**Reference:** GW-161

## PATIENT GROUP DIRECTION (PGD)

Further 20 days’ supply of ciprofloxacin 500mg tablets to adults and children aged 12 years and over with a known or suspected exposure to anthrax

## For the further supply of ciprofloxacin 500mg tablets by INSERT HEALTHCARE PROFESSIONAL GROUPS WHICH CAN SUPPLY UNDER THE PGD to adults and children aged 12 years and over with a known or suspected exposure to anthrax

Reference no: *Ciprofloxacin500mgfurthersupplyanthrax20dayPGD*

Version number: *03.00*

Valid from: *01 January 2019*

Review date: *01 January 2021*

Expiry date: *01 January 2022*

**Public Health England has developed this PGD for local authorisation**

Those using this PGD must ensure that 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). **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION** **IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

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.

**INDIVIDUAL PRACTITIONERS 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. Current versions of PHE 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

# **Change history**

|  |  |  |
| --- | --- | --- |
| **Version number** | **Change details** | **Date** |
| PGD 2014/1 | Original template developed and ratified | 02 July 2014 |
| PGD 02.00 | 1. Put into the new PHE template format
2. For use in anthrax only, tularemia put in separate PGD
3. Clinical indications: “another biological agent” removed
4. 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.
5. Interactions: advice simplified.
6. References updated.
 | 01 May 2016 |
| PGD 03.00 | 1. Put into the new PHE template format
2. Duration of further supply changed to 20 days
3. Off-label use changed to ‘yes’ – treatment duration other than in SPC.
4. References updated
 | 07 December 2018 |

1. **PGD development**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Developed by:** | **Name** | **Signature** | **Date** |
| Pharmacist(Lead Author) | Judith FieldUK National Countermeasure ManagerEmergency Response DepartmentPublic Health England |  | 07 December 2018 |
| Doctor | Nick GentConsultant in Health ProtectionEmergency Response DepartmentPublic Health England |  | 07 December 2018 |
| Registered Nurse | Joanne BosanquetDeputy Chief NursePublic Health England |  | 07 December 2018 |

This PGD 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 Delivery Board.

**Expert panel**

|  |  |
| --- | --- |
| **Name** | **Post** |
| John Simpson (Chair) | Director of Emergency Preparedness, Resilience and ResponsePublic Health England |
| Jacqueline Lamberty | Lead Pharmacist Medicines Management ServicesPublic Health England |
| Sally Millership | Consultant in Communicable Disease Control Public Health England East of England |
| Rosie Furner | Community Services PharmacistEast Sussex Healthcare NHS Trust |
| Tim Brooks | Head & Clinical Service Director, Rare & Imported Pathogens Laboratory Public Health England |
| Ed Kaczmarski | Consultant Medical Microbiologist, ManchesterLead Public Health Microbiologist, Public Health England NWHead of the National Meningococcal Reference Unit |
| Calum Semple | Professor of Child Health and Outbreak Medicine University of Liverpool and Consultant in Paediatric Respiratory Medicine Alder Hey Children’s Hospital |

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 |
| 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 |
|  |   |   |   |
|  |   |   |   |
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|  |   |   |   |

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.

#### Characteristics of staff

|  |  |
| --- | --- |
| **Qualifications and professional registration**  | To be completed by the organisation authorising the PGD eg: 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).
* Additional registered healthcare professionals to be added by organisation authorising the PGD
 |
| **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](https://www.nice.org.uk/guidance/mpg2/resources) 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
* must have access to the Patient Group Direction and associated online resources.
* should fulfil any additional requirements defined by local policy
* authorising organisation to insert any additional requirements

**THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.** |
| **Continued training requirements** | * authorising organisation to insert
 |

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

|  |  |
| --- | --- |
| **Clinical condition or situation to which this PGD applies** | Chemoprophylaxis in known or suspected exposure to anthrax |
| **Criteria for inclusion** | Adults and children aged 12 years and over who:* + - * have a known or suspected exposure to anthrax, and have already received ten days’ supply of antibiotic for known or suspected exposure
			* are unsuitable for treatment with doxycycline

The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in **growing adolescents, pregnant and nursing mothers** who **should be given ciprofloxacin** in the situation criteria set out above.Individuals with the following conditions are included because the benefits of taking the medicine outweigh any risks, but provide the recommended advice given under the [Cautions](#Cautions) section:1.  History of tendon disorder related to quinolone use2.  Conditions with risk factor for QT interval prolongation3.  History of epilepsy4.  Myasthenia gravis5.  Vitamin K antagonist concomitant treatment (warfarin, phenindione and acenocoumarol)  |
| **Criteria for exclusion**[[1]](#footnote-1) | 1. Children aged under 12 years.
2. Known anaphylaxis, or severe allergy or sensitivity, to ciprofloxacin or other quinolones.
3. Individuals who have experienced side effects while taking the initial ten days’ supply.
4. Concomitant administration of ciprofloxacin and:
* aminophylline
* theophylline
* tizanidine
 |
| **Cau****tions including any relevant action to be taken** | This PGD contains abbreviated lists of warnings and contra-indications that take into account this medicine must be offered in all cases where known or suspected exposure to anthrax may have occurred, unless there is very significant clinical reason (life-threatening contra-indications) not to do so.Supply the chemoprophylaxis to individuals with the conditions listed below, because the benefits of taking the medicine outweigh any risks, but provide the recommended advice.History of tendon disorder related to quinolone use:*Warn to self-monitor for tendinitis**Do not discontinue ciprofloxacin if tendinitis develops; switch to* [*doxycycline*](https://www.england.nhs.uk/ourwork/eprr/hm/) *as soon as reasonably possible.*Conditions with risk factor for QT interval prolongation:* acute myocardial infarction
* bradycardia
* congenital long QT syndrome
* heart failure with reduced left ventricular ejection
* history of symptomatic arrhythmias

*Warn to self-monitor for any exacerbation of symptoms**If symptomatic switch to doxycycline or amoxicillin immediately*History of epilepsy:*Warn to self-monitor for any increase in frequency or severity of seizures**Do not discontinue ciprofloxacin if increase in frequency or severity of seizures; switch to* [*doxycycline*](https://www.england.nhs.uk/ourwork/eprr/hm/) *as soon as reasonably possible, or refer to supervising doctor for prescription of amoxicillin or co-amoxiclav if not contra-indicated as soon as reasonably possible.** + - 1. Myasthenia gravis:

*Warn to self-monitor for any increase severity of disease**Do not discontinue ciprofloxacin if increase in severity of disease; switch to* [*doxycycline*](https://www.england.nhs.uk/ourwork/eprr/hm/) *as soon as reasonably possible or refer to supervising doctor for prescription of amoxicillin or co-amoxiclav if not contra-indicated as soon as reasonably possible.** + - 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 during long term ciprofloxacin use* |
| **Action to be taken if the patient or carer declines prophylaxis** | 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.  |
| **Action to be taken if the patient is excluded** | Explain why they have been excluded and refer the individual to the supervising doctor. |

1. **Description of treatment**

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| --- | --- |
| **Name, strength & formulation of drug** | Ciprofloxacin 500mg tablets |
| **Legal category** | Prescription Only Medicine (POM) |
| **Black triangle▼**  | No |
| **Off-label use** | Yes –the SPC states a treatment duration of 60 days but [PHE advice on CBRN incidents](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/712888/Chemical_biological_radiological_and_nuclear_incidents_clinical_management_and_health_protection.pdf) recommends a treatment duration of 20 days. Where a product is recommended off-label consider, as part of the consent process, informing the individual/carer that the product is being offered in accordance with national guidance but that this is outside the product licence. |
| **Route/method of administration** | OralTo be swallowed whole with fluid, preferably on an empty stomach |
| **Dose and frequency of administration** | **Adults (and children aged 12 years or over)**:One tablet (500mg) to be taken twice a dayWhen 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. |
| **Duration of treatment** | 20 days (total length of course 30 days) Note: these individuals have previously received an initial ten day supply |
| **Quantity to be supplied**  | 40 (forty) tablets |
| **Storage** | Store in original container below 25 oCStore out of reach of children |
| **Disposal** | Any unused product or waste material should be disposed of in accordance with local requirements. |
| **Drug interactions** | On the balance of risk to benefit, individuals taking medications which might interact with ciprofloxacin should normally receive chemoprophylaxis with ciprofloxacin if exposed to a biological agent. However individuals taking aminophylline, theophylline or tizanidine are excluded from this PGD.See [Cautions](#Cautions) for advice for individuals taking vitamin K analogues. |
| **Identification & management of adverse reactions**[[2]](#footnote-2) | Most commonly nausea and diarrhoea. Ciprofloxacin may affect reaction times. Other side effects are classified as uncommon to very rare. If any side effects become serious, severe or prolonged, or if the individual notices any side effects not listed in the Patient Information leaflet, individuals should not stop antibiotic treatment, but should contact their local doctor or pharmacist.Tendon inflammation and rupture may occur with ciprofloxacin. Such reactions have been observed particularly in older individuals and those treated concurrently with corticosteroids.If there is pain or inflammation, **individuals should not stop antibiotic treatment**, but must see their doctor at the earliest opportunity to change to doxycycline, amoxicillin or co-amoxiclav.A detailed list of adverse reactions is available in the Summary of Product Characteristics, which is available from the [Electronic Medicines Compendium](http://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](http://yellowcard.mhra.gov.uk/) system. 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). The additional information leaflet covering the use of ciprofloxacin in response to known or suspected exposure to anthrax should also be provided. |
| **Patient advice/follow up treatment** | Explain the treatment. Ensure the individual is aware of the need to maintain adequate fluid intake. Do not take milk, indigestion remedies or medicines containing calcium, iron or zinc, 2 hours before or after you take this medicine.Do not take with dairy products (eg milk, yoghurt) or mineral-fortified fruit-juice (eg calcium-fortified orange juice).Space the doses evenly throughout the day. Keep taking this medicine until the course is finished, unless you are told to stop.Swallow this medicine whole with water, preferably on an empty stomach. Do not chew or crush. Inform individual/carer of possible side effects and their management. 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.Advise the individual or their carer to read the PIL leaflet before taking the antibiotic and to seek medical advice if side effects, including painful or inflamed joints, or any other unexplained side effects on health are experienced.For individuals with conditions listed in the [Cautions](#Cautions) section, provide the additional recommended advice. |
| **Records** | Record: * whether valid informed consent was given
* name of individual, address, date of birth and GP with whom the individual is registered
* 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 Patient Group Direction (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 of ciprofloxacin or an alternative antibiotic, where appropriate.A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy.  |

#### Key references

|  |  |
| --- | --- |
| **Key references**  | Ciprofloxacin Summary of Product Characteristics [www.medicines.org.uk/emc/](http://www.medicines.org.uk/emc/) Inhalational Anthrax-Antibiotic Schedule and Dosing Rationale for People of All Ages (expert advice)Opinion on antibiotics to be used in children for chemoprophylaxis following exposure to Bacillus anthracis spores (PHE expert advice)CBRN Handbook <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/712888/Chemical_biological_radiological_and_nuclear_incidents_clinical_management_and_health_protection.pdf>British National Formulary (BNF) <https://bnf.nice.org.uk/drug/ciprofloxacin.html>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>  |

1. **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.

1. Exclusion under this Patient Group Direction does not necessarily mean the antibiotic is contraindicated, but it would be outside its remit and another form of authorisation will be required [↑](#footnote-ref-1)
2. Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list [↑](#footnote-ref-2)