



**Publications number: PRN01579** 

# Patient Group Direction (PGD) for the further supply of doxycycline 100mg capsules for post-exposure prophylaxis to anthrax in adults and children 12 years and over

This PGD is for the further supply of doxycycline 100mg capsules, to adults and children aged 12 years and over exposed to a known deliberate release of anthrax, by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference: Doxycycline 100mg capsules PGD further supply anthrax

Version no: 5.00b

Valid from: 1 April 2025
Review date: 1 April 2027
Expiry date: 31 March 2028

#### The UK Health Security Agency (UKHSA) has developed this PGD for local authorisation

Those using this PGD must ensure it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)<sup>1</sup>.

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Authorising organisations must not alter, amend or add to 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. Sections 2, 3 and 7 must be completed and amended within the designated editable fields provided, but only for the purposes for which these sections are provided, that is the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in Section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.

The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

## Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSAChemical, Biological, Radiological and Nuclear (CBRN) PGD templates for authorisation can be found from: <a href="NHS England">NHS England</a> » Hazardous Materials (HAZMAT) and Chemical, Biological, Radiological and Nuclear (CBRN)

Any queries regarding the content of this PGD should be addressed to: SMA@ukhsa.gov.uk

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<sup>&</sup>lt;sup>1</sup> This includes any relevant amendments to legislation

#### **Change history**

Version number	Change details	Date
PGD 2014/1	Original template developed and ratified	2 July 2014
PGD 2.00	<ol> <li>Put into the new PHE template format</li> <li>For use in anthrax only, tularemia put in separate PGD</li> <li>Clinical indications: "another biological agent" removed</li> <li>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</li> <li>Interactions: advice simplified</li> <li>References updated</li> </ol>	1 May 2016
PGD 3.00	<ol> <li>Put into the new PHE template format</li> <li>Duration of further supply changed to 20 days</li> <li>Off-label use changed to 'yes'</li> <li>Cautions: "Hepatic impairment: Only use where mild stable hepatic disease present; otherwise initiate chemoprophylaxis with ciprofloxacin, amoxicillin or co-amoxiclav" removed.</li> <li>References updated</li> </ol>	16 October 2018
PGD 4.00	<ol> <li>Addition of 'following deliberate release' to page 1, clinical indication and criteria for inclusion for clarity</li> <li>Note under clinical condition to use doxycycline wherever possible, reserving continuity of prophylaxis with ciprofloxacin for children under 12 years of age.</li> <li>Retinoid treatment moved from cautions to criteria for exclusion</li> <li>Under actions to be taken if the individual is excluded, consider supply of ciprofloxacin if not contraindicated or refer to the supervising doctor for assessment and prescription of amoxicillin or co-amoxiclav.</li> <li>Minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates</li> </ol>	26 October 2021
PGD 5.00	<ol> <li>Minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates</li> <li>Qualification and professional registration section updated with other registered professionals</li> <li>Amoxicillin and co-amoxiclav recommendations changed to assessment and consideration of alternative antibiotics throughout</li> <li>Notes under clinical condition or situation to which this PGD applies replaced with link to guidance</li> </ol>	26 September 2024

	5. Criteria for inclusion updated to remove 'suspected' and to include 'not showing symptoms compatible with anthrax infection'	
	6. Under 12s, no valid consent, known severe hepatic impairment, enzyme inducing antiepileptics, and unacceptable side effects added to exclusion criteria	
	7. Wording under cautions: 'Where there is an established history of severe allergic reaction to ciprofloxacin', removed and replaced with alternative wording	
	8. Cautions updated to remove renal impairment, and include advice for individuals with liver impairment, chronic alcohol dependence and those taking ciclosporin, lithium, penicillin, other tetracyclines. Wording slightly amended for existing cautions	
	Wording under actions to be taken if the individual is excluded updated	
	10. Symptoms added to action to be taken if individual declines treatment, link to CBRN guidance and document advice given and decision reached	
	11. Arrangements for referral for medical advice section added as per PGD template	
	12. Dose and frequency updated with consideration of other formulations if individuals unable to swallow	
	13. Duration of treatment updated with 'following an initial 10-day supply of antibiotics'	
	14. Drug interactions updated with 'This list is not exhaustive. Full details of drug interactions are available in the SPC or the BNF online, referral back to cautions or exclusion criteria added for relevant interactions, 2-3 hours added to antacid interaction	
	<ol> <li>Hypersensitivity and rash added to adverse reactions and advice on management added</li> </ol>	
	<ul><li>16. Avoiding alcohol, to read the PIL, advice if symptoms develop, added to advice and follow up</li><li>17. 'or password-controlled on records' added to 'All records</li></ul>	
	should be signed and dated	
PGD 5.00a	Correction of typo and mail hyperlink on page 1: changed to SMA@ukhsa.gov.uk	4 November 2024
PGD 5.00b	<ol> <li>Title and clinical condition updated for consistency with ciprofloxacin PGDs</li> <li>Wording in cautions amended for greater clarity</li> <li>Wording aligned across PGDs</li> <li>Addition of vaccine interaction consistent with ciprofloxacin PGD</li> </ol>	1 April 2025

#### 1. PGD development

This PGD has been developed by the following on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Doctor (Expert panel chair)	Ruth Milton, Head of Advice, All Hazards Public Health Response, UKHSA		1 April 2025
Pharmacist (Lead Author)	Anna Wilkinson, Clinical Response Pharmacist, All Hazards Public Health Response, UKHSA	Ald dismon	1 April 2025
Registered Nurse	Gemma Hudspeth, Senior Health Protection Practitioner, UKHSA	Sh	1 April 2025

This PGD has been peer reviewed by the CBRN PGD expert panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee.

#### **Expert panel**

Name	Designation
Claire Gordon	Consultant in Infectious Diseases and Deputy head of the UKHSA Rare and Imported Pathogens Laboratory
Diane Ashiru-Oredope	Lead Pharmacist, HCAI, Fungal, AMR, AMU and Sepsis Division, UKHSA
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Michelle Jones	Principal Medicines Optimisation Pharmacist NHS Bristol, North Somerset and South Gloucestershire ICB
Kiran Attridge	Senior Medical Advisor, All Hazards Public Health Response, UKHSA
Craig Prentice	Consultant Practitioner Paramedic, Surrey and Sussex Healthcare NHS Trust
Kelly Stoker	Nurse Consultant for Adult Social Care, Health Equity and Inclusion Health Division, UKHSA
Sherine Thomas	Consultant in Emerging Infections and Zoonoses, UKHSA
Sarah Upton	Lead Pharmacist for Medication Safety, community services, Locala Health and Wellbeing

#### 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.

**Insert authorising body name** authorises this PGD for use by the services or providers listed below:

Authorised for use by the following	ng organisations and/or	services	
_			
Limitations to authorisation			
For instance any local limitations	the authorising organic	sation feels the	v need to apply in-line with
the way services are commission			
PGD by	led locally. This organis	sation does not	authorise the use of this
PGD by			
Organisational approval (legal	requirement)		
Organisational approval (legal	requirement)	Sign	Date
		Sign	Date

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to insert contact details

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement, or a multiple practitioner authorisation sheet as included at the end of this PGD

#### 3. Characteristics of staff

Γ			
Qualifications and professional registration	To be completed by the organisation authorising the PGD for example: registered professional with one of the following bodies:		
	<ul> <li>nurses currently registered with the Nursing and Midwifery Council (NMC)</li> </ul>		
	<ul> <li>pharmacists currently registered with the General Pharmaceutical Council (GPhC)</li> </ul>		
	<ul> <li>paramedics currently registered with the Health and Care Professions Council (HCPC)</li> </ul>		
	<ul> <li>additional registered practitioners, appropriate for the role, who can legally operate under a PGD</li> </ul>		
	The practitioners above must also fulfil the <u>Additional requirements</u> detailed below.		
	Check <u>Section 2 Limitations to authorisation</u> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD		
Additional requirements	Additionally, practitioners:		
	must be authorised by name as an approved practitioner under the current terms of this PGD before working to it		
	must have undertaken appropriate training for working under PGDs for supply or administration of medicines		
	must have undertaken training appropriate to this PGD		
	must be competent in the use of PGDs (see <u>NICE Competency framework</u> for health professionals using PGDs)		
	<ul> <li>must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC)</li> </ul>		
	must be competent to assess the individual and discuss treatment options		
	must have access to the PGD and associated online resources		
	should fulfil any additional requirements defined by local policy		
	authorising organisation to insert any additional requirements		
	Individual practitioners must be authorised by name, under the current version of this PGD before working according to it		
Continued training requirements	Authorising organisation to insert any continued training requirements		

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

Clinical condition or situation to which this	Where continuing chemoprophylaxis is required following exposure to a known deliberate release of anthrax.		
PGD applies	Use doxycycline wherever possible, reserving continuity of prophylaxis with ciprofloxacin for children under 12 years of age.		
	For additional information on anthrax, including post-exposure prophylaxis, see <a href="CBRN guidance">CBRN guidance</a>		
Criteria for inclusion	Adults and children aged 12 years or over following exposure to a known deliberate release of anthrax		
	and		
	who have already received chemoprophylaxis for 10 days with doxycycline or ciprofloxacin.		
	and		
	Are not showing symptoms compatible with anthrax infection. Individuals with symptoms should be referred urgently to the supervising doctor. See Action to be taken if individual or carer declines prophylaxis below and the CBRN guidance for symptoms		
Criteria for exclusion <sup>2</sup>	Individuals are excluded from this PGD if:		
	1. They are under 12 years of age		
	They are pregnant or suspected to be pregnant as doxycycline affects teeth and bone growth in the baby, notably in the second and third trimester		
	They are currently breastfeeding		
	4. They have known severe liver impairment		
	<ol> <li>They have a known history of severe allergic reaction to doxycycline, other tetracyclines or to any of the listed excipients (see <u>SPC</u>)</li> </ol>		
	They have experienced unacceptable side effects while taking the initial ten days' supply of doxycycline		
	7. They are receiving systemic retinoid treatment (for example, acitretin, alitretinoin, isotretinoin, tretinoin) due to possible increased risk of benign intracranial hypertension when tetracyclines are given with retinoids		
	8. They are taking enzyme inducing anti-epileptic medicines (carbamazepine, fosphenytoin, phenobarbitone/phenobarbital, primidone, phenytoin) as effectiveness of doxycycline may be reduced		
	9. They have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained)  Output  Description:		
	See Action to be taken if individual is excluded section of this PGD		

 $^2$  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

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# Cautions including any relevant action to be taken

(continued overleaf)

For individuals where the following cautions apply, supply doxycycline unless there are life-threatening contraindications as benefit outweighs risk in the case of a deliberate release of anthrax. Provide affected individuals with the advice given below.

Refer to the supervising doctor if concerned about an individual's risk for assessment and consideration of alternative antibiotics

#### 1. Myasthenia gravis:

Advise to self-monitor for any increase in severity of myasthenia gravis If an increase in severity of myasthenia gravis occurs, advise individuals to seek urgent medical advice

**Note:** ciprofloxacin is also cautioned for individuals with myasthenia gravis

#### 2. Systemic lupus erythematosus (SLE):

Consider supply of ciprofloxacin (see ciprofloxacin further supply PGD) if no contraindications or advise to self-monitor for any increase in severity of SLE. If increase in severity of SLE advise individual to seek medical advice

#### 3. Liver impairment:

Doxycycline has been associated with rare incidents of hepatic injury. Manufacturers advise caution in those with liver impairment or those receiving potentially hepatotoxic medicines. Those with known severe liver impairment are excluded from this PGD (see exclusion criteria)

#### 4. Chronic alcohol dependence:

Alcohol may reduce the half-life of doxycycline, particularly for individuals with chronic alcohol dependence. Twice daily dosing may reduce the significance of this interaction. If ciprofloxacin is contraindicated, advise of risk and to seek immediate medical advice if symptoms compatible with anthrax infection develop

#### 5. Severely immunocompromised individuals:

Individuals who are severely immunocompromised (as defined in Chapter 28a Green book) should be advised to arrange an appointment with their GP or specialist to determine whether they need to continue treatment beyond the course outlined in this PGD

# 6. Taking vitamin K antagonists (for example, warfarin, phenindione and acenocoumarol):

Advise individual to arrange for INR to be monitored 3-5 days after starting treatment and to speak to their GP or anticoagulant clinic if they notice any signs of bleeding or unexplained/excessive bruising

#### 7. Taking penicillin:

Doxycycline may reduce the effect of penicillin. For individuals taking penicillin for a serious infection, seek advice from the supervising doctor.

#### 8. Taking ciclosporin or lithium:

Consider supply of ciprofloxacin (see ciprofloxacin further supply PGD) if appropriate or advise individual to contact the service who prescribe/monitor the affected medicines to arrange monitoring and any dose adjustments. Advise to be aware of any signs of toxicity.

#### Cautions including any 9. Already taking doxycycline or other tetracycline for another relevant action to be condition: taken Advise individual to stop their existing course. They should now take doxycycline at the dose and frequency outlined in this PGD. (continued) If doxycycline or another tetracycline has previously been prescribed for ongoing treatment, the individual can be advised to continue at the previous dose once the course for anthrax postexposure prophylaxis is complete. If unclear, seek advice from the supervising doctor. Refer to the SPC for doxycycline for full details on special warnings and precautions for use. Action to be taken if the Explain why they have been excluded individual is excluded Consider supply of ciprofloxacin (see ciprofloxacin further supply PGD). Where ciprofloxacin is contraindicated refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics Document reasons for exclusion and any referrals that have been made Action to be taken if the Refer the individual to the supervising doctor individual or carer Advise the individual or their parent/carer of the possible declines prophylaxis consequences of declining prophylaxis and of alternative options Advise about the protective effects of the prophylaxis, risks of infection, and disease complications Advise to seek urgent medical attention if they develop symptoms compatible with anthrax infection or signs or symptoms of sepsis. Symptoms of anthrax will depend on the type of exposure: Inhalational: flu-like illness (fever, malaise, nausea/vomiting, headache, non-productive cough) **Cutaneous:** initial pimple/pauple that enlarges, blisters. ulcerates over 2 to 6 days to form a black scab Gastrointestinal: severe abdominal pain, nausea, vomiting, bloody diarrhoea See CBRN guidance for information on symptoms Document the advice given and the decision reached Arrangements for referral Follow local procedures for referral to the supervising doctor and/or for medical advice other services

#### 5. Description of treatment

Name atrangth and	Developing 100mg concules		
Name, strength and formulation of drug	Doxycycline 100mg capsules		
Legal category	Prescription Only Medicine (POM)		
Black triangle▼	No		
Off-label use	Anthrax post-exposure prophylaxis is not included under the therapeutic indications in the <u>SPC</u> but is recommended in the <u>Guidance on CBRN incidents.</u>		
	Where a product is recommended off-label consider, as part of the consent process, informing the individual/carer the product is being offered in accordance with national guidance but this is outside the product licence.		
Route / method of administration	Oral		
Dose and frequency of	One capsule (100mg) to be taken twice a day		
administration	For individuals who are unable to swallow the capsules, refer to the supervising doctor for assessment and consideration of alternative antibiotics or formulation.		
Duration of treatment	20 days following an initial 10-day supply of antibiotics		
Quantity to be supplied / administered	40 (forty) capsules When supplying under a PGD, this must be a complete over-labelled manufacturer's original pack or over-labelled pre-packs. The individual's name, the date and additional instructions must be written on the label at the time of supply. As split manufacturers packs cannot be supplied, if an over-supply is required, individuals must be advised to take any remaining medicine to a community pharmacy for destruction.		
Storage	Store in original container below 25 °C		
Disposal	Any unused product or waste material should be disposed of in accordance with local requirements.		
Drug interactions (continued overleaf)	This list is not exhaustive. Full details of drug interactions are available in the <u>SPC</u> or the <u>BNF online</u> .		
	<ul> <li>individuals taking systemic retinoids or enzyme-inducing anti- epileptics are excluded from this PGD (see <u>exclusion criteria</u>)</li> </ul>		
	<ul> <li>Individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be advised to contact the administering clinic or GP as soon as possible for advice as doxycycline may reduce the efficacy of these vaccines</li> <li>anticoagulants, vitamin K antagonists, ciclosporin, lithium, penicillin and alcohol: see cautions for advice to be given</li> </ul>		
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#### **Drug interactions** oral contraceptives: additional contraceptive precautions are (continued) recommended if vomiting or diarrhoea occurs. Advise individuals to follow the instructions given with their contraceptive. antacids, aluminium, calcium, iron, magnesium, bismuth and zinc salts: greatly decrease the absorption of doxycycline. Administration should be separated by 2 to 3 hours Identification and A detailed list of adverse reactions is available in the SPC. management of adverse Commonly reported side effects include: reactions nausea, vomiting and headache hypersensitivity reactions photosensitivity and rash including maculopapular and erythematous rashes. Advise individuals to take doxycycline after food or with a drink of milk instead of water to help with nausea To help with photosensitivity, advise individuals to wear clothes that cover them up and a hat and sundlasses when going outside. Advise they use a high SPF sunscreen of at least 30 to prevent any sunburn. In the event of a severe adverse reaction (for example, anaphylaxis, severe skin reactions, visual disturbance), the individual should seek urgent medical advice If individuals are concerned about other side effects, they should be advised to continue with treatment and contact their GP or pharmacist Reporting procedure of All suspected adverse reactions in children and severe adverse adverse reactions reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store. Any serious adverse reaction to the medicine should be documented in the individual's record and the individual's GP informed. Supply the marketing authorisation holder's patient information leaflet Written information to be given (PIL). Provide the following advice: Advice /follow up treatment • the dose, frequency and method of administration • to swallow the capsules whole with plenty of fluid during meals in (Continued overleaf) either the sitting or standing position • to not lie down within an hour of taking the medication, so not to take at bedtime to not take on an empty stomach because of the risk of oesophagitis • to not take indigestion remedies or medicines containing aluminium, calcium, iron, magnesium zinc or bismuth, 2 to 3 hours before or after taking the medicine • if gastric irritation occurs, the capsules may be taken with milk • if a dose is missed, advise to refer to the PIL supplied with the product • to space the doses evenly throughout the day and finish the course unless told to stop

### Advice /follow up treatment

#### (continued)

- to avoid exposure to direct sunlight or ultraviolet light including sunbeds and sun lamps. If unavoidable, advise to cover up and use high SPF sun cream
- to avoid alcohol

For individuals with conditions listed in the <u>Cautions</u> section, provide the additional recommended advice.

#### Inform the individual/carer:

- to read the PIL provided with the medicine
- of possible side effects and their management
- to seek medical advice if side effects or any other unexplained effects on health are experienced
- if side effects become serious severe or prolonged, or if the individual notices any side effects not listed in the PIL, they should contact their GP or pharmacist immediately
- if symptoms compatible with anthrax infection develop to seek medical advice immediately
- to return any unused medicine to a pharmacy

#### Records

#### Record:

- whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005
- name of individual, address, date of birth, allergies and GP with whom the individual is registered (or record where an individual is not registered with a GP)
- name of member of staff who supplied the product
- name and brand of the product
- date of supply
- dose, form, and route of administration of the product
- quantity supplied
- batch number and expiry date
- advice given; including advice given if the individual is excluded or declines treatment
- details of any adverse drug reactions and actions taken
- that the product was supplied via PGD

All records should be signed and dated (or password-controlled on records)

All records should be clear, legible and contemporaneous.

Contact details for the individual must be recorded. Local arrangements must ensure that contact is made between the designated centre and all individuals to discuss further supplies or an alternative antibiotic, where appropriate.

A computerised or manual record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

#### 6. Key references

#### **Key references**

- Doxycycline SPC last updated 6 December 2021
- Doxycycline PIL last updated 20 June 2024
- Chemical, biological, radiological and nuclear incidents: clinical management and health protection (2018)
- British National Formulary (BNF) accessed June 2024
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions last updated 27 March 2017
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions last updated 27 March 2017
- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. 7 March 2023

#### 7. Practitioner authorisation sheet

Name PGD vXX.XX Valid from: XX/XX/20XX Expiry: XX/XX/20XX

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

#### **Practitioner**

By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs 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 PGD 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 practitioners 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 abovenamed health care professionals 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 practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.