance Lead</b>  Name  Position  Signature  Date	Dr Andrew McAlavey  Joint Medical Director NHS Cheshire Clinical Commissioning Group   17.09.21

**TARGET UTI leaflet.** Copies may be printed from <https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/amr/target-antibiotics-toolkit/-/media/85AAD1D4DDEF455A85E0416C3BB714AE.ashx>



## TREATING YOUR INFECTION – URINARY TRACT INFECTION (UTI)



For women under 65 years with suspected lower urinary tract infections (UTIs) or lower recurrent UTIs (cystitis or urethritis)

Possible urinary signs & symptoms	The outcome	Recommended care	COVID-19 specific advice
<p><b>Key signs/symptoms:</b>  Dysuria: Burning pain when passing urine (wee)  New nocturia: Needing to pass urine in the night  Cloudy urine: Visible cloudy colour when passing urine</p> <p><b>Other signs/symptoms to consider:</b>  Frequency: Passing urine more often than usual  Urgency: Feeling the need to pass urine immediately  Haematuria: Blood in your urine  Suprapubic pain: Pain in your lower tummy</p> <p><b>Other things to consider:</b>  Recent sexual history  • Inflammation due to sexual activity can feel similar to the symptoms of a UTI  • Some sexually transmitted infections (STIs) can have symptoms similar to those of a UTI  Changes during menopause  • Some changes during the menopause can have symptoms similar to those of a UTI</p>	<p><b>Non-pregnant women:</b></p> <p><input type="checkbox"/> If none or only one of: dysuria, new nocturia, cloudy urine; AND/OR vaginal discharge</p> <p>• UTI much less likely  • You may need a urine test to check for a UTI  • Antibiotics less likely to help  • Usually lasts 5 to 7 days</p> <p><input type="checkbox"/> If 2 or more of: dysuria, new nocturia, cloudy urine; OR bacteria detected in urine; AND NO vaginal discharge</p> <p>• UTI more likely; antibiotics should help  • You should start to improve within 48 hours  • Symptoms usually last 3 days</p> <p><b>Pregnant women:</b> Always request urine culture</p> <p><input type="checkbox"/> If suspected UTI</p>	<p><input type="checkbox"/> Self-care and pain relief.  • Symptoms may get better on their own  <input type="checkbox"/> Delayed or backup prescription with self-care and pain relief  Start antibiotics if symptoms:  • Get worse  • Do not get a little better with self-care within 48 hours</p> <p><input type="checkbox"/> Immediate antibiotic prescription plus self-care</p> <p><input type="checkbox"/> If mild symptoms, delayed or back-up antibiotic prescription plus self-care</p> <p><input type="checkbox"/> Immediate antibiotic prescription plus self-care</p>	<p>Common symptoms of COVID-19 to look out for are:</p> <ul style="list-style-type: none"> <li>• A loss of, or change to your sense of smell or taste</li> <li>• A high temperature</li> <li>• A new continuous cough</li> </ul> <p>• If you have any of these symptoms and think you may have a UTI please do not ignore the UTI symptoms.</p> <p>• Book a COVID-19 test and self-isolate for 10 days or until you get a negative test result (<a href="http://www.gov.uk/get-coronavirus-test">www.gov.uk/get-coronavirus-test</a>)</p> <p><b>AND</b></p> <p>• Book a remote / online GP appointment to discuss your potential UTI and explain that you have also booked a COVID-19 test.</p> <p>Follow the latest advice on COVID-19 at <a href="http://www.gov.uk/coronavirus">www.gov.uk/coronavirus</a> and <a href="http://www.nhs.uk">www.nhs.uk</a></p>
<p><b>Self-care to help yourself get better more quickly</b></p> <ul style="list-style-type: none"> <li>• Drink enough fluids to stop you feeling thirsty. Aim to drink 6 to 8 glasses</li> <li>• Avoid too much alcohol, fizzy drinks or caffeine that can irritate your bladder</li> <li>• Take paracetamol or ibuprofen at regular intervals for pain relief, if you have had no previous side effects</li> <li>• There is currently no evidence to support taking cranberry products or cystitis sachets to improve your symptoms</li> <li>• Consider the risk factors in the 'Options to help prevent UTI' column to reduce future UTIs</li> </ul>	<p><b>Options to help prevent a UTI</b></p> <p><u>It may help you to consider these risk factors:</u></p> <ul style="list-style-type: none"> <li>• Stop bacteria spreading from your bowel into your bladder. Wipe from front (vagina) to back (bottom) after using the toilet.</li> <li>• Avoid waiting to pass urine. Pass urine as soon as you need to.</li> <li>• Go for a wee after having sex to flush out any bacteria that may be near the opening to the urethra.</li> <li>• Wash the external vagina area with water before and after sex to wash away any bacteria that may be near the opening to the urethra.</li> <li>• Drink enough fluids to make sure you wee regularly throughout the day, especially during hot weather.</li> </ul> <p><u>If you have a recurrent UTI, the following may help:</u></p> <ul style="list-style-type: none"> <li>• Cranberry products and D-mannose: There is some evidence to say that these work to help prevent recurrent UTI</li> <li>• After the menopause: Topical hormonal treatment may help; for example, vaginal pessaries.</li> <li>• Antibiotics at night or after sex may be considered</li> </ul>	<p><b>Antibiotic resistance</b></p> <p>Antibiotics can be lifesaving. But antibiotics are not always needed for urinary symptoms.</p> <p>Antibiotics taken by mouth, for any reason, affect our gut bacteria making some resistant.</p> <p>This may make future UTI more difficult to treat</p> <p>Common side effects to taking antibiotics include thrush, rashes, vomiting and diarrhoea. Seek medical advice if you are worried.</p> <p>Keep antibiotics working; only take them when advised by a health professional. This way they are more likely to work for a future UTI.</p>	<p><b>When should you get help?</b>  Contact your GP practice or contact NHS</p> <p>The following symptoms are possible signs of serious infection and should be assessed urgently.</p> <p>Phone for advice if you are not sure how urgent the symptoms are.</p> <ol style="list-style-type: none"> <li>1. You have shivering, chills and muscle pain</li> <li>2. You feel confused, or are very drowsy</li> <li>3. You have not passed urine all day</li> <li>4. You are vomiting</li> <li>5. You see blood in your urine</li> <li>6. Your temperature is above 38°C* or less than 36°C</li> <li>7. You have kidney pain in your back just under the ribs</li> <li>8. Your symptoms get worse</li> <li>9. Your symptoms are not starting to improve within 48 hours of taking antibiotics</li> </ol> <p>*Temperature above 38°C is also a symptom of COVID-19. Please see COVID-19 specific advice.</p>

Developed in collaboration with professional medical bodies. Version 23 October 2020. Review October 2021. KAW19-07 ©