**PATIENT GROUP DIRECTION (PGD) FOR:**

**Doxycycline 100mg Capsules**

**YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT**

<table>
<thead>
<tr>
<th>Clinical Condition</th>
<th>Indication</th>
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<tbody>
<tr>
<td></td>
<td>For the treatment of genital Chlamydia and/or epidemiological treatment of genital Chlamydia. May be used instead of azithromycin 1g stat PO for patients who have a known allergy to azithromycin or other macrolides (erythromycin or clarithromycin).</td>
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<tr>
<th>Inclusion criteria</th>
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<tr>
<td>• Male or female patients with a laboratory confirmed diagnosis of genital Chlamydia trachomatis, including those with an equivocal result</td>
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<tr>
<td>• Male or female patients who are known contacts of an index patient who has had a positive test for genital Chlamydia, as epidemiological treatment</td>
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<tr>
<td>• Aged 13 years or over (those below 13 years must be referred to GP/ Multi-Agency Safeguarding Hub (MASH) if safeguarding issue is suspected)</td>
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<tr>
<td>• If aged under 16 years must be accompanied by a responsible adult/parent or must satisfy Fraser Guidelines (Gillick competent) – Please refer to Department of Health (DH) document “Best practice guidance for Doctors and other Health Professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health” Gateway Ref 3382</td>
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<tr>
<td>• The child should be seen individually if assessed as Gillick competent.</td>
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<tr>
<td>• If aged under 16 years and not Fraser Guidelines (Gillick competent) and accompanied by adult/parent and treatment is indicated as above, dispense treatment and a referral to the specialist service should also be made for assessing risk</td>
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<tr>
<td>• If under 18 years of age or an adult with learning difficulties ascertain as far as if possible that there are no unaddressed child protection or vulnerable adult issues</td>
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<tr>
<td>• As a second course may be given for the current episode for patients who have been at further risk of infection (e.g. who had genital, oral or anal intercourse with an index patient during the first 7 days of treatment)</td>
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<tr>
<th>Contraindications</th>
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<td>Patients who are pregnant or have a known risk of pregnancy or are breast feeding</td>
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<tr>
<td>Patients with a known allergy to Doxycycline or any other tetracycline antibiotic or any of the excipients in doxycycline tablets</td>
</tr>
<tr>
<td>Patients with a history of significant side effects with Doxycycline (e.g. marked photosensitivity, blood disorders)</td>
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<tr>
<td>Patients with myasthenia gravis or systemic lupus erythematos</td>
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</table>
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- Patients with a history of hepatic impairment
- Patients with known alcohol dependence
- Patients with conditions of unknown significance to the pharmacist/nurse
- Patients with anxieties regarding treatment that cannot be alleviated pharmacist/nurse

Exclusions

- Patients who are currently symptomatic e.g. urinary tract infection, abdominal or testicular pain, unusual vaginal/penile discharge. These patients require urgent referral to GUM clinic or GP
- Aged under 13 years
- Patients aged under 16 years and weighing less than 45kg
- Patient aged under 16 years who is not accompanied by an adult/parent or felt not to satisfy the Fraser Guidelines
- No valid consent
- Patients with Myasthenia Gravis

Drug Interactions (See BNF appendix 1 / manufacturers Summary of Product Characteristics)

- ACE inhibitor - Quinapril as contains magnesium carbonate
- Antibacterial – Rifampicin, penicillins
- Antiepileptic liver inducers - Carbamazepine, primidone, and Phenytoin, Phenobarbital
- Lipid regulators - Colestipol, Colestyramine
- Strontium Ranelate
- Ulcer healing drugs - Tripotassium dicitratobismuthate and sucralfate
- Ergotamine and ergot derivatives
- Atovaquone
- Cyclosporin
- Methotrexate
- Retinoids
- Antidiabetic - Sulphonylureas
- Oral anti-coagulants: e.g. warfarin, phenindione
- Oral Typhoid Vaccine

Medication should NOT be supplied/administered to the patient if they have any medical condition or take any medication that is of unknown significance to the nurse/pharmacist.

Cautions

Cautions in use

- Reduced absorption of doxycycline with some OTC medications. Patients taking calcium, aluminium, magnesium, zinc, adsorbents (Kaolin), antacids or more than 40mg of oral iron should be advised
to take these 2-3 hours either side of their doxycycline.

- Always refer to accompanying product information leaflet.

**Action if patient declines**

- Advise on genital Chlamydia and the potential consequences of no treatment
- If a patient declines treatment s/he will be advised to attend a Genito-Urinary Medicine service or an integrated sexual health service or their GP
- If patient is symptomatic refer to Genito-urinary medicine service. The patient should be advised that they need to be seen urgently
- Document advice given in PMR or health record

**Action if patient is excluded**

- If a patient is excluded from the PGD treatment s/he will be referred to a Genito-Urinary Medicine service or an integrated sexual health service or to their GP.
- If patient is symptomatic refer to Genito-urinary medicine service. The patient should be advised that they need to be seen urgently.
- Document action taken in PMR or health record.

**Drug Details**

<table>
<thead>
<tr>
<th>Name, form &amp; strength of medicine, legal status</th>
<th>Doxycycline 100mg capsules</th>
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<tbody>
<tr>
<td>Route/Method</td>
<td>Oral</td>
</tr>
</tbody>
</table>

**Dosage**

One 100mg capsule

**Frequency**

One 100mg capsule to be taken twice daily for 7 days

**Duration of treatment/number of times treatment may be administered**

To be given once during current episode.

A second dose may also be given for the current episode if the patient is considered at risk of re-infection due to non-compliance with advice on avoiding sexual intercourse (e.g. the patient had genital, oral or anal sexual intercourse with or without a condom with an index patient within 7 days of taking initial dose).

**Quantity to supply/administer**

Fourteen (14) 100mg capsules

**Side effects and potential adverse drug reactions**

- Gastrointestinal disorders: nausea, vomiting, diarrhoea, dysphagia, antibiotic associated colitis, abdominal discomfort and dyspepsia.
- Oesophageal irritation
- Rare side effects including hepatotoxicity, pancreatitis, blood disorders, Benign intracranial hypertension
- Anorexia, dry mouth, flushing, anxiety and tinnitus
- Allergic skin reactions including pruritus, rash, photosensitivity, oedema, urticaria and angioedema.
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<table>
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<tr>
<th>Advice to patient/carer</th>
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<tr>
<td>- Rare serious allergic reactions including angioneurotic oedema and anaphylaxis have been reported.</td>
</tr>
<tr>
<td>- This list is not exhaustive. Refer to BNF and SPC via <a href="http://www.medicines.org.uk/emc">www.medicines.org.uk/emc</a> for complete list.</td>
</tr>
<tr>
<td>- All adverse drug reactions should be clearly reported in the patient’s health record or PMR and with the patient’s permission should be reported to their GP.</td>
</tr>
<tr>
<td>- Report all serious and minor adverse reactions in children (under 18 years) and serious adverse reactions in adults to the MHRA by completing a yellow card. Yellow cards and guidance on their use are available in BNF or reports can be made online at <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a></td>
</tr>
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</table>

- Patients should be given the Patient advice leaflet and the product information leaflet and possible side effects should be discussed. |
- Patients should be advised about the possibility of an allergic reaction to doxycycline. They should be advised to see their GP if they develop a rash or photosensitivity while taking the medications, or alternatively A&E if wheezing, severe urticaria or oedema develop. |
- Doxycycline can cause oesophageal irritation and ulceration when taken orally. The patient should be advised to take the capsules with a glass full of water, in the sitting or standing position, at least 30 minutes before retiring at night. Doxycycline can be given with food or milk, since studies indicate that the absorption of doxycycline is not markedly influenced by simultaneous ingestion of food or milk. |
- Patients should be advised to avoid direct exposure to sunlight or ultraviolet light (sunbeds). |
- Alcohol may decrease the half-life of doxycycline therefore the patient should be advised to avoid alcohol while taking the medicine. |
- Patients should be advised no sexual intercourse (included protected and oral) whilst taking treatment and until partner(s) have completed treatment (and waited 7 days if treated with Azithromycin) |
- The patient should be advised to finish the course of medication. |
- Appropriate sexual health promotion advice should be given. This should include the advisability of, and how to access screening for other sexually transmitted infections and advice about the use of condoms. |
- If the contact/partner has presented for treatment, he/she should be encouraged to self-screen prior to taking treatment. This will enable further partner/contact notification if it is returned as a positive result. |
- If patient has a past history of *C difficile* infection or glutamate
PATIENT GROUP DIRECTION (PGD) FOR:
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| dehydrogenase (GDH) positive please tell patient to seek medical advice should they develop diarrhoea following treatment |
| Emphasise importance and need for patient’s sexual partner(s) to be treated. |

### Staff Characteristics

**Class of Qualified Health Professional for whom PGD is applicable**

1. Registered Nurse on the NMC Register.
2. Pharmacist registered with the GPhC.

**Qualifications**

1. First level nursing qualification with current NMC Registration.
2. Degree in pharmacy with current GPhC registration.

### Additional requirements considered relevant to the medicines to be supplied/administered according to this PGD

All named nurses/pharmacists should be able to demonstrate:

- Training and experience in sexual health & Chlamydia screening.
- Confidence and competence in identifying the signs and symptoms of an upper genital tract infection.
- The ability to identify the risk of pregnancy.
- Confidence and competence in treating asymptomatic genital Chlamydia and the epidemiological treatment of genital Chlamydia.
- A knowledge and understanding of the use of doxycycline for the treatment of genital Chlamydia and as epidemiological treatment
- A knowledge and understanding of the contraindications, specific considerations and possible side effects of doxycycline 100mg twice a day for 7 days.
- An ability to supply fourteen doxycycline 100mg capsules with relevant information and advice.
- Adequate standards of documentation that meet the requirements listed below under Method of Recording.
- That they have undertaken appropriate training and successfully completed the competencies to undertake the clinical assessment of individuals leading to diagnosis that requires treatment according to the indications listed in this PGD.
- That they have undertaken appropriate training for working under PGDs for the supply and administration of medicines.
- That they have undertaken training appropriate to this PGD.
Continuing training & education

- A commitment to continuing professional development in the speciality, including maintenance of PREP/CPD requirements and a Personal and Professional Portfolio.

Referral Arrangements and Audit Trail

Referral arrangements

As per local arrangements

Method of Recording supply/administration sufficient to enable audit trail

The following should be clearly documented in the patient’s health record where available or in the PMR with the patient’s consent:

- Patient’s name, address, date of birth and consent given.
- Contact details of GP (if registered).
- Diagnosis or working diagnosis.
- Details of any adverse drug reaction and actions taken including documentation in the patient’s health record.
- The date, medication name, dose and form administered or supplied, signature/name of the health professional providing treatment.
- That the product information leaflet has been given to the patient.
- That the patient has been given instructions regarding the taking of the medication when the patient declines to take it at the treatment centre.
- That the patient has been given advice on how long they should abstain from sexual intercourse.
- That the patient has been given verbal and written advice on how to access GUM sexual health services or an integrated sexual health service.
- The arrangements that have been made for test of cure following completion of treatment, if the patient is pregnant.

References/Resources and comments

Summary of Product Characteristics – Doxycycline Actavis UK Ltd. Last update 19.5.16
https://www.medicines.org.uk/EMC/medicine/23950/SPC/Doxycycline+Capsules+BP+100mg/

https://www.evidence.nhs.uk/formulary/bnf/current

Paediatric Formulary Committee (2016) BNF for children September 2016 edition. London: British Medical Association, the Royal Pharmaceutical, the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists Group
https://www.evidence.nhs.uk/formulary/bnfc/current

BASHH (2015) UK National Guideline for the Management of Infection with Chlamydia trachomatis
<table>
<thead>
<tr>
<th>Link</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing and Midwifery Council (2008) Standards for Medicines Management</td>
<td></td>
</tr>
<tr>
<td><a href="http://www.nmc-uk.org/Documents/Standards/nmcTheCodeStandardsofConductPerformanceAndEthicsForNursesAndMidwives_LargePrintVersion.PDF">http://www.nmc-uk.org/Documents/Standards/nmcTheCodeStandardsofConductPerformanceAndEthicsForNursesAndMidwives_LargePrintVersion.PDF</a></td>
<td></td>
</tr>
<tr>
<td>Please direct comments specifically relating to information on this PGD to the Prescribing and Medicines Management Team NEL Commissioning Support Unit 01603 257132</td>
<td></td>
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</table>
PATIENT GROUP DIRECTION (PGD) FOR:
Doxycycline 100mg Capsules

This patient group direction must be agreed to and signed by all health care professionals involved in its use. NEL (Anglia) will hold the original signed copy on behalf of Norfolk County Council. The PGD must be easily accessible in the clinical setting.

This PGD has been agreed to be appropriate, necessary and an advantage to patient care by Norfolk County Council PGD Development and Authorisation Group.

Organisation: Norfolk County Council

This PGD is developed and peer reviewed by the following on behalf of Norfolk County Council Public Health:

Lead Doctor: Dr Augustine Pereira Consultant in Public Health Medicine NCC

Lead Nurse: Sue Marshall Registered Nurse

Lead Pharmacist: Françoise Price Senior Pharmacist NEL CSU

Patient Group Direction prepared and peer reviewed by:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tracey Milligan</td>
<td>Registered Nurse</td>
<td>24.10.2016</td>
</tr>
<tr>
<td>Françoise Price</td>
<td>Senior Pharmacist NEL CSU</td>
<td>19.10.2016</td>
</tr>
<tr>
<td>Tony Dean</td>
<td>CEO Norfolk Local Pharmaceutical Committee</td>
<td>8.11.2016</td>
</tr>
<tr>
<td>NCC PGD Development and Authorisation Group</td>
<td>Body with delegated authority to develop and review PGDs on behalf of NCC</td>
<td>24.10.2016 and via email communication</td>
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</table>

Patient Group Direction Authorisation:

This PGD is authorised by Norfolk County Council:

Dr Augustine Pereira Consultant in Public Health Medicine and Chair of the PGD group
Individual Authorisation

PGDs DO 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 their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD.

<table>
<thead>
<tr>
<th>Name of Professional</th>
<th>Signature</th>
<th>Authorising Manager</th>
<th>Date</th>
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</table>
The medicine that you have been given is an antibiotic called Doxycycline 100mg.

You should take 1 capsule in the morning and 1 capsule in the evening. You have been given enough for 7 days and you should finish all the capsules.

You should take the capsules with a full glass of liquid while sitting upright – to make sure that they are well washed down.

Alcohol can make the medicine less effective, so we would advise that you avoid alcohol while taking the treatment. You should also avoid sunbathing and the use of sunbeds while taking this medicine.

The infection will not have been completely treated until all the capsules have been taken. We would advise that you do not have sex (not even with a condom or oral sex) until you have finished the capsules, otherwise you could still pass the infection on.

If your partner was not treated at the same time as you we would advise you not to have sex with them until 7 days after they have been treated, otherwise you could become infected again.

A Health Adviser from the Chlamydia Screening Office will telephone you in about 2 weeks to make sure that you didn’t have any problems with your medication.

If you have any urgent concerns about your medicines you should contact:

- Your GP (family doctor)
- NHS 111