

PATIENT GROUP DIRECTION FOR THE SUPPLY OF

DOXYCYCLINE 100MG CAPSULES

By registered pharmacist for the treatment of
Chlamydia trachomatis infection in
community pharmacies

Version: 2.2

Valid from: 1st April 2019

Expires on: 31st March 2021

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.

PATIENT GROUP DIRECTION (PGD) FOR

DOXYCYCLINE 100MG CAPSULES
COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS

P.O.M.
[Prescription Only Medicine]

DOCUMENT CONTROL – PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from

Name:	Manchester City Council
Address:	Public Health Manchester, Manchester City Council, Town Hall Extension, Manchester M60 2LA
Telephone:	0161 234 3391

Revision History

The latest and master version of the unsigned PGD is held by Manchester Health and Care Commissioning

REVISION DATE	ACTIONED BY	SUMMARY OF CHANGES	VERSION
05/02/2019	SMcK	Updated MHRA website details	2 1
05/02/2019	SMcK	Updated approval group and signatories	2 1
05/02/2019	SMcK	Reference 9 added	2 1
28/02/2019	JKS	Minor amendments to references, addition of reference 10	2 2
28/02/2019	JKS	Addition of statement 'Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list' on page 9	2 2

Approvals

This PGD must be approved by the following before distribution

NAME	TITLE	DATE OF ISSUE	VERSION
David Regan	Director of Public Health at Manchester City Council	12/03/2019	2 2
Connie Chen	GP Prescribing Lead, Manchester Health and Care Commissioning, Chair of the Manchester Area Prescribing Committee	06/03/2019	2 2
Dipesh Raghvani	Clinical Lead Greater Manchester Local Pharmaceutical Committee (GM LPC)	06/03/2019	2 2

Distribution

This PGD has been distributed to during its development

NAME	TITLE	DATE OF ISSUE	VERSION
Susan McKernan	Lead Pharmacist and Deputy Head of Medicines Optimisation for Manchester CCG	12/03/2019	2 2
Paula Russell	Principal Pharmacist, Regional Drug and Therapeutics Centre	12/03/2019	2 2
Jatinder Sambi	Medicines Optimisation Pharmacist and NMP Lead, Manchester Health and Care Commissioning	12/03/2019	2 2
Dr Philipa James	Dr Philippa James Cornbrook Medical Practice (DFSRH)	12/03/2019	2 2
Dr Ahmed Qamruddin	Consultant Microbiologist @ ORC Site	12/03/2019	2 2

<p>DOXYCYCLINE 100MG CAPSULES COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS</p>	<p>P.O.M. [Prescription Only Medicine]</p>
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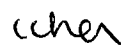


PGD Development

<p>Reviewed by: Jatinder Saimbi (author)</p>	<p>Medicine Optimisation Pharmacist and NMP Lead Manchester Health and Care Commissioning</p>
<p>Susan McKernan</p>	<p>Lead Pharmacist and Deputy Head of Medicines Optimisation for Manchester CCG</p>
<p>Paula Russell</p>	<p>Principal Pharmacist, Regional Drug and Therapeutic Centre</p>

<p>Date applicable:</p>	<p>1st April 2019</p>
<p>Review date:</p>	<p>1st October 2020</p>
<p>Expiry date:</p>	<p>31st March 2021</p>

PGD Authorisation

This Patient Group Direction has been approved for use in the Manchester City Council area by:

<i>Designation</i>	Name	Signature	Date
<p>Senior Pharmacist (Lead Pharmacist and Deputy Head of Medicines Optimisation)</p>	<p>Susan McKernan</p>		<p>26/3/19</p>
<p>Doctor (GP Prescribing Lead)</p>	<p>Connie Chen</p>		<p>20/3/19.</p>
<p>Clinical Lead (Greater Manchester Local Pharmaceutical Committee (GM LPC)</p>	<p>Dipesh Raghvani</p>		<p>27/3/19</p>
<p>Authorised Signatory for Manchester City Council (Director of Public Health)</p>	<p>David Regan</p>		<p>3/4/19</p>

<p>DOXYCYCLINE 100MG CAPSULES COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS</p>	<p>P.O.M. [Prescription Only Medicine]</p>
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1. Characteristics of Staff

<p>Qualifications required</p>	<ul style="list-style-type: none"> ▪ Pharmacist with a current General Pharmaceutical Council registration ▪ Work in a Community Pharmacy within the Manchester City Council area
<p>Additional requirements</p>	<ul style="list-style-type: none"> ▪ Has had training in the use of PGDs ▪ Has had 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 CPPE and NHS Health Education North West <i>Declaration of Competence for community pharmacy services – Chlamydia screening and treatment</i> document https://www.cppe.ac.uk/services/declaration-of-competence ▪ Is competent in the assessment of the individuals using Fraser guidelines ▪ Has undergone regular training and updating in safeguarding children and vulnerable adults ▪ 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
<p>Continued training requirements</p>	<ul style="list-style-type: none"> ▪ 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 <i>Declaration of Competence for community pharmacy services – Chlamydia screening and treatment</i> 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.
<p>Suggested supporting learning</p>	<p>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 community pharmacy services – Chlamydia screening and treatment</i> document</p>

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.

DOXYCYCLINE 100MG CAPSULES
COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS

P.O.M.
[Prescription Only Medicine]

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 RUClear

There are two Patient Group Directions (PGD) in the Manchester City 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. RUClear 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.
- 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 doctor / independent nurse prescriber.*

DOXYCYCLINE 100MG CAPSULES
COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS

P.O.M.
[Prescription Only Medicine]

Criteria for exclusion¹

- Individuals under 13 years of age. Doxycycline is contraindicated in under 12 years and this PGD does not cover treatment of individuals under 13 years.
- Individuals aged under 16 years assessed as not competent using Fraser Guidelines
- Complicated *Chlamydia* infection in males e.g with epididymitis or testicular pain
- Complicated *Chlamydia* infection in females e.g with pelvic pain or suspected Pelvic Inflammatory Disease (PID)
- Severe hepatic impairment
- Severe renal impairment
- Acute porphyria
- Pregnancy or at risk of pregnancy
- Breastfeeding
- Patients with myasthenia gravis
- Patients with systemic lupus erythematosus
- Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency
- Non-genital *Chlamydia trachomatis* infection
- Doxycycline may be given with warfarin or ciclosporin providing appropriate monitoring can be accessed
- Known allergy or hypersensitivity to doxycycline, tetracycline antibiotics or any constituent of the medication.
- Patients taking concomitant medication which may interact with doxycycline – check for interactions in the current British National Formulary (BNF) (<http://www.bnf.org/bnf/index.htm>) or the Summary of Product Characteristics (<http://www.medicines.org.uk/emc/>)

Reference to national / local policies or guidelines

British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness Guidelines

Cautions (including any relevant action to be taken)

- *Photosensitivity* - 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. Advice on the use of sun screens and avoidance of exposure to the sun should be given.
- *Oesophagitis* -Instances of oesophagitis and oesophageal ulcerations have been reported in patients receiving capsule and tablet forms of drugs in the tetracycline class, including doxycycline. Most of these patients took medications immediately before going to bed or with inadequate amounts of fluid.
- The absorption of doxycycline may be impaired by concurrently

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
COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS

P.O.M.
[Prescription Only Medicine]

administered antacids containing aluminium, calcium, magnesium or other drugs containing these cations; oral zinc, iron salts or bismuth preparations. Dosages should be maximally separated.

- Alcohol may decrease the half-life of doxycycline
- Reinforce need for screening for other sexually transmitted infection (STI)
- Refer back to RUClear for any medical condition / medicine for which the pharmacist is unsure / uncertain

Action if excluded

- Refer back to RUClear
- 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 a discussion with a named or designated nurse or doctor for child protection, with a record of the decision stating the reason ²
- Document all actions taken

Action if patient or carer declines treatment

- Make individual aware of the need for treatment and refer back to RUClear
- Document all actions taken

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)



DOXYCYCLINE 100MG CAPSULES
COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS

P.O.M.
[Prescription Only Medicine]

3. Details of medicine

Name, strength & formulation of drug	Doxycycline (as hyclate) 100mg Capsules
Presentation	Oral capsules
Storage	Do not store above 25°C
Legal category	POM
Black Triangle ▼	No
Unlicensed / off label use	None
Route / method	<ul style="list-style-type: none"> ▪ Oral ▪ Capsules should be swallowed whole with plenty of fluid during meals while sitting or standing
Dose and frequency	100mg to be taken twice a day for 7 days
Quantity to be administered and/or supplied	Supply 14 capsules
Maximum or minimum treatment periods	7 days treatment to be provided
Disposal	Any unused medicinal product or waste material should be disposed of safely.

DOXYCYCLINE 100MG CAPSULES
COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS

P.O.M.
[Prescription Only Medicine]

Drug interactions³

- If the patient is taking any concomitant medication or treatment it is the practitioner’s responsibility to ensure that treatment with the drug detailed in this PGD is appropriate (For drug interaction see Appendix 1 of BNF (<https://www.medicinescomplete.com/mc/>) or the SPC (<http://www.medicines.org.uk/emc/>) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF
- In the 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 Patient Group Direction cannot be complied with the patient must be referred back to RUClear

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 erythematosus exacerbated
Nausea	

For a full adverse effects profile, refer to the SPC (www.medicines.org.uk) or the most current edition of the BNF (<https://www.medicinescomplete.com/mc/>)

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 www.mhra.gov.uk/yellowcard)

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

DOXYCYCLINE 100MG CAPSULES
COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS

P.O.M.
[Prescription Only Medicine]

4. Records

Records

The pharmacist must keep a record of the consultation as required in the service specification for a period of time in line with *Records Management Code of Practice for Health and Social Care 2016* (<https://digital.nhs.uk/codes-of-practice-handling-information>) and service specification.

The minimum required information to be collected is

- Patient's name, address, date of birth and consent given
- Contact details of GP (if registered)
- Dose, form and date administered
- 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
- Signature/name of health professional who administered or supplied the medication.
- Details of any adverse drug reaction and actions taken including documentation in the patient's record
- Record any follow up or referral arrangements
- Record refusal of treatment by pharmacist if the individual does not meet the inclusion criteria/ by individual
- Complete and return via a secure method any relevant forms to the screening/treatment coordinating organisation.

Records Management Code of Practice for Health and Social Care 2016 recommends the following storage periods for health records

- 8 years (in adults) or until 25th birthday in a child (or if the patient was 17 at the conclusion of the treatment, until their 26th birthday), or 8 years after death.

Computerised patients medication records can be used where considered appropriate

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

DOXYCYCLINE 100MG CAPSULES
COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS

P.O.M.
[Prescription Only Medicine]

5. Patient Information

Written information to be given to the patient or carer

The patient should be given the following written information if appropriate:

- The product specific patient information sheet supplied with the medicine.
- Any other suitable information with regard to their treatment.

Advice to be given to the patient or carer

The patient/carers should be given the following information verbally if appropriate and requested:

- Information on *Chlamydia trachomatis*
- 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 capsules whole with plenty of fluids 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 between taking the capsules and antacids
- Reinforce importance of sexual partners seeking treatment.
- Repeat testing should be performed 3 to 6 months after treatment in under 25-years olds diagnosed with *Chlamydia* and when there is a change in sexual partner
- Abstain completely from sexual intercourse (even with condom), including oral and anal sex, until treatment is completed and their partner has completed treatment or are 7 days post- azithromycin treatment
- Provide information on practising safer sex

Labelling

Medication supplied to the patient must be labelled in accordance with current legislation

DOXYCYCLINE 100MG CAPSULES
COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS

P.O.M.
[Prescription Only Medicine]

6. References used to develop this PGD

References

1. 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). Accessed 7th November 2018
 - UK national guideline for the management of gonorrhoea in adults, 2011. Accessed 7th November 2018.
 - 2015 UK National Guideline on the management of non-gonococcal urethritis (Updated May 2017) Accessed 7th November 2018.
 - 2018 United Kingdom Guideline for the Management of PID Accessed 7th November 2018
2. Manufacturers' Summaries of Product Characteristics (SPC)
 - Doxycycline 100mg Capsules, Kent Pharmaceuticals Ltd Date of last revision of the text 03/09/2018 <https://www.medicines.org.uk/emc/medicine/26378>. Accessed 7th November 2018
3. British National Formulary Online
BNF Online <https://www.medicinescomplete.com>. Accessed 7th November 2018
4. Centre for Pharmacy Postgraduate Education
Declaration of competence for community pharmacy services; Chlamydia Testing and Treatment Service. Version 8 (Feb 2014) <https://www.cppe.ac.uk/services/commissioners>. Accessed 7th November 2018
5. General Pharmaceutical Council
Standards for pharmacy professionals, May 2017 <https://www.pharmacyregulation.org/standards> Accessed 7th November 2018
Guidance on maintaining clear sexual boundaries, May 2017. <https://www.pharmacyregulation.org/standards/guidance> Accessed on 7th November 2018
6. NHS Digital
Records Management Code of Practice for Health and Social Care 2016 <https://digital.nhs.uk/article/1202/Records-Management-Code-of-Practice-for-Health-and-Social-Care-2016> Accessed 7th November 2018
7. National Institute for Health and Care Excellence (NICE) Patient group directions Medicines practice guideline [MPG2] Published August 2013, Updated March 2017 <https://www.nice.org.uk/guidance/mpg2> .



DOXYCYCLINE 100MG CAPSULES
COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS

P.O.M.
[Prescription Only Medicine]

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/736122/NCSPre-testingauditfinalversion.pdf
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9. GMMMG. Greater Manchester Antimicrobial Guidelines Published December 2018. <http://gmmmg.nhs.uk/docs/guidance/GM-Antimicrobial-guidelines-Dec-2018-v3-0.pdf> Accessed on 5th January 2019.
10. National Institute for Health and Care Excellence (NICE) CKS Chlamydia - uncomplicated genital. Revised January 2019.
<https://cks.nice.org.uk/chlamydia-uncomplicated-genital> Accessed on 5th February 2019

DOXYCYCLINE 100MG CAPSULES COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS	P.O.M. [Prescription Only Medicine]
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The Patient Group Direction is to be read, agreed to and signed by the healthcare professional and their employer. The healthcare professional retains a copy of the PGD. The employer retains a record of all PGDs held by healthcare professionals employed or contracted by them.

Individual Authorisation

By signing this PGD you are agreeing that

- You have read and understood the content,
- To the best of your knowledge, the content of the PGD is correct and supports best practice;
- You will act within the parameters of the PGD;
- You take responsibility for maintaining your competence and on-going training requirements to continue to use the PGD safely

Named Healthcare Professional _____

Designation _____

The above named healthcare professional is authorised to work within the confines of this Patient Group Direction

Name of Employer _____
/ Contractor

Address of Employer _____
/ Contractor

Signature of Employer _____
/ Contractor

I, the undersigned, have read and understood this PGD and agree to work within its confines

Signature of Named
Healthcare Professional _____

Date _____

One copy to be retained by the named healthcare professional

One copy to be retained by the employer / contractor

The healthcare professional's details must be recorded on a register of PGDs held by their employer/contractor.