Public Health England

NHS England

Reference: XXXXXXX

PATIENT GROUP DIRECTION (PGD)

Further supply of doxycycline 100mg capsules to adults and children aged 12 years and over exposed to a known or suspected release of tularemia

For the initial supply of doxycycline 100mg capsules by **IN HEALTHCARE PROFESSIONALS** to adults and children aged 12 years and over exposed to a known or suspected release of tularemia

Reference no:	*DoxycyclinefurthersupplytularemiaPGDTemplate*
Version no:	*02.00*
Valid from:	*1st May 2016*
Review date:	*1st May 2018*
Expiry date:	*1st May 2019*

Public Health England has developed this PGD Template for local authorisation

Those using this PGD must ensure that it is formally authorised and signed by a clinical governance or patient safety lead, who has designated responsibility for signing PGDs, so this document meets legal requirements for a PGD. **THE PGD IS NOT LEGAL OR VALID WITHOUT THIS LOCAL, FORMAL AUTHORISATION.**

Authorising organisations must not alter or amend the *clinical* content of this document (sections 4, 5 and 6); such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of commissioners and service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD. Therefore sections 2, 3 and 7 can be amended.

THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Change history

Version number	Change details	Date
PGD2014/1	Original template developed and ratified	2nd July 2014
PGD02.00	1. Put into the new PHE template format 2. For use in tularemia only, anthrax put in separate PGD 3. Clinical indications: “another biological agent” removed 4. Clinical indications: reference to children aged under 12 removed as they are not covered by this PGD 5. Abbreviated lists of warnings and contra-indications included- these medicines must be offered in all cases where exposure to these biological agents may have occurred unless there are life-threatening contra-indications. 6. Interactions: advice simplified. 7. References updated.	1st May 2016

1. PGD template development

This PGD template has been developed by the following on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Judith Field UK National Countermeasure Manager Emergency Response Department Public Health England		1st May 2016
Doctor	Nick Gent Consultant in Health Protection Emergency Response Department Public Health England		1st May 2016
Registered Nurse	Nicky Brown Senior Nurse Chief Nurse Directorate Public Health England		1st May 2016

This PGD template has been peer reviewed by an Expert Panel in accordance with the PHE PGD Policy. It has been agreed by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Steering Group.

Expert panel

Name	Designation
John Simpson (Chair)	Director of Emergency Preparedness, Resilience and Response Public Health England
Jackie Lamberty	Pharmacist Medicines Management Adviser Public Health England
Sally Millership	Consultant in Communicable Disease Control Public Health England East of England
Calum Semple	Senior Lecturer & Consultant Respiratory Paediatrician University of Liverpool
Rosie Furner	Community Services Pharmacist East Sussex Healthcare NHS Trust
Ed Kaczmarski	Consultant Medical Microbiologist, Manchester Lead Public Health Microbiologist, Public Health England NW Head of the National Meningococcal Reference Unit

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

SEE SEPARATE GGC AUTHORISATION AND LOCAL AUTHORISATION SHEET authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Limitations to authorisation
eg Any local limitations the authorising organisation feels they need to apply in-line with the way services are commissioned locally. This organisation does not authorise the use of this PGD by ….

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Complete eg NHSE Governance Lead, Medical Director			

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Organisations must add an individual practitioner authorisation sheet or list of authorised practitioners. This varies according to local policy but this should be a signature list or an individual agreement as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	**Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions and have current registration.**
Additional requirements	• must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions). • must be familiar with the product and alert to changes in the Summary of Product Characteristics • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards for Immunisation Training (2005) • have access to the Patient Group Direction and associated online resources. **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Continued training requirements	• All health care professionals working under the direction will be expected to maintain their competence as specified in hospital, local and national policies e.g. Nursing & Midwifery Council guidelines

4. Clinical condition or situation to which this PGD applies.

Clinical condition or situation to which this PGD applies	Where continuing chemoprophylaxis is required because there is known or suspected exposure to tularemia
Criteria for inclusion	Adults and children aged twelve (12) years or over where there is a known or suspected exposure to tularemia **and** who have already received chemoprophylaxis for 10 days with doxycycline or ciprofloxacin.
Criteria for exclusion[1]	Hypersensitivity to doxycycline or other tetracyclines. Patients who have experienced side effects while taking the initial ten days' supply. Pregnant or breastfeeding mothers, as doxycycline affects teeth and bone growth in the baby, notably in the second and third trimester.
Cautions including any relevant action to be taken	Patients with the conditions listed below SHOULD normally receive chemoprophylaxis with doxycycline if exposed to one of the biological agents listed in this PGD or advised by PHE. 1. Myasthenia gravis: *Warn to self-monitor for any increase severity of disease.* *Do not discontinue doxycycline if increase in severity of disease; switch to ciprofloxacin or amoxicillin as soon as reasonably possible.* 2. Systemic lupus erythematosus: *Warn to self-monitor for any increase severity of disease.* *Do not discontinue doxycycline if increase in severity of disease: develops; switch to ciprofloxacin or amoxicillin as soon as reasonably possible.* 3. Renal impairment, renal (kidney) damage requiring patient to be in renal replacement therapy (dialysis): *Use if recommended first choice agent; warn to avoid exceeding guideline dose in PHE advice.* 4. Hepatic impairment: *Only use where mild stable hepatic disease present; otherwise initiate chemoprophylaxis with ciprofloxacin or amoxicillin.* 5. Retinoid concomitant treatment: *Due possible increased risk of benign intracranial hypertension when tetracyclines given with retinoids avoid concomitant use if ciprofloxacin or amoxicillin available and not contra-indicated.* 6. Vitamin K antagonist concomitant treatment (warfarin, phenindione and acenocoumarol) *Warn patient of increased risk of bleeding.* *Check INR and adjust dose of anticoagulant treatment weekly during long term doxycycline use.*

[1] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Action to be taken if the patient is excluded	Explain why they have been excluded and refer the individual to the supervising doctor.
Action to be taken if the patient or carer declines treatment	Refer the individual to the supervising doctor.

5. Description of Treatment

Name, strength & formulation of drug	Doxycycline 100mg capsules
Legal category	Prescription Only Medicine (POM)
Black Triangle▼	No
Off-label use	No
Route / method of administration	Oral
Dose and frequency of administration	One capsule to be taken twice daily
Duration of treatment	4 days
Quantity to be supplied / administered	8 (eight) capsules
Storage	Store in original container below 25 ^{o}C Store out of reach and sight of children
Disposal	Any unused product or waste material should be disposed of in accordance with local requirements.
Drug interactions	1. Doxycycline can affect anticoagulants eg warfarin, antiepileptic drugs eg phenobarbital, carbamazepine, primidone and phenytoin and some other antibiotics e.g. penicillin. Consult the BNF online for more detailed information: http://www.evidence.nhs.uk/formulary/bnf/current/5-infections/51-antibacterial-drugs/513-tetracyclines/doxycycline 2. A few cases of pregnancy or breakthrough bleeding have been attributed to the concurrent use of tetracycline antibiotics with oral contraceptives. If vomiting or diarrhoea occurs, additional contraceptive precautions are advised. 3. Antacids and aluminium, calcium, iron, magnesium, bismuth and zinc salts decrease the absorption of doxycycline; doses should be maximally separated.
Identification & management of adverse reactions[2]	1. Tetracyclines have a low pH and can cause side effects of nausea, vomiting, diarrhoea (antibiotic-associated colitis reported occasionally), dysphagia, and oesophageal irritation, although these are normally mild and do not necessitate discontinuation of therapy. 2. Doxycycline can cause loss of appetite, dry mouth, flushing, anxiety, headache and tinnitus. 3. As a broad spectrum antibiotic, doxycycline may predispose women to vaginal candidiasis ('thrush'). They may wish to take

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

	treatment or prophylaxis for this in their personal medical supplies. 4. Other rare side-effects include hepatotoxicity, pancreatitis, blood disorders, skin reactions, arthralgia, myalgia, photosensitivity and hypersensitivity reactions. The individual should be informed of possible side effects and their management by giving them a copy of the marketing authorisation holder's Patient Information Leaflet and drawing their attention to the information on possible side effects. If any of the side effects become serious severe or prolonged, or if the patient notices any side effects not listed in the Patient Information leaflet, patients should not stop antibiotic treatment, but should contact their local doctor or pharmacist. A detailed list of adverse reactions is available in the Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of adverse reactions	All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the yellow card system on http://yellowcard.mhra.gov.uk Any serious adverse reaction to the drug should be documented in the individual's record. Medical staff should also be informed.
Written information to be given to patient or carer	Supply marketing authorisation holder's patient information leaflet (PIL).
Patient advice /follow up treatment	Explain the treatment. Advise the individual to swallow the capsules whole with plenty of fluid during meals in either the resting or standing position. The individual should not lie down within an hour of taking the medication, so do not take it at bedtime. Do not take on an empty stomach; risk of oesophagitis. If gastric irritation occurs, the capsules may be taken with milk without significant reduction in absorption. Do not take indigestion remedies or medicines containing iron or zinc, 2 hours before or after you take this medicine. Space the doses evenly throughout the day. Keep taking this medicine until the course is finished, unless you are told to stop. Inform individual/carer of possible side effects and their management. Ensure that the individual is aware that medical advice should be sought if side effects or any other unexplained effects on health are experienced. Advise the individual or their carer that this medicine can make the skin more sensitive to direct sunlight. They should avoid exposure to excessive sunlight or use high SPF sunblock if prolonged exposure to the sun is unavoidable. When applicable, advise parent/carer when the subsequent dose is due.

Records	Record: • whether valid informed consent was given • name ofindividual, address, date of birth and gp with whom the individual is registered • name of member of staff who administered the product • name and brand of product • date of administration • dose, form and route of administration of product • quantity administered • batch number and expiry date • advice given; including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • record supplied via Patient Group Direction (PGD) • records should be signed and dated All records should be clear, legible and contemporaneous. Contact details for the patient must be recorded. Local arrangements must ensure that contact is made between the designated centre and all patients to discuss further supplies or an alternative antibiotic, where appropriate. A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	• Doxycycline Summary of Product Characteristics www.medicines.org.uk/emc/ • Notes on prophylactic and post-exposure medication for CBRN incidents (expert advice) • Antibiotic prophylaxis in the UK for suspected exposure likely to give rise to inhalational, gastrointestinal or systemic anthrax infection (expert advice) • CBRN Incidents: A Guide to Clinical Management and Health Protection: Pre and Post exposure prophylaxis https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/340709/Chemical_biological_radiological_and_nuclear_incidents_management.pdf • British National Formulary (BNF) http://www.evidence.nhs.uk/formulary/bnf/current/5-infections/51-antibacterial-drugs/513-tetracyclines/doxycycline • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions https://www.nice.org.uk/guidance/mpg2/resources • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20th March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste

6. Individual practitioner authorisation sheet

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

Practitioner

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

Signed……..Date…….....

Name (Print)…….....

Designation…….....

Authorising manager

Manager to give authorisation on behalf of **INSERT NAME OF ORGANISATION** for the named healthcare professional who has signed the PGD

Signed…… Date…….....

Name (Print)…….....

Designation…….....

Note to authorising manager

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so

You must give this signed PGD to each authorised practitioner as it shows their authorisation to use the PGD