**Publications reference number: B1116**

**Doxycycline Initial Supply Anthrax Patient Group Direction (PGD)**

For the initial supply of doxycycline 100mg capsules, to adults and children aged 8 years and over exposed to a known or suspected deliberate release of anthrax, by registered healthcare practitioners identified in [Section 3](#section3), subject to any limitations to authorisation detailed in [Section 2](#section2).

Reference: Doxycycline PGD initial supply anthrax

Version no: 04.00

Valid from: 1 November 2021

Review date: 1 May 2024

Expiry date: 31 October 2024

**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)[[1]](#footnote-1). **The PGD is not legal or valid without signed authorisation in accordance with** [**HMR2012 Schedule 16 Part 2**](http://www.legislation.gov.uk/uksi/2012/1916/schedule/16/part/2/made)**.**

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.

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 UKHSA PGD templates for authorisation can be found from: <https://www.england.nhs.uk/ourwork/eprr/hm/>

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: insert local contact details

**Change history**

|  |  |  |
| --- | --- | --- |
| **Version number** | **Change details** | **Date** |
| PGD2014/1 | Original template developed and ratified | 2 July 2014 |
| PGD 02.00 | 1. Put into the new PHE template format
2. For use in anthrax only, tularemia and plague put in separate PGDs
3. Clinical indications: “another biological agent” removed
4. Clinical indications: co-amoxiclav added as alternative second-line treatment for young children
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.
 | 1 May 2016 |
| PGD 03.00 | 1. Put into the new PHE template format
2. Off-label use changed to ‘yes’
3. Cautions: “Hepatic impairment: Only use where mild stable hepatic disease present; otherwise initiate chemoprophylaxis with ciprofloxacin, amoxicillin or co-amoxiclav” removed.
4. References updated
 | 16 October 2018 |
| PGD 04.00 | 1. Addition of ‘following deliberate release’ to page 1, clinical indication and criteria for inclusion for clarity
2. Addition to indications of note ciprofloxacin is the 1st line choice and doxycycline is 2nd line treatment
3. Retinoid treatment moved from cautions to criteria for exclusion
4. Removal of consideration for ciprofloxacin for myasthenia gravis and systemic lupus erythematosus as this should already have been considered
5. Removal of under 12-years from off-label use
6. Addition to off-label use the dose for 8 to12 year olds is higher than in the SPC but follows the Guidance on CBRN incidents
7. Addition to dose and frequency for children who are unable to swallow the capsules, refer to the supervising doctor for assessment and prescription of amoxicillin or co-amoxiclav if not contra-indicated.
8. Minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates
 | 26 October 2021 |

1. **PGD development**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Developed by:** | **Name** | **Signature** | **Date** |
| Pharmacist(Lead Author) | Jacqueline LambertyLead Pharmacist Medicines Governance, UKHSA |  | 26 October 2021 |
| Doctor | Nick GentConsultant in Health ProtectionEmergency Response Department, UKHSA |  | 26 October 2021 |
| Registered Nurse | Kelly StokerLead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA |  | 26 October 2021 |

This PGD has been peer reviewed by the CBRN PGD Expert panel in accordance with the UKHSA PGD Policy. It has been agreed by the UKHSA Medicines Governance Group and the UKHSA Quality and Clinical Governance Delivery Board.

**Expert panel**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Ruth Milton (Chair) | Senior Medical Adviser, Consultant in Public Health Emergency Response Department, UKHSA |
| Nicholas Aigbogun | Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA |
| Diane Ashiru-Oredope | Lead Pharmacist, HCAI, Fungal, AMR, AMU & Sepsis Division, UKHSA |
| Tim Brooks | Consultant Medical Microbiologist / Virologist, UKHSA |
| Rosie Furner | Community Services Pharmacist, East Sussex Healthcare NHS Trust |

1. **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 organisations and/or services |
|  |
| Limitations to authorisation |
| For instance 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 |
|   |   |   |   |

|  |
| --- |
| Additional signatories according to locally agreed policy |
| Role | Name  | Sign | Date |
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Local enquiries regarding the use of this PGD may be directed to […………………

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.

#### Characteristics of staff

|  |  |
| --- | --- |
| **Qualifications and professional registration**  | To be completed by the organisation authorising the PGD for instance, registered professional with one of the following bodies:* nurses currently registered with the Nursing and Midwifery Council (NMC)
* pharmacists currently registered with the General Pharmaceutical Council (GPhC)

The practitioners above must also fulfil the [Additional requirements](#addrequirements) detailed below. Check [Section 2 Limitations to authorisation](#limitations) 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 [NICE Competency framework](https://www.nice.org.uk/guidance/mpg2/resources/mpg2-patient-group-directions7) for health professionals using PGDs)
* must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC)
* 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
* insert any additional requirements

**The individual practitioner must be authorised by name, under the current version of this PGD before working according to it** |
| **Continued training requirements** | insert any continued training requirements |

1. **Clinical condition or situation to which this PGD applies.**

|  |  |
| --- | --- |
| **Clinical condition or situation to which this PGD applies** | **Initial** chemoprophylaxis is required following a known or suspected deliberate release of anthrax.**Notes:** Ciprofloxacin is first line treatment, so doxycycline should only be supplied where there is contraindication or exclusion to ciprofloxacin such as an established history of severe allergic reaction For children eight to twelve years of age, follow on treatment after the initial ten (10) day course must be with a different antibiotic, not doxycycline |
| **Criteria for inclusion** | Adults and children aged 8 years and over following a known or suspected deliberate release of anthrax. |
| **Criteria for exclusion[[2]](#footnote-2)** | Individuals are excluded from this PGD if:1. They have a history of severe allergic reaction to doxycycline, other tetracyclines or to any of the listed excipients
2. They are pregnant or breastfeeding mothers, as doxycycline affects teeth and bone growth in the baby, notably in the second and third trimester.
3. They are receiving retinoid treatment due to possible increased risk of benign intracranial hypertension when tetracyclines are given with retinoids.
 |
| **C****autions including any relevant action to be taken** | Where there is an established history of severe allergic reaction to ciprofloxacin, supply doxycycline unless there are life-threatening contra-indications, because the benefits outweigh any risks, but provide the recommended advice given below.1. Myasthenia gravis:

*Warn to self-monitor for any increase severity of disease. If increase in severity of disease consult supervising doctor for assessment and prescription of amoxicillin or co-amoxiclav if not contra-indicated.*1. Systemic lupus erythematosus:

*Warn to self-monitor for any increase severity of disease. If increase in severity of disease consult supervising doctor for assessment and prescription of amoxicillin or co-amoxiclav if not contra-indicated.*1. Renal (kidney) impairment, renal damage requiring individual to be in renal replacement therapy (dialysis):

*Studies to date indicate usual recommended doses do not lead to excessive accumulation in individuals with renal impairment*1. Vitamin K antagonist concomitant treatment (warfarin, phenindione and acenocoumarol):

*Warn individual of increased risk of bleeding. Check INR and adjust dose of anticoagulant treatment weekly if necessary* |
| **Action to be taken if the patient is excluded** | Explain why they have been excluded. If ciprofloxacin has not already been excluded, consider supply of ciprofloxacin (see [ciprofloxacin initial supply PGD](https://www.england.nhs.uk/ourwork/eprr/hm/)). If ciprofloxacin has already been excluded, refer the individual to the supervising doctor for assessment and prescription of amoxicillin or co-amoxiclav if not contra-indicated. |
| **Action to be taken if the patient or carer declines treatment** | Refer the individual to the supervising doctor.Advise the individual or their carer of the possible consequences of declining prophylaxis and of alternative options. Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. Advise on the need for vigilance for symptoms of the potential disease, recognising symptoms and the need to seek urgent medical attention should symptoms occur. |

1. **Description of treatment**

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| --- | --- |
| **Name, strength & formulation of drug** | Doxycycline 100mg capsules |
| **Legal category** | Prescription Only Medicine (POM) |
| **Black triangle▼**  | No |
| **Off-label use** | Yes: anthrax is not included under the therapeutic indications in the [SPC](https://www.medicines.org.uk/emc/) but is recommended in the [Guidance on CBRN incidents.](https://www.gov.uk/government/publications/chemical-biological-radiological-and-nuclear-incidents-recognise-and-respond) The dose for 8-12 year olds is higher than in the SPC but follows the recommendations in the [Guidance on CBRN incidents.](https://www.gov.uk/government/publications/chemical-biological-radiological-and-nuclear-incidents-recognise-and-respond)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 administration** | One capsule to be taken twice dailyFor children who are unable to swallow the capsules, refer to the supervising doctor for assessment and prescription of amoxicillin or co-amoxiclav if not contra-indicated. |
| **Duration of treatment** | 10 days |
| **Quantity to be supplied / administered** | 20 (twenty) capsules When supplying under a PGD, this must be a complete 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 oC |
| **Disposal** | Any unused product or waste material should be disposed of in accordance with local requirements. |
| **Drug interactions**Continued overleaf**Drug interactions**(continued) | 1. Doxycycline can affect anticoagulants such as warfarin, antiepileptic drugs such as phenobarbital, carbamazepine, primidone and phenytoin and some other antibiotics such as penicillin. Consult the [BNF online](https://bnf.nice.org.uk/drug/doxycycline.html) for more detailed information.
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.
4. Benign intracranial hypertension has been associated with the use of retinoids and tetracyclines including doxycycline – see [Criteria for exclusion](#exclusion)
 |
| **Identification & management of adverse reactions** | Commonly reported side effects include nausea, vomiting, headache and photosensitivity. A detailed list of adverse reactions is available in the [SPC.](https://www.medicines.org.uk/emc/)  |
| **Reporting procedure of adverse reactions** | All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the [Yellow Card](http://yellowcard.mhra.gov.uk) 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. |
| **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 sitting or standing position
* not lie down within an hour of taking the medication, so not to take at bedtime
* not take on an empty stomach because of the risk of oesophagitis
* not take indigestion remedies or medicines containing calcium, iron or zinc, 2 hours before or after taking the medicine
* space the doses evenly throughout the day
* to keep taking this medicine until the course is finished, unless they are told to stop.

Inform the individual/carer:* 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 not stop the treatment, but should contact their local doctor or pharmacist immediately
* if gastric irritation occurs, the capsules may be taken with milk without significant reduction in absorption
* the skin may become more sensitive to direct sunlight and to avoid exposure to excessive sunlight or use high SPF sunblock if prolonged exposure to the sun is unavoidable.

For individuals with conditions listed in the [Cautions](#Cautions) section, provide the additional recommended advice. Advise individual/carer when the subsequent supply is due. |
| **Records**(continued overleaf)**Records** (continued) | 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](https://www.legislation.gov.uk/ukpga/2005/9/contents)
* name of individual, address, date of birth 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 product
* date of supply
* dose, form and route of administration of product
* quantity supplied
* 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 PGD
* records should be signed and dated

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

#### Key references

|  |  |
| --- | --- |
| **Key references**  | * Doxycycline SPC last updated 18 April 2020 [www.medicines.org.uk/emc/](http://www.medicines.org.uk/emc/)
* Doxycycline PIL last updated 18 April 2020 www.medicines.org.uk/emc/
* Chemical, biological, radiological and nuclear incidents: clinical management and health protection (2018) https://www.gov.uk/government/publications/chemical-biological-radiological-and-nuclear-incidents-recognise-and-respond
* British National Formulary (BNF) accessed 12 October 2021 <https://bnf.nice.org.uk/drug/doxycycline.html>
* NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions last updated 27 March 2017 <https://www.nice.org.uk/guidance/mpg2>
* NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions last updated 27 March 2017

<https://www.nice.org.uk/guidance/mpg2/resources>* Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <https://www.england.nhs.uk/wp-content/uploads/2021/05/HTM_07-01_Final.pdf>
 |

1. **Individual practitioner authorisation sheet**

By signing this PGD you are indicating you agree to the contents and you will work within it

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

**Practitioner**

**I confirm I have read and understood the content of this PGD and 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 you have assessed the staff member as competent to work under this PGD and 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

1. This includes any relevant amendments to legislation (such as [2013 No.235](http://www.legislation.gov.uk/uksi/2013/235/contents/made), [2015 No.178](http://www.legislation.gov.uk/nisr/2015/178/contents/made), [2015 No.323](http://www.legislation.gov.uk/uksi/2015/323/contents/made) and [2020 No.1125](https://www.legislation.gov.uk/uksi/2020/1125/contents/made) [↑](#footnote-ref-1)
2. Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required [↑](#footnote-ref-2)