



PATIENT GROUP DIRECTION

Supply of doxycycline 100mg capsules by registered pharmacists for the treatment of uncomplicated genital Chlamydia trachomatis infection in Community Pharmacy

Version 2.0

Valid from: 7th January 2021

Expires on: 6th January 2023

This Patient Group Direction (PGD) must only be used by registered health professionals 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.







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DOCUMENT CONTROL - PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from:

Name:	Rochdale Council
Address:	No. 1 Riverside, Smith Street, Rochdale OL16 1XU
Telephone:	01706 652888

Revision History

The latest and master version of the unsigned PGD is held by Greater Manchester Joint Commissioning Team.

Revision date & actioned by		Version	
18/10/2018 S Woods	Initial draft for discu	ssion with development group.	0.1
19/12/2018 S Woods	Final formatting for	sign off.	1.0
	Technical review of	the PGD	
	Section of the PGD	Changes made:	
29/10/2020 K Osowska	Title of the PGD	Patient Group Direction for the supply of doxycycline 100mg capsules by registered pharmacists for the treatment of Chlamydia trachomatis in Community Pharmacy To Patient Group Direction Supply of doxycycline 100mg capsules by registered pharmacists for the treatment of uncomplicated genital Chlamydia trachomatis infection in Community Pharmacy	1.1
	Characteristics of staff	As per national PGD on the treatment of Chlamydia trachomatis (version 1.1) the pharmacists providing azithromycin under PGD are required to complete local training on safeguarding children and vulnerable adults. The same requirement applies to pharmacists supplying doxycycline treatment under PGD therefore this section was amended to reflect this training requirement.	

Page 2 of 19 Valid from: 07/01/2021 Expires on: 06/01/2023 Ve







DOXYCYCLINE 100MG CAPSULES

P.O.M.
[Prescription Only Medicine]

29/10/2020 K Osowska	Exclusion criteria	Individuals under 13 years of age. Doxycycline is contraindicated in individuals under 12 years and this PGD does not cover treatment of individuals under 13 years. Changed to Individuals under 13 years of age should not be treated under this PGD. Added new exclusion criteria as per national PGD and SmPC for doxycycline: Consent not given Individuals under 16 years of age assessed as lacking capacity to consent using Fraser Guidelines Individuals 16 years of age and over and assessed as lacking capacity to consent Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase	1.1
	Cautions (including any relevant action to be taken)	Amended the advice on the management of photosensitivity (as per BNF and patient.co.uk) Advice on the use of sun creams with high sun protection factor and avoidance of exposure to the strong sunlight or sun lamps should be given. Addition of the 2 situations when caution and advice is required when patients are treated with doxycycline (as per SmPC for doxycycline): Serious skin reactions Benign intracranial hypertension Addition of advice on prevention of oesophagitis. Amendment of the advice on taking antacids at least 2 to 3 hours after or before doxycycline.	
	Action if patient excluded from treatment	Addition of 2 bullet points: Explain the reasons for exclusion to the individual and document in the consultation record along with all actions taken.	

Valid from: 07/01/2021 Expires on: 06/01/2023

Page 3 of 19





DOXYCYCLINE 100MG CAPSULES

P.O.M.
[Prescription Only Medicine]

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	Consider azithromycin PGD	
Action if patient or carer declines treatment	Addition of one bullet point: Document reason for decline in the consultation record and document all actions taken	
Storage	Information amended as per national PGD (version 1.1): Medicines must be stored securely according to national guidelines and in accordance with the product SmPC.	
Dose and frequency	Information amended as per SmPC for doxycycline. Capsules should be swallowed whole with plenty of fluid during meals while sitting or standing. changed to: Capsules should be swallowed whole with plenty of water during meals while sitting or standing.	
Records	This section was amended as per national PGD (version 1.1) around the minimum required information which is required to be recorded in patients: • Under 13 years of age • Under 16 years of age • Over 16 years of age Record Management Code of Practice for Health and Social Care 2016 recommends the following storage periods for health records: • 8 years (in adults) or until 25 th birthday in a child (age 26 if entry made when young person was 17), or 8 years after death. changed to: PGD records should be stored for adults aged 18 years and over for 8 years and for children until the 25th birthday or for 8 years after a child's death (as per SPS Retention of Pharmacy Record and SPS Retaining PGD documentation).	





DOXYCYCLINE 100MG CAPSULES

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	References used to develop this PGD	All references were reviewed, updated and amended where required.	
29/10/2020 K Osowska	Individual authorisation	This section name was changed to: 'Pharmacist authorisation sheet' The whole form was updated as per most recent SPS national PGD template	1.1
	Criteria for exclusion	Addition of 4 criteria for exclusion as per Doxycycline national PGD template(version 1.2) Individuals with clinical proctitis Individuals with confirmed Lymphogranuloma venereum (LGV) or a contact of LGV. Presence of concomitant conjunctivitis and/or joint pain/swelling Individuals with oesophagitis and oesophageal ulcerations	
11/12/2020 K Osowska	Quantity to be administered and/or supplied	Addition of the note on remote consultations. 'The service is usually delivered face to face at the pharmacy premises. For the duration of the COVID-19 pandemic, to reduce risk of transmission, pharmacists may use their professional judgement on how they provide Chlamydia treatment service (e.g. remotely via telephone or appropriate digital methods). If the service is to be delivered remotely, the pharmacist must ensure that an appropriate consultation/clinical review takes place and the patient is seen face to face if required. Remote consultations must be conducted in a manner that ensures patient confidentiality. If the service is provided remotely, products must be supplied in a timely fashion. Supplies made utilising this temporary adjustment should be recorded as such. '	1.2
	Records	In Rochdale council all Chlamydia treatment consultations under this PGD are recorded via PharmOutcomes therefore there was a note added to reflect this. 'The pharmacist must make an entry for each patient on the PharmOutcomes system and complete all mandatory entries as required by the service specification and this PGD'	
		Bullet point 'Complete and return via a secure method any relevant forms to screening/treatment coordination organisation' was removed as it is no longer relevant.	
		Statement 'Ensure patient attendance fed back to relevant screening/treatment coordinating organisation in order to complete the audit trail'	

Page 5 of 19





DOXYCYCLINE 100MG CAPSULES P.O.M. [Prescription Only Medicine]

		was removed as it is no longer relevant.	
		Statement 'Computerised patients' medication records can be used where considered appropriate' was removed as it is no longer relevant.	
11/12/2020 K Osowska	Final formatting for	sign off.	2.0

ApprovalsThis PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr Aggy York	Clinical Lead Heywood, Middleton & Rochdale CCG	15.12.2020	2.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GM Joint Commissioning Team	10.12.2020	2.0
Andrea Fallon	Director of Public Health, Rochdale Metropolitan Borough Council	05.01.2021	2.0
Luvjit Kandula	Director of Pharmacy Transformation GM LPC	30.12.2020	2.0

Distribution

This PGD has been distributed, during its development, to:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr Aggy York	Clinical Lead Heywood, Middleton & Rochdale CCG	04.11.2020 14.12.2020	1.1 2.0
Luvjit Kandula	Director of Pharmacy Transformation, GM LPC	04.11.2020 14.12.2020	1.1 2.0
Dr Keith Pearson	Head of Medicines Optimisation, HMR CCG	04.11.2020 14.12.2020	1.1 2.0
Lianne Davies	Public Health Specialist Public Health & Wellbeing, Rochdale Borough Council	04.11.2020 14.12.2020	1.1 2.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GM Joint Commissioning Team	04.11.2020 10.12.2020	1.1 2.0







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PGD Development

Originally developed / Reviewed by:	Steph	nen Woods (author)	Senior Medicines Optimisation Pharmacist, Greater Manchester Joint Commissioning Team	
Kari		a Osowska (reviewer)	Advanced Medicines Optimisation Pharmacist Greater Manchester Joint Commissioning Team	
	Dr Ag	ıgy York	Clinical Lead HMR CCG	
Luvji		Kandula	Director of Pharmacy Transformation, GM LPC	
	Dr Ke	ith Pearson	Head of Medicines Optimisation, HMR CCG	
Date applicable:		7th January 2021		
Review date:		1 st September 2022		
Expiry date:		6th January 2023		

PGD Authorisation

This Patient Group Direction has been approved for use in the Rochdale Metropolitan Borough Council area by:

Designation	Name	Signature	Date
Senior Pharmacist (Strategic Medicines Optimisation Pharmacist, GM JCT)	Andrew Martin	A. Martin	10.12.2020
Doctor (Clinical Lead Heywood, Middleton & Rochdale CCG)	Dr Aggy York		15.12.2020
Community Pharmacy Representative (Director of Pharmacy Transformation, Greater Manchester LPC)	Luvjit Kandula	Luvjit Kandula	30.12.2020
Reviewer (Advanced Medicines Optimisation Pharmacist, GM JCT)	Karina Osowska	Korowne	10.12.2020

Borough Council)





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Page 8 of 19 Valid fr Expires

Valid from: 07/01/2021 Expires on: 06/01/2023







P.O.M.
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1. Characteristics of staff

Qualifications required	 Pharmacist with current General Pharmaceutical Council registration Work in a Community Pharmacy within Rochdale Metropolitan Borough Council area 		
Additional requirements	 Has undertaken training in the use of PGDs. Has undertaken training which enables the pharmacist to make a clinical assessment in order to establish the need and supply doxycycline according to this PGD as detailed in the service specification. Has satisfied the competencies appropriate to this PGD, as detailed in the Centre for Postgraduate Pharmacy Education (CPPE) and NHS Health Education England Declaration of Competence for pharmacy services – Chlamydia screening and treatment document (https://www.cppe.ac.uk/services/declaration-of-competence). Has an understanding of how to deal with a possible anaphylactic reaction, this could include access to a member of staff trained in basic life support. Has completed locally required training (including updates) in safeguarding children and vulnerable adults. 		
Continued training requirements	 The pharmacist should be aware of any change to the recommendations for the medicine listed. Must be able to show regular update in the field of contraceptive and reproductive health care, in particular sexually transmitted diseases. Must assess and maintain their own competence on the medicine supplied under this PGD in line with the requirements contained within the Declaration of Competence for pharmacy services – Chlamydia screening and treatment document. It is the responsibility of the pharmacist to keep up-to-date with continuing professional development. It is the responsibility of the pharmacist to maintain their own competency to practice within this PGD. Further training may be necessary when the PGD is reviewed. 		
Suggested supporting learning	It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education North West <i>Declaration of Competence for pharmacy services – Chlamydia screening and treatment</i> document.		

The Pharmacy Contractor is responsible for ensuring that only suitable pharmacists sign up to this PGD and should maintain a record of the names of individual pharmacists and evidence of their self-declaration and sign up to the current PGD.





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2. Clinical condition or situation to which the direction applies.

Indication (Clinical condition or situation to which this PGD applies

Patients either known or suspected of having uncomplicated genital Chlamydia trachomatis infection identified by the local screening service and in line with the current service specification.

There are two Patient Group Directions (PGDs) in the Rochdale Metropolitan Borough Council area for the treatment of Chlamydia trachomatis infection.

- This PGD for doxycycline must be considered for first line use, unless exclusions apply or there are concomitant medication considerations.
- The PGD for azithromycin can be considered for second line use where doxycycline is contraindicated or not tolerated.

Criteria for inclusion

- Male or female patients either with a laboratory-confirmed positive genital Chlamydia trachomatis infection or who is a sexual contact of any patient who has a laboratory-confirmed positive genital Chlamydia trachomatis infection. The local screening service will notify pharmacies of infected individuals and identified sexual contacts asking to attend that site.
- Have no known contraindications or allergies to doxycycline or its excipients (see Cautions section for further information)
- Understand the risks, benefits and side effects.
- Are competent to consent to treatment.
- Meet Fraser guidelines, if under 16 years of age. Note children under 13 years of age must be notified to the local Safeguarding Team and treatment provided by an appropriate prescriber.

Criteria for exclusion¹

Continued on next page.

- Consent not given
- Individuals under 13 years of age should not be treated under this **PGD**
- Individuals under 16 years of age assessed as lacking capacity to consent using Fraser Guidelines
- Individuals 16 years of age and over and assessed as lacking capacity to consent
- Known allergy or hypersensitivity to doxycycline, tetracycline antibiotics or any constituent of the medication (consider if individual would be eligible for treatment with azithromycin)
- Pregnancy or at risk of pregnancy
- Breastfeeding
- Taking medicine known to interact with doxycycline see the current British National Formulary (BNF) (https://bnf.nice.org.uk/interaction/doxycycline-2.html) or the Summary of Product Characteristics (SmPC) (http://www.medicines.org.uk/emc/)
- Non-genital Chlamydia trachomatis infection
- Complicated Chlamydia infection in males e.g. with epididymitis or testicular pain

Valid from: 07/01/2021 Expires on: 06/01/2023 Page 10 of 19

¹ Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it may be outside the remit of the PGD and another form of authorisation may be suitable.





DOXYCYCLINE 100MG CAPSULES

P.O.M. [Prescription Only Medicine]

- Complicated Chlamydia infection in females, e.g. pelvic pain or suspected pelvic inflammatory disease.
 - Severe renal impairment
- Severe hepatic impairment
- Acute porphyria
- Patients with myasthenia gravis
- Patients with systemic lupus erythematosus
- Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency
- Individuals with clinical proctitis
- Individuals with confirmed Lymphogranuloma venereum (LGV) or a contact of LGV
- Presence of concomitant conjunctivitis and/or joint pain/swelling
- Individuals with oesophagitis and oesophageal ulcerations

Cautions (including any relevant action to be taken)

- Photosensitivity photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracycline, 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. Advice on the use of sun creams with high sun protection factor and avoidance of exposure to the strong sunlight or sun lamps should be given.
- Serious skin reactions 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 appropriate therapy should be instituted.
- Oesophagitis instances of oesophagitis and oesophageal ulcerations have been reported in patients receiving capsule and tablet forms of druas in the tetracycline class, including doxycycline. Most of these patients took medication immediately before going to bed or with inadequate amounts of fluid. Advice on taking doxycycline during a mealtime, with a glassful of water should be given.
- Benign intracranial hypertension has been associated with the use of tetracyclines including doxycycline. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted
- The absorption of doxycycline may be impaired by concurrently administered antacids containing aluminium, calcium, magnesium or other drugs containing these cations; oral zinc, iron salts or bismuth preparations. Advice on taking antacids or any such supplements at least 2 to 3 hours after or before doxycycline should be given.

Action if patient excluded from

- Explain the reasons for exclusion to the individual and document in the consultation record along with all actions taken.
- Consider azithromycin PGD. If this is not applicable refer to

Page 11 of 19 Valid from: 07/01/2021 Expires on: 06/01/2023





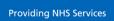
DOXYCYCLINE 100MG CAPSULES

P.O.M. [Prescription Only Medicine]

treatment	 appropriate prescriber or sexual health clinic; this should be done in conjunction with the local screening service. If excluded because the patient is under 13 years of age, information should usually be shared in accordance with local guidance, but if a decision is made not to disclose there should be discussion with a named or designated healthcare professional for child protection, with a record of the decision stating the reasons.²
Action if patient or carer declines treatment	 Document reason for decline in the consultation record and document all actions taken. Make individual or carer aware of the need for treatment and the potential consequences of not receiving it and refer to appropriate doctor/independent nurse prescriber or sexual health clinic; this should be done in conjunction with local screening service.

Page 12 of 19 Valid from: 07/01/2021 Expires on: 06/01/2023

² Clinical Effectiveness Group, British Association for Sexual Health and HIV, United Kingdom National Guideline on the Management of Sexually Transmitted Infections and Related Conditions in Children and Young People (2010)







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3. Details of medicine

Name, strength & formulation of drug	Doxycycline (as hyclate) 100mg capsules	
Presentation	Oral capsules	
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SmPC	
Legal category	POM	
Black Triangle ▼	No	
Unlicensed / off label use	None	
Route / method	Oral	
Dose and frequency	100mg to be taken twice a day for 7 days	
	Capsules should be swallowed whole with plenty of water during meals while sitting or standing.	
Quantity to be	Supply 14 capsules	
administered and/or supplied	Note on provision of the service during COVID 19 pandemic:	
	The service is usually delivered face to face at the pharmacy premises. For the duration of the COVID-19 pandemic, to reduce risk of transmission, pharmacists may use their professional judgement on how they provide Chlamydia treatment service (e.g. remotely via telephone or appropriate digital methods). If the service is to be delivered remotely, the pharmacist must ensure that an appropriate consultation/clinical review takes place and the patient is seen face to face if required. Remote consultations must be conducted in a manner that ensures patient confidentiality. If the service is provided remotely, products must be supplied in a timely fashion. Supplies made utilising this temporary adjustment should be recorded as such.	
Maximum or minimum treatment periods	7 days treatment to be provided	
Disposal	Any unused medicinal product or waste material should be disposed of safely.	

Page 13 of 19 Valid from: 07/01/2021 Expires on: 06/01/2023





P.O.M.
[Prescription Only Medicine]

Drug interactions³

- If the patient is taking any concomitant medication or treatment it is the pharmacist's responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. (For drug interaction see BNF (https://bnf.nice.org.uk/interaction/doxycycline-2.html) or the SPC (https://www.medicines.org.uk/emc/) or contact the Medicine Information Service at <a href="https://www.ukmi.nhs.uk/ukmi/directory/results/results.asp?RegID=4&S
- ubmit32=Search&type=R).
 In case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given.
- If the requirements of this PGD cannot be complied with the patient must be referred to a suitable independent prescriber.

Identification & management of adverse reactions³

Very common and common adverse effects			
Angioedema	Headache		
Vomiting	Henoch-Schönlein purpura		
Diarrhoea	Pericarditis		
Hypersensitivity	Photosensitivity reaction		
Skin reactions	Systemic lupus erythematous		
Nausea	exacerbated		

For a full adverse effects profile, refer to the SmPC (www.medicines.org.uk) or the most current edition of the BNF (https://bnf.nice.org.uk/drug/doxycvcline.html#sideEffects)

In the event of any adverse reaction:

- Record the adverse reaction in the patient consultation note
- Inform the patient's GP if the patient consents to this

If appropriate report the adverse reaction under the Yellow Card scheme (forms can be found at the back of the BNF or completed online at http://yellowcard.mhra.gov.uk).

Page 14 of 19 Valid from: 07/01/2021 Expires on: 06/01/2023

³ Refer to British National Formulary (BNF) and Summary of Product Characteristics (SmPC) for complete list





P.O.M.
[Prescription Only Medicine]

4. Records

Records

The pharmacist must make an entry for each patient on the PharmOutcomes system and complete all mandatory entries as required by the service specification and this PGD.

The recorded information should include:

- The consent of the individual and :
 - If individual is under 13 years of age record action taken
 - If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
 - If individual over 16 years of age and not competent, record action taken
- Patient's name, address, date of birth
- Contact details of GP (if registered)
- Name of the medication supplied
- Dose, form and date of supply
- Quantity, batch number and expiry date.
- Advice given to patient (including side effects and self-care)
- Significant information e.g. if used off licence reason why
- Name of pharmacist who supplied the medication.
- Details of any adverse drug reaction and actions taken
- Record any follow up or referral arrangements
- Record refusal of treatment by pharmacist if the individual does not meet the inclusion criteria

As per SPS Retention of Pharmacy Record and SPS Retaining PGD documentation:

 PGD records should be stored for adults aged 18 years and over for 8 years and for children until the 25th birthday or for 8 years after a child's death.

Data must be stored in accordance with Caldicott guidance, the Data Protection Act and the General Data Protection Regulation.

Page 15 of 19 Valid f rom: 07/01/2021 Expires on: 06/01/2023





DOXYCYCLINE 100MG CAPSULES

P.O.M.
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5. Patient Information

Written information to be given to the patient or carer	The patient/carer should be given the following written information if appropriate: The product specific patient information leaflet (PIL) supplied with the	
	original pack. • Any other suitable information with regard to their treatment.	
Advice to be given to the patient or carer	The patient/carer should be given the following information verbally if appropriate and requested:	
	 Information on <i>Chlamydia trachomatis</i>. Discuss possible side effects of treatment as listed in patient information leaflet. Advise patients that they may get a skin rash, itching, redness or severe sunburn when out in sunlight or after using a sun bed. Recommend they avoid exposure to bright sunlight and not to use sun beds. Advise to swallow the whole capsule with plenty of water during meals while sitting or standing and well before bedtime to prevent irritation to the oesophagus. Doxycycline capsules can be taken at any time in relation to food but there should be a gap, of at least 2 to 3 hours, between taking the capsules and antacids. Reinforce importance of sexual partners seeking treatment. Repeat testing should be performed from 3 months after treatment in under 25-years olds diagnosed with <i>Chlamydia</i> and when there is a change in sexual partner. Reinforce the possible need for screening for other sexually transmitted infection (STI). Abstain completely from sexual intercourse (even with condom), 	
	 including oral and anal sex, until patient's treatment is completed and the partner has completed treatment or wait 7 days if treated with azithromycin treatment. Provide information on practising safer sex. 	
Labelling	Medication supplied to the patient must be labelled in accordance with current legislation.	

Page 16 of 19 Valid from: 07/01/2021 Expires on: 06/01/2023 Version 2.0





P.O.M.
[Prescription Only Medicine]

6. References used to develop this PGD

- British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness Guidelines (all available at https://www.bashh.org/guidelines):
 - 2015 UK national guideline for the management of Chlamydia trachomatis. (Updated September 2018).
 - Update on the treatment of Chlamydia trachomatis (CT) infection, September 2018
 - The use of antibiotics to treat genital infections in pregnant women, August 2017
 - British Association for Sexual Health and HIV national guideline for the management of infection with Mycoplasma genitalium (2018)
 - 2015 UK National Guideline on the management of nongonococcal urethritis. (Updated May 2018)
- 2. Manufacturers' Summaries of Product Characteristics (SmPCs)
 - Doxycycline 100mg capsules, Kent Pharmaceuticals Ltd.
 Date of last revision of the text 04/07/2019.
 - <u>Doxycycline 100mg capsules</u>, Healthcare Pharma Ltd, Date of last revision of the text 18/04/2020
- 3. BNF online
- 4. Centre for Pharmacy Postgraduate Education
 - Declaration of competence for community pharmacy services; Chlamydia Testing and Treatment Service.
 Version 8 (Feb 2014).
- 5. General Pharmaceutical Council.
 - Standards for pharmacy professionals. May 2017.
 - Guidance on maintaining clear sexual boundaries, May 2017.
- 6. NHS Digital
 - Records Management Code of Practice for Health and Social Care 2016.
- 7. NCSP: re-testing of positive chlamydia cases report, August 2013
- 8. Stewart M., Doxycycline tablets and capsules, May 2019
- 9. Public Health England
 - Summary of antimicrobial prescribing guidance: managing common infections, last updated February 2020
- 10. Specialist Pharmacy Service
 - Recommendations for the Retention of Pharmacy Records 2019
 - Retaining PGD documentation, December 2019
 - National PGD, Supply of azithromycin for the treatment of uncomplicated Chlamydia trachomatis, uncomplicated

Page 17 of 19 Valid from: 07/01/2021 Expires on: 06/01/2023 Version 2.0





DOXYCYCLINE 100MG CAPSULES

P.O.M.
[Prescription Only Medicine]

Mycoplasma genitalium and non-gonococcal/non-specific urethritis, Version 1.1, May 2020 (currently under review)

- National PGD template, August 2020
- Doxycycline for Chlamydia national PGD template version 1.2, October 2020

Valid from: 07/01/2021 Expires on: 06/01/2023







DOXYCYCLINE 100MG CAPSULES

P.O.M.
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Pharmacist authorisation sheet

Doxycycline PGD Version 2.0 Valid from: 07/01/2021 Expiry: 06/01/2023

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

Pharmacist

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

I confirm that the registered pharmacists 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 pharmacists 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.

A copy of this PGD with completed pharmacist authorisation sheet should be retained and available at the pharmacy premises as a record of those pharmacists authorised to work under this PGD.

Page 19 of 19 Valid from: 07/01/2021 Expires on: 06/01/2023