Reference: XXXXXXX

PATIENT GROUP DIRECTION (PGD)

Initial supply of ciprofloxacin 500mg tablets to adults and children aged 12 years and over with known or suspected exposure to anthrax

For the initial supply of ciprofloxacin 500mg tablets by healthcare professionals to adults and children aged 12 years and over with known or suspected exposure to anthrax

Reference no: Ciprofloxacin500mginitialsupplyanthraxPGDTemplate
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

Ciprofloxacin500mginitialsupplyanthraxPGD v02.00 Valid from: 1st May 2016 Expiry: 1st May 2019
<table>
<thead>
<tr>
<th>Version number</th>
<th>Change details</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>PGD 2014/1</td>
<td>Original template developed and ratified</td>
<td>2nd July 2014</td>
</tr>
</tbody>
</table>
| 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. 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.                                                                                     | 1st May 2016  |
1. PGD template development

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

<table>
<thead>
<tr>
<th>Developed by:</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Simpson (Chair)</td>
<td>Director of Emergency Preparedness, Resilience and Response Public Health England</td>
</tr>
<tr>
<td>Jacqueline Lamberty</td>
<td>Pharmacist Medicines Management Adviser Public Health England</td>
</tr>
<tr>
<td>Sally Millership</td>
<td>Consultant in Communicable Disease Control Public Health England East of England</td>
</tr>
<tr>
<td>Rosie Furner</td>
<td>Community Services Pharmacist East Sussex Healthcare NHS Trust</td>
</tr>
<tr>
<td>Tim Brooks</td>
<td>Head &amp; Clinical Service Director, Rare &amp; Imported Pathogens Laboratory Public Health England</td>
</tr>
<tr>
<td>Ed Kaczmarski</td>
<td>Consultant Medical Microbiologist, Manchester Lead Public Health Microbiologist, Public Health England NW Head of the National Meningococcal Reference Unit</td>
</tr>
<tr>
<td>Calum Semple</td>
<td>Senior Lecturer &amp; Consultant Respiratory Paediatrician University of Liverpool</td>
</tr>
</tbody>
</table>

Ciprofloxacin500mgInitialSupplyanthraxPGD v02.00 Valid from: 1st May 2016 Expiry: 1st May 2019
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:

<table>
<thead>
<tr>
<th>Authorised for use by the following organisations and/or services</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Limitations to authorisation</th>
</tr>
</thead>
</table>

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 ….

<table>
<thead>
<tr>
<th>Organisational approval (legal requirement)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Sign</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete eg NHSE Governance Lead, Medical Director</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional signatories according to locally agreed policy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Sign</th>
<th>Date</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Qualifications and professional registration</th>
<th>Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions and have current registration.</th>
</tr>
</thead>
</table>

| 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  
• must have access to the Patient Group Direction and associated online resources.  
• should fulfil any additional requirements defined by local policy |

| 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 |

THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.
4. Clinical condition or situation to which this PGD applies.

<table>
<thead>
<tr>
<th>Clinical condition or situation to which this PGD applies</th>
<th>Initial chemoprophylaxis is required because of known or suspected exposure to anthrax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria for inclusion</td>
<td>Adults and children aged 12 years and over with known or suspected exposure to anthrax. The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in <strong>growing adolescents, pregnant and nursing mothers</strong> who should be given ciprofloxacin in the situation criteria set out above.</td>
</tr>
</tbody>
</table>
| Criteria for exclusion\(^1\) | 1. Known anaphylaxis, or severe allergy or sensitivity, to ciprofloxacin or other quinolones.  
2. Concomitant administration of ciprofloxacin and:  
   - aminophylline  
   - theophylline  
   - tizanidine |
| Cautions including any relevant action to be taken | This Patient Group Direction contains abbreviated lists of warnings and contra-indications that take into account this medicine must be offered in all cases where exposure to these biological agents may have occurred unless there is very significant clinical reason (life-threatening contra-indications) not to do so.  

**Individuals with these conditions SHOULD normally receive chemoprophylaxis with ciprofloxacin if exposed to one of the biological agents listed in this PGD or advised by PHE.**  
1. History of tendon disorder related to quinolone use:  
   Warn to self-monitor for tendinitis  
   Do not discontinue ciprofloxacin if tendinitis develops; switch to doxycycline or amoxicillin as soon as reasonably possible.  
2. 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  
3. 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 or amoxicillin as soon as reasonably possible |

\(^1\) 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
4. 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 or amoxicillin as soon as reasonably possible

5. 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. |
### 5. Description of treatment

<table>
<thead>
<tr>
<th>Name, strength &amp; formulation of drug</th>
<th>Ciprofloxacin 500mg tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal category</td>
<td>Prescription Only Medicine (POM)</td>
</tr>
<tr>
<td>Black triangle▼</td>
<td>No</td>
</tr>
<tr>
<td>Off-label use</td>
<td>No</td>
</tr>
<tr>
<td>Route / method of administration</td>
<td>Oral</td>
</tr>
<tr>
<td></td>
<td>To be swallowed whole with fluid, preferably on an empty stomach</td>
</tr>
<tr>
<td>Dose and frequency of administration</td>
<td>Adults (aged 12 years or over):</td>
</tr>
<tr>
<td></td>
<td>Initial dose: 500mg (one tablet) to be taken twice a day</td>
</tr>
<tr>
<td>Duration of treatment</td>
<td>10 days</td>
</tr>
<tr>
<td>Quantity to be supplied</td>
<td>20 (twenty) tablets</td>
</tr>
<tr>
<td>Storage</td>
<td>Store in original container below 25 °C</td>
</tr>
<tr>
<td></td>
<td>Store out of reach of children</td>
</tr>
<tr>
<td>Disposal</td>
<td>Any unused product or waste material should be disposed of in accordance with local requirements.</td>
</tr>
<tr>
<td>Drug interactions</td>
<td>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 on page 7 for advice for individuals taking vitamin K analogues.</td>
</tr>
<tr>
<td>Identification &amp; management of adverse reactions²</td>
<td>Most commonly nausea and diarrhoea. Ciprofloxacin may affect reaction times. Other side effects are classified as uncommon to very rare. The individual should be informed of possible side effects and their management by giving the individual 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 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.</td>
</tr>
</tbody>
</table>

² Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list
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 or amoxicillin.

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](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 system on [http://yellowcard.mhra.gov.uk](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).
The additional information leaflet covering the use of ciprofloxacin in response to exposure to a biological agent 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 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.

Do not give these tablets to anyone else.

Inform individual/carer of possible side effects and their management.

Advise the individual or their carer to read the PIL leaflet before taking the medication and to seek medical advice if side effects, including painful or inflamed joints, or any other unexplained side 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 individual/carer when the subsequent supply is due. |
| 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 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 | Ciprofloxacin Summary of Product Characteristics  
|               | www.medicines.org.uk/emc/  
|               | Inhalational Anthrax-Antibiotic Schedule and Dosing Rationale for People of All Ages (PHE expert advice)  
|               | Opinion on antibiotics to be used in children for chemoprophylaxis following exposure to *Bacillus anthracis* spores (expert advice)  
|               | CBRN Incidents: A Guide to Clinical Management and Health Protection: Pre and Post exposure prophylaxis  
| General       | British National Formulary (BNF)  
|               | 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  

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