

Patient Group Direction

For community pharmacists presented with a treatment voucher for the treatment of non complicated Chlamydia, contacts of Chlamydia or contacts of Non-Gonococcal urethritis (NGU)to Supply/Administer

Doxycycline Capsules 100mg

To patients aged 16 years and over

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It is the responsibility of the person using this PGD to ensure that they are using the most recent issue.

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This Patient group Direction has been approved on behalf of NHS Fife by:

Name	Designation	Signature	Date
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^{*} If this PGD is past its review date then the content will remain valid until such time as the PGD review is complete and the new issue published



1. Clinical condition to which the patient group direction applies

Indication	Treatment of uncomplicated Chlamydial infection
Inclusion criteria	 Patients aged 16 years and over Patients who have been diagnosed with chlamydia/Non Gonoccocal Urethritis (NGU) presenting with a valid treatment voucher issued by Sexual Health Fife Contacts of patients who have been diagnosed with chlamydia/NGU presenting with a valid treatment voucher issued by Sexual Health Fife Valid consent to treatment in accordance with NHS Fife Consent Policy
Exclusion criteria	 Patient under 16 years old Patients who are pregnant or breast-feeding Patients who are HIV positive Women with signs and symptoms of acute pelvic inflammatory disease (PID) i.e. febrile, clinically unwell, pelvic pain. Women with pelvic pain even if no other signs or symptoms of acute pelvic inflammatory disease (PID) Men with signs and symptoms of acute conditions like epididymo-orchitis or other potential testicular pathology e.g. scrotal pain, swelling or erythema, pyrexia, significant dysuria or penile discharge, rectal pain, tenesmus or discharge. These men should be referred to Sexual Health or A&E (if out of hours) Patients with myasthenia gravis: due to a potential for weak neuromuscular blockade, care should be taken in administering tetracyclines to patients with myasthenia gravis Patients with porphyria Patients with hepatic impairment or taking hepatotoxic drugs Patients with a hypersensitivity to doxycycline or any of the constituents of the capsule (see manufacturer's PIL and SPC) Patients with a hypersensitivity to other antibiotics in the tetracycline group Patients with a hypersensitivity to other antibiotics in the tetracycline for example certain antiepileptics, ciclosporin, ergot alkaloids, methotrexate, methoxyflurane, penicillins, rifampicin, retinoids, oral typhoid vaccine N.B. This list is not exhaustive. Doxycycline has the potential to interact with many drugs. Please check the BNF (Appendix 1) and manufacturer's SPC. No valid consent to treatment according to NHS Fife policy
Cautions / Circumstances when further advice should be given to the patient	 Patient already taking a prescribed antibiotic Patients taking anticoagulants - there have been reports of prolonged prothrombin time in patients taking anticoagulants and doxycycline. Regular monitoring of INR is required Patients taking antacids containing aluminium, calcium, magnesium or other drugs containing these cautions; oral zinc, iron salts or bismuth preparations - absorption of doxycycline may be impaired by concurrent administration - dosages should be maximally separated Patients with systemic lupus erythematous (SLE) - tetracyclines can cause exacerbation of SLE It is the responsibility of the designated, authorised staff, using this PGD to ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt, advice should be sought and recorded before the drug is administered
Action if excluded	 Do not use the PGD Refer to Sexual health Fife or own GP if patient does not wish to attend Sexual health, If acutely unwell refer to A&E The reason for the exclusion should be documented along with voucher code



	on the pharmacy claim form • Document actions taken, advice given or any follow up arrangements
Action if pt. declines treatment	 The reason for declining treatment should be documented with voucher code on pharmacy claim form Discuss implications of declining treatment. Offer referral to Sexual Health Fife Document actions taken, advice given, or any follow up arrangements

2. Medication details		
Name strength & form. of drug	Doxycycline capsules 100mg	
Route of administration	Oral	
Dosage & frequency of administration	1 x 100mg capsule TWICE daily	
Duration of treatment & quantity to be supplied	7 days – 14 x 100mg capsules	
Patient advice verbal and written	 The patient information leaflet should be given The capsules should be swallowed with plenty of fluid in either the sitting or standing position and well before going to bed for the night to reduce the 	
WITHE	likelihood of oesophageal irritation and ulceration	
	If gastric irritation occurs, it is recommended that doxycycline capsules be given with food or milk	
	 Absorption of doxycycline may be impaired by concurrently administered antacids containing aluminium, calcium, magnesium or other drugs containing these ingredients; oral zinc, iron salts or bismuth preparations, dosages should be maximally separated. 	
	Alcohol may decrease the half life of doxycyline patients should be advised to avoid alcohol during treatment with doxycycline.	
	 Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines, including doxycycline. Patients likely to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur with tetracycline drugs and treatment should be discontinued at the first evidence of skin erythema. Wherever possible patients should avoid exposure of skin to direct sunlight or sunlamps May cause nausea, vomiting, diarrhoea, indigestion and rash. Please seek medical advice if symptoms are severe 	
	 Serious skin reactions, such as exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in patients receiving doxycycline. If serious skin reactions occur, doxycycline should be discontinued immediately and patient should seek medical advice. Visual disturbances such as blurring of vision may occur during treatment. If affected advise patients to refrain from driving or operating machinery Complete the course unless otherwise directed 	
	Provide client with NHS/FPA patient information leaflet on 'Chlamydia' or 'Non-gonococcal urethritis (NGU)	
	 Advise patient not to have sex with untreated partner(s) because of significant risk of re-infection even if using a condom. Advise not to have sex for seven days after self and partner have been treated 	
	Seek further medical advice if condition worsens or fails to improve with treatment	
	Patient should be made aware that additional testing for Gonorrhoea, syphilis and HIV is advisable in the presence of a sexually transmitted infection and	



	 how testing can be accessed. This is particularly important for patients presenting with as a Contact Voucher as these patients may not have been seen at Sexual Health Fife recently for an STI screen and should be signposted to Sexual Health Fife to access testing. All patients should be offered advice on prevention of transmission of STIs and offered free condoms. All patients should offered advice on contraception and signposted to Sexual Health Fife services where appropriate
Legal category	• POM
Storage requirements	 Store below 25°C Ensure within expiry date
Identification and management of adverse reactions	 Hypersensitivity reactions including anaphylaxis are rare-advise patient to call 999 if experiencing a hypersensitivity reaction. Gastric side effects may cause nausea and vomiting. If a patient is taking the oral contraceptive pill and vomits within 2 hours of taking the pill or has severe diarrhoea follow advice as for missed pills (see most recent FSRH advice for directions to minimise the risk of contraceptive failure) Advise patient to seek medical advice for significant side effects or if concerned All suspected serious reactions should be reported directly to the MHRA/Commission on Human Medicines through the Yellow Card scheme and recorded in the patient's medical notes. Reports should be made online at https://yellowcard.mhra.gov.uk
Follow up –	 The patient should be advised to contact Sexual Health Fife or their own GP if there is no improvement in symptoms within 3 weeks of treatment. Where further STI screening is indicated refer patient to Sexual Health Fife or own GP. Where contraception advice is indicated refer patient to Sexual Health Fife or own GP Where a concern about Gender Based Violence (GBV) is identified during the consultation patient should be signposted to access support from Fife GBV team or where patient gives permission a direct referral can be made by the pharmacist. Fife GBV team 01592729133 Information for professionals and patients can be found on the Sexual Health Fife: Welcome to Sexual Health Fife

3. Staff characteristics

Define Practitioner Group	Pharmacists working in community pharmacy within NHS Fife
Professional qualifications	Registered pharmacist with current General Pharmaceutical Council (GPhC) registration
Additional training requirements	 Undertaken Continued Professional Development (CPD) to ensure understanding of pharmacist responsibility in treating Chlamydia and NGU Undertaken appropriate training for working under PGDs for the supply of medicines Able to assess the patients capacity to understand the nature and purpose of the treatment in order to give informed consent.
Continued training requirements	It is the responsibility of the designated, authorised staff using this PGD to keep up-to-date with information on contraindications, cautions and interactions for doxycyline from the BNF, SPC and PIL and ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt,



	advice should be sought and recorded before the product is supplied.	
•	Maintain own competence and knowledge in this area.	

Namitain own competence and knowledge in this area.
 A 2 yearly update of the PGD e-learning programme is essential

4. Referral arrangements/Audit trail			
Arrangements	Patients should be referred to Sexual Health Fife or their own GP if treatment		
for referral to	proves to be ineffective in relieving the symptoms.		
medical advice	Patient may be referred to Sexual Health Fife or their own GP at any stage if		
	this is necessary in the professional opinion of the pharmacist.		
Records/Audit	PMR/consultation record		
trail	Enter in record (as appropriate)		
	- date		
	name of patientDate of birth/ CHI no		
	- Date of birth/ CHI no - Address		
	- name of medicine		
	- batch number and manufacturer		
	- expiry date		
	- dose		
	- quantity administered		
	 route of administration name of clinician providing treatment 		
	signature / individual details of clinician providing treatment		
	- Signature / individual details of clinician providing treatment		
	Retain paper vouchers and return to Pharmacy services		
	Record Text voucher codes and return to Pharmacy services		
	Witness patient delete text voucher codes		
	These records should be retained in accordance with local/national guidance.		
	UCF can be used to generate a prescription and trigger payment for drug		
	 issued. Please add youcher code in the directions if using UCF as this improves audit 		
	Please add voucher code in the directions if using UCF as this improves audit of voucher redemption.		
	or voucher redemption.		
References/	British National Formulary (BNF/BNFc) Latest edition available at		
Resources &	www.medicinescomplete.com		
comments	NHS Fife Consent Policy		
	<u>NMC/RPS Administration of Medicines Guidance Jan 2019</u>		
	NHS Fife Safe and Secure Use of Medicines Policy and Procedures		
	(SSUMPP) SPC for doxycycline –available at www.medicines.org.uk		
	http://www.fifeadtc.scot.nhs.uk/formulary/support%20info/Primary%20Care%2		
	0Antibiotic%20Guidelines.pdf.		
	Faculty of Sexual & Reproductive Health (FSRH) Clinical Effectiveness Unit		
	Guideline - Drug Interactions with Hormonal Contraception, January 2012		
	https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-		
	guidance-drug-interactions-with-hormonal/		
	Faculty of Sexual & Reproductive Health (FSRH) Clinical Effectiveness Unit		
	Guideline – The management of vaginal discharge in non-genitourinary medicine settings complaining of vaginal discharge, February 2012.		
	British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness		
	Group National Guidelines –		
	SIGN 109 Guideline: Management of Genital Chlamydia trachomatis		
	Infection, March 2009. http://www.sign.ac.uk/pdf/sign109.pdf		
	https://www.bashhguidelines.org/media/1045/chlamydia-2015.pdf		
	British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness Once Notice of Control of the Control of Control		
	Group National Guideline – Management of Non-gonococcal Urethritis (2006, updated 2008). https://www.bashhguidelines.org/media/1051/ngu-2015.pdf		
	upuateu 2000). https://www.bashriguluelines.org/media/1051/rigu-2015.pdf		
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This Patient Group Direction has been assessed for Equality and Diversity Impact

5. Management and monitoring of Patient Group Direction 322

PATIENT GROUP DIRECTION 322 FOR COMMUNITY PHARMACISTS to Supply/Administer Doxycycline Capsules 100mg for the treatment of non complicated Chlamydia, contacts of Chlamydia or contacts of NonGonococcal urethritis (NGU) To patients aged 16 years and over

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 **Doxycycline Capsules 100mg**

Name of Pharmacist		
GPhC Registration Number		_
Normal Pharmacy Location		
Name & Contractor code		_
Please indicate your position within the	he pharmacy by ticking one of the following:	
Locum Employee	Manager Owner	
Signature	Date	_

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Please e-mail a copy to Fife.pgd@nhs.scot