

Publications reference number: PRN01665

## **Patient Group Direction (PGD) for the further supply of ciprofloxacin 500mg tablets for post-exposure prophylaxis to tularemia in adults and children 12 years and over**

This PGD is for the further supply of ciprofloxacin 500mg tablets, to adults and children aged 12 years and over exposed to a known deliberate release of tularemia, by registered healthcare practitioners identified in [Section 3](#), subject to any limitations to authorisation detailed in [Section 2](#).

|                 |   |
|-----------------|---|
| Reference       | Ciprofloxacin 500mg tabs further supply tularemia |
| Version number: | 6.0a  |
| 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>.

### **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, 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 UKHSA Chemical, Biological, Radiological and Nuclear (CBRN) PGD templates for authorisation can be found from: [NHS England » 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](mailto:SMA@ukhsa.gov.uk)

---

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

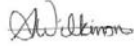

## Change history

| Version number | Change details  | Date            |
|----------------|---|-----------------|
| PGD 2014/1     | Original template developed and ratified  | 2 July 2014     |
| PGD 2.0        | <ol style="list-style-type: none"> <li>1. Put into the new PHE template format</li> <li>2. For use in tularemia only, anthrax put in separate PGD</li> <li>3. Clinical indications: “another biological agent” removed</li> <li>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.</li> <li>5. Interactions: advice simplified.</li> <li>6. References updated.</li> </ol>  | 1 May 2016      |
| PGD 3.0        | <ol style="list-style-type: none"> <li>1. Cautions “or amoxicillin” removed</li> <li>2. Identification &amp; management of adverse reactions “or amoxicillin” removed</li> </ol>  | 28 October 2016 |
| PGD 4.0        | <ol style="list-style-type: none"> <li>1. Put into the new PHE template format</li> <li>2. References updated</li> </ol>  | 7 December 2018 |
| PGD 5.0        | <ol style="list-style-type: none"> <li>1. Addition of ‘following deliberate release’ to page 1, clinical indication and criteria for inclusion for clarity</li> <li>2. Removal of concurrent administration of aminophylline and theophylline from exclusion criteria</li> <li>3. Cautions: amended wording for additional advice / actions to be taken; renal impairment and other medications added</li> <li>4. Additional information under drug interactions section, adverse reactions and patient advice section</li> <li>5. Minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates</li> </ol>   | 17 January 2022 |
| PGD 6.0        | <ol style="list-style-type: none"> <li>1. Minor rewording, layout and formatting changes in line with UKHSA PGD templates and references updated</li> <li>2. Clinical condition changed to “known exposure” from known or suspected</li> <li>3. Not showing symptoms added to inclusion criteria, unsuitable for doxycycline removed</li> <li>4. Previous severe reactions, history of tendon disease with quinolones, stages of renal impairment, additional drug interactions, no consent added to exclusion criteria</li> <li>5. Wording under cautions changed, tendinitis risk, heart valve regurgitation and aortic aneurysm risk, diabetes, G6PD deficiency, medications requiring monitoring and immunosuppressed added with advice</li> <li>6. Symptoms of tularemia added to advice if declines</li> <li>7. Information for individuals unable to swallow added to dose and frequency of administration</li> <li>8. Drug interactions updated to include specific information on interactions and medicines to avoid</li> </ol> | 14 January 2025 |

|          |   |              |
|----------|---|--------------|
|          | 9. Identification and management of adverse effects updated with specific advice regarding what to do if rare adverse effects occur as per MHRA alerts<br>10. MHRA leaflet added to written information to be provided  |              |
| PGD 6.0a | 1. Wording amendments for consistency across PGDs<br>2. Wording in cautions amended for greater clarity<br>3. Off-label use updated with information for breastfeeding and pregnancy<br>4. Drug interactions section refined to exclude rarely used or non-UK medicines | 1 April 2025 |

## 1. PGD development

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

| Developed by:                         | Name  | Signature  | Date         |
|---------------------------------------|---|--|--------------|
| <b>Doctor</b><br>(Expert panel chair) | Ruth Milton, Head of Advice, All Hazards Public Health Response, UKHSA                  |  | 1 April 2025 |
| <b>Pharmacist</b><br>(Lead Author)    | Anna Wilkinson, Clinical Response Pharmacist, All Hazards Public Health Response, UKHSA |  | 1 April 2025 |
| <b>Registered Nurse</b>               | Gemma Hudspeth, Senior Health Protection Practitioner, UKHSA                            |  | 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                 | Post  |
|----------------------|---|
| 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                             |
| Rachel Berry         | Chief Pharmaceutical Officer's Clinical Fellow, HCAI, Fungal, AMR, AMU and Sepsis Division, UKHSA     |
| Sherine Thomas       | Consultant in Emerging Infections and Zoonoses, UKHSA   |
| Sarah Upton          | Lead Pharmacist for Medication Safety, community services, Locala Health and Wellbeing                |
| Kelly Stoker         | Nurse Consultant for Adult Social Care, Health Equity and Inclusion Health Division, UKHSA            |

## 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 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   |
| <br><br><br><br><br><br><br><br><br><br>  |
| 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 |
|   |      |      |      |
|   |      |      |      |
|   |      |      |      |
|   |      |      |      |

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

|   |  |
|---|--|
| <b>Qualifications and professional registration</b> | <p>To be completed by the organisation authorising the PGD for instance registered professionals with one of the following bodies:</p> <ul style="list-style-type: none"> <li>• nurses currently registered with the Nursing and Midwifery Council (NMC).</li> <li>• pharmacists currently registered with the General Pharmaceutical Council (GPhC)</li> <li>• paramedics currently registered with the Health and Care Professions Council (HCPC)</li> <li>• additional registered healthcare professionals to be added by organisation authorising the PGD</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD</p>   |
| <b>Additional requirements</b>                      | <p>Additionally, practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>• must have undertaken training appropriate to this PGD</li> <li>• must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using PGDs)</li> <li>• must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC)</li> <li>• must be competent to assess the individual and discuss treatment options</li> <li>• must have access to the PGD and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> <li>• authorising organisation to insert any additional requirements</li> </ul> <p><b>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it</b></p> |
| <b>Continued training requirements</b>              | <p>Authorising organisation to insert any continued training requirements</p>  |

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

|  |  |
|--|--|
| <b>Clinical condition or situation to which this PGD applies</b> | <p>Where continuing chemoprophylaxis is required following exposure to a known deliberate release of tularemia</p> <p><b>Note:</b> doxycycline is the preferred antibiotic for follow-on supplies to individuals aged 12 years and over (see Doxycycline further supply PGD).</p> <p>Ciprofloxacin as a follow-on supply should only be provided to individuals aged 12 years and over who have a contraindication to doxycycline or in line with incident specific advice</p> <p>For additional information on tularemia, including post-exposure prophylaxis see CBRN guidance</p>   |
| <b>Criteria for inclusion</b>                                    | <p>Adults and children aged 12 years and over following exposure to a known deliberate release of tularemia</p> <p><b>And</b></p> <p>Who have already received chemoprophylaxis for 10 days with ciprofloxacin or doxycycline</p> <p><b>And</b></p> <p>Are not showing symptoms compatible with tularemia infection. Individuals with symptoms should be referred urgently to the supervising doctor. See <a href="#">Action to be taken if individual or carer declines prophylaxis</a> section of this PGD and <a href="#">CBRN incident guidance</a> for symptoms</p> <p><b>Note:</b> The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in <b>growing adolescents, pregnant or breastfeeding individuals who should be given ciprofloxacin</b> in the situation criteria set out above</p>  |
| <b>Criteria for exclusion<sup>2</sup></b>                        | <p>Individuals are excluded from this PGD if:</p> <ol style="list-style-type: none"> <li>1. They have a known history of severe allergic reaction to ciprofloxacin, other fluoroquinolones or quinolones or to any of the listed excipients (see <a href="#">SPC</a>)</li> <li>2. They are under 12 years of age</li> <li>3. They have experienced unacceptable side effects while taking the initial ten days' supply of ciprofloxacin</li> <li>4. They have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to a quinolone or fluoroquinolone antibiotic</li> <li>5. They have a history of tendon disease/disorder related to ciprofloxacin or other fluoroquinolones or quinolones</li> <li>6. They are taking an interacting medicine as listed in the <a href="#">Drug interactions</a> section of this PGD</li> <li>7. They have known Chronic Kidney Disease (CKD) stages 4 or 5 (eGFR &lt; 30ml/min/1.73m<sup>2</sup>) or are on dialysis</li> <li>8. They have not given valid consent (or for whom a best-interests decision in accordance with the <a href="#">Mental Capacity Act 2005</a> has not been obtained)</li> </ol> <p>See <a href="#">Action to be taken if individual is excluded</a> section of this PGD</p> |

<sup>2</sup> Exclusion under this PGD does not necessarily mean the antibiotic is contraindicated, but it would be outside its remit and another form of authorisation will be required

|   |   |
|---|---|
| <p><b>Cautions including any relevant action to be taken</b><br/>(Continued overleaf)</p> | <p>Caution is advised for individuals with the following conditions or who are taking certain medicines.</p> <p>Doxycycline is the preferred option for these individuals if it is not contraindicated and is available. See the <a href="#">doxycycline further supply PGD</a>.</p> <p>If doxycycline is contraindicated, or not available, then ciprofloxacin can be supplied as the benefit of taking it to prevent tularemia outweighs the risks. Individuals should be provided with the advice outlined below.</p> <p>Refer to the supervising doctor if concerned about an individual's risk for assessment and consideration of alternative antibiotics.</p> <p><b>1. At increased risk of tendinitis or tendon rupture:</b></p> <ul style="list-style-type: none"> <li>• over 60 years of age</li> <li>• have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD)</li> <li>• are taking corticosteroids</li> <li>• have a solid organ transplant</li> </ul> <p>Advise to self-monitor for tendinitis (for example, painful swelling, inflammation). If signs of tendinitis occur, individuals should be advised to stop taking ciprofloxacin and contact their healthcare provider as soon as possible for assessment and consideration of an alternative antibiotic</p> <p><b>2. Conditions with risk factor for QT interval prolongation:</b></p> <ul style="list-style-type: none"> <li>• cardiac disease (for example, heart failure, myocardial infarction, bradycardia)</li> <li>• congenital long QT syndrome</li> <li>• history of symptomatic arrhythmias</li> <li>• concomitant use of drugs known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics)</li> <li>• electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia)</li> </ul> <p>Advise to monitor for the exacerbation of or development of <a href="#">symptoms associated with QT interval prolongation</a>. If symptoms develop, advise individuals to seek immediate medical advice for assessment and consideration of alternative antibiotics</p> <p><b>3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:</b></p> <ul style="list-style-type: none"> <li>• a positive family history of aneurysm disease or congenital heart valve disease</li> <li>• pre-existing aortic aneurysm and/or aortic dissection or heart valve disease</li> <li>• presence of other risk factors or conditions predisposing for <i>both</i> aortic aneurysm and dissection and heart valve regurgitation/incompetence, such as: <ul style="list-style-type: none"> <li>○ connective tissue disorders such as Marfan's syndrome or Ehlers-Danlos syndrome</li> <li>○ Turner syndrome</li> <li>○ Behçet's disease</li> <li>○ hypertension</li> <li>○ rheumatoid arthritis</li> </ul> </li> </ul> |
|---|---|



|  |  |
|--|--|
| <p><b>Cautions including any relevant action to be taken</b></p> <p>(Continued overleaf)</p> | <ul style="list-style-type: none"> <li>• presence of other risk factors or conditions for aortic aneurysm and dissection, such as: <ul style="list-style-type: none"> <li>○ vascular disorders including Takayasu arteritis or giant cell arteritis</li> <li>○ known atherosclerosis</li> <li>○ Sjögren's syndrome</li> </ul> </li> <li>• heart valve regurgitation / incompetence caused, for example, by infective endocarditis</li> </ul> <p>Advise individuals of the possibility of these rare events, and that they should seek urgent medical attention by dialling 999 if they develop sudden-onset severe abdominal, chest or back pain</p> <p>Advise to seek immediate medical attention by dialling 111 or via their GP if individuals experience a rapid onset of shortness of breath, especially when lying down flat in bed, swelling of the ankles, feet or abdomen or new-onset heart palpitations</p> <p><b>4. Epilepsy or conditions that predispose to seizures and/or those taking medications that may predispose to seizures (for example, NSAIDs):</b></p> <p>Advise to self-monitor for any increase in frequency or severity of seizures. If an increase in frequency or severity of seizures occurs, advise individuals to stop taking ciprofloxacin and seek immediate medical attention</p> <p><b>5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):</b></p> <p>Disturbances in blood glucose can occur. Advise individuals to carefully monitor blood glucose during treatment, to be alert to symptoms of hypoglycaemia and hyperglycaemia and to seek medical advice if required</p> <p><b>6. G6PD deficiency:</b></p> <p>There is a risk of haemolysis when ciprofloxacin is given to individuals with G6PD deficiency. If other antibiotics are not suitable and ciprofloxacin must be used, advise the individual to self-monitor for signs of haemolysis. If signs of haemolysis develop, advise individuals to stop taking ciprofloxacin and seek urgent medical advice</p> <p><b>7. Myasthenia gravis:</b></p> <p>Advise to self-monitor for any increase severity of myasthenia gravis. If an increase in severity of disease occurs, advise individuals to seek urgent medical advice</p> <p><b>Note:</b> doxycycline is also cautioned for individuals with myasthenia gravis</p> <p><b>8. Severely immunocompromised individuals:</b></p> <p>Individuals who are severely immunocompromised (as defined in <a href="#">Chapter 28a Green book</a>) 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</p> <p><b>9. Concomitant treatment with vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol):</b></p> <p>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.</p> <p><b>Note:</b> INR also needs to be monitored with doxycycline</p> |
|--|--|

|   |  |
|---|--|
| <p><b>Cautions including any relevant action to be taken</b></p> <p>(continued)</p> | <p><b>10. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine:</b></p> <p>Advise individual to self-monitor for any signs of toxicity and to contact the service responsible for monitoring these medicines as soon as possible to inform them of the treatment and to arrange appropriate follow up and monitoring</p> <p>Refer to the <a href="#">SPC</a> for ciprofloxacin for full details on special warnings and precautions for use.</p>  |
| <p><b>Action to be taken if the individual or carer declines prophylaxis</b></p>    | <p>Refer the individual to the supervising doctor</p> <p>Advise the individual or their parent/carer of the possible consequences of declining prophylaxis and of alternative options</p> <p>Advise about the protective effects of the prophylaxis, risks of infection, and disease complications</p> <p>Advise to seek urgent medical attention if they develop symptoms compatible with tularemia infection or <a href="#">signs or symptoms of sepsis</a>.</p> <p>Symptoms of tularemia will depend on the type of exposure. Symptoms of pneumonic tularemia include:</p> <ul style="list-style-type: none"> <li>fever, chills, headache, myalgia, sore throat, dry cough, pleuritic chest pain, dyspnoea</li> </ul> <p>See <a href="#">CBRN guidance</a> for further information on other symptoms to be aware of depending on the type of exposure</p> <p>Document the advice given and the decision reached</p> |
| <p><b>Action to be taken if the individual is excluded</b></p>                      | <p>Explain why they have been excluded</p> <p>Consider supply of doxycycline: see <a href="#">doxycycline further supply PGD</a></p> <p>Where doxycycline is contraindicated, refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics</p> <p><b>Note:</b> Tularemia is not sensitive to penicillins such as amoxicillin or co-amoxiclav</p> <p>Document reasons for exclusion and any referrals that have been made</p>   |
| <p><b>Arrangements for referral for medical advice</b></p>                          | <p>Follow local procedures for referral to the supervising doctor and/or other services</p>  |

## 5. Description of treatment

|   |  |
|---|--|
| <b>Name, strength &amp; formulation of drug</b> | Ciprofloxacin 500mg tablets  |
| <b>Legal category</b>                           | Prescription Only Medicine (POM)   |
| <b>Black triangle▼</b>                          | No   |
| <b>Off-label use</b>                            | <p>Yes: Ciprofloxacin is not licensed for use in tularemia. <a href="#">UK national guidance</a> recommends its use.</p> <p><b>Pregnancy</b></p> <p>The manufacturers advise as a precautionary measure to avoid the use of ciprofloxacin during pregnancy. However, the data available indicates no malformative or feto/neonatal toxicity but the <a href="#">SPC</a> does state that because of the effects of ciprofloxacin on immature cartilage observed in juvenile animals it cannot be excluded that the drug could cause damage to cartilage in the foetus. However, the benefits of using ciprofloxacin to prevent the onset of tularemia outweigh these potential risks in pregnancy. A patient information leaflet for ciprofloxacin in pregnancy is available here: <a href="#">bumps - best use of medicine in pregnancy (medicinesinpregnancy.org)</a></p> <p><b>Breastfeeding</b></p> <p>The manufacturers advice is to avoid breastfeeding during treatment with ciprofloxacin. However, quinolones are generally accepted for use during breastfeeding with caution. There have been concerns about adverse effects on infants “developing joints”, although this has only been reported in infants taking quinolone antibiotics directly. The calcium in breast milk may prevent or reduce infant absorption of quinolones. Use with caution in breast fed infants with known G6PD deficiency due to the risk of haemolysis and in breast fed infants with epilepsy.</p> <p>Ciprofloxacin may cause some babies to have mild stomach upsets and oral candidiasis.</p> <p>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</p> |
| <b>Route / method of administration</b>         | <p>Oral</p> <p>To be swallowed whole with water, as this will help to prevent the formation of tiny crystals in the urine (crystalluria), and preferably on an empty stomach</p>   |
| <b>Dose and frequency of administration</b>     | <p><b>Adults and children aged 12 years or over:</b></p> <p>One tablet (500mg) to be taken twice a day</p> <p>For individuals who are unable to swallow the tablets, refer to the supervising doctor for assessment and consideration of alternative antibiotics or formulation.</p>   |

|  |  |
|--|--|
| <b>Duration of treatment</b>                     | 4 days (total length of course 14 days)<br><b>Note:</b> these individuals have previously received an initial ten-day supply of an antibiotic  |
| <b>Quantity to be supplied</b>                   | 8 (eight) tablets<br><b>Instruct the individual to take one tablet twice daily for 4 days only (that is 8 tablets) and to take the remaining tablets to a community pharmacy for disposal.</b><br><br>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. <b>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.</b>  |
| <b>Storage</b>                                   | Store in original container below 25 °C  |
| <b>Disposal</b>                                  | Any unused product or waste material should be disposed of in accordance with local requirements.  |
| <b>Drug interactions</b><br>(continued overleaf) | <p>Concurrent medications should be checked for interactions. This list is not exhaustive. Full details of drug interactions are available in the <a href="#">SPC</a> and the <a href="#">BNF</a>.</p> <p><b><u>Excluded from PGD</u></b></p> <p>Where it is known an individual is concurrently taking one of the following medicines, ciprofloxacin should not be supplied under this PGD. If doxycycline is contraindicated (see <a href="#">doxycycline further supply PGD</a>) refer individuals to the supervising doctor or other prescriber</p> <ul style="list-style-type: none"> <li>- agomelatine</li> <li>- domperidone</li> <li>- ergometrine, ergotamine or dihydroergotamine</li> <li>- fezolinetant</li> <li>- tizanidine</li> </ul> <p>The following medicines may require dose adjustment. If doxycycline is contraindicated (see <a href="#">doxycycline further supply PGD</a>), individuals should be referred to the supervising doctor or other prescriber:</p> <ul style="list-style-type: none"> <li>- olanzapine</li> <li>- capivasertib</li> <li>- elacestrant</li> <li>- eliglustat</li> <li>- ibrutinib</li> <li>- tolvaptan</li> <li>- daridorexant</li> <li>- venetoclax</li> <li>- zanubrutinib</li> <li>- ropinirole</li> <li>- guanfacine</li> <li>- pifenidone</li> <li>- pomalidomide</li> </ul> <p><b><u>Caution</u></b></p> <p>Individuals who have <b>received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days</b> should be advised to contact the clinic where the vaccine was administered or a GP for advice as ciprofloxacin may reduce the efficacy of these vaccines</p> <p>Ciprofloxacin may increase the likelihood of side effects when taken with some medicines (for example, <b>anagrelide, chlorpromazine, duloxetine, melatonin, rasagiline, riluzole, roflumilast, sildenafil</b>). Advise individuals to be alert to any increase in adverse effects and to</p> |

|  |  |
|--|--|
| <p><b>Drug interactions</b><br/>(continued)</p>                    | <p>Speak to their usual healthcare provider as soon as possible if side effects occur.</p> <p>Individuals taking <b>zolmitriptan</b> should be advised that a maximum dose of 5mg of zolmitriptan should be taken in any 24-hours</p> <p>See <a href="#">Cautions</a> section for advice for individuals taking medicines that prolong the QT interval, NSAIDs, vitamin K antagonists, corticosteroids, methotrexate, aminophylline, theophylline, phenytoin, fosphenytoin, ciclosporin, clozapine, erlotinib or ruxolitinib</p> <p>Ciprofloxacin should be given 2 hours before, or 4 hours after <b>sevelamer, lanthanum, sucralfate, antacids</b> and any medicines or supplements containing <b>calcium, magnesium, aluminium, iron</b> or <b>zinc</b> that may reduce the absorption of ciprofloxacin.</p>  |
| <p><b>Identification &amp; management of adverse reactions</b></p> | <p>Although there are some potential and serious side effects, the benefit of using ciprofloxacin to prevent disease associated with tularemia exposure outweighs these risks</p> <p>Most commonly reported adverse reactions are nausea and diarrhoea. Nausea may be relieved by taking ciprofloxacin after food.</p> <p>Other side effects are classified as uncommon to very rare.</p> <p>There have been cases of prolonged, disabling and potentially irreversible serious drug reactions reported rarely.</p> <p>Advise individuals to stop taking ciprofloxacin immediately and seek urgent medical advice by dialling 999 if the following severe adverse effects occur:</p> <ul style="list-style-type: none"> <li>• <a href="#">anaphylaxis</a> (delayed or immediate)</li> <li>• sudden, severe pain in the stomach, chest or back</li> <li>• seizures</li> <li>• thoughts about harming themselves or ending their life</li> </ul> <p>Advise individuals to stop taking ciprofloxacin and seek immediate medical advice by calling 111 or their GP if any of the following rare effects occur:</p> <ul style="list-style-type: none"> <li>• changes to vision, taste, smell or hearing</li> <li>• signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach)</li> <li>• symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking)</li> <li>• diarrhoea that lasts more than 4 days or contains blood or mucus</li> <li>• sudden breathlessness, especially when lying down</li> <li>• new onset heart palpitations</li> <li>• swollen ankles, feet or stomach</li> <li>• changes in mood or behaviour, severe tiredness, anxiety, panic attacks, problems with memory or sleep (particularly for those individuals with a history of depression or psychosis)</li> <li>• pain, swelling or inflammation of joints such as the shoulders, arms or legs or tendon pain or swelling</li> </ul> <p>A detailed list of adverse reactions is available in the <a href="#">SPC</a></p> |

|   |  |
|---|--|
| <b>Reporting procedure of adverse reactions</b>               | <p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the <a href="#">Yellow Card</a> system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any serious adverse reaction to the drug should be documented in the individual's record and the individual's GP informed.</p>  |
| <b>Written information to be given to individual or carer</b> | <p>Supply the marketing authorisation holder's Patient Information Leaflet (PIL).</p> <p>Consider providing the <a href="#">MHRA information leaflet</a> on side effects.</p>  |
| <b>Advice/follow up treatment</b>                             | <p>Explain the treatment.</p> <p>Advise the individual or their carer to:</p> <ul style="list-style-type: none"> <li>• drink plenty of fluids</li> <li>• not take indigestion remedies, sevelamer, lanthanum, sucralfate or medicines containing calcium, magnesium, aluminium, iron or zinc, 2 hours before or 4 hours after taking this medicine</li> <li>• not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice)</li> <li>• swallow the medicine whole with water, as this will help to prevent the formation of tiny crystals in the urine (crystalluria), and preferably on an empty stomach</li> <li>• not chew the tablets</li> <li>• space the doses evenly throughout the day</li> <li>• keep take the medicine until the course is finished, unless they are told to stop</li> <li>• not give these tablets to anyone else</li> <li>• return any unused tablets at the end of the course to a community pharmacy for destruction</li> </ul> <p><b>Inform the individual or their carer:</b></p> <ul style="list-style-type: none"> <li>• of possible side effects and their management</li> <li>• to read the PIL 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</li> <li>• the 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</li> <li>• ciprofloxacin may affect reaction times; if affected, they should avoid driving or operating machinery</li> <li>• to seek immediate medical attention if the individual develops signs or symptoms compatible with tularemia or other serious adverse effects (see <a href="#">Identification and management of adverse reactions</a>)</li> <li>• to only take the medicine for 4 days and to return the excess tablets to a community pharmacy for destruction</li> </ul> <p>For individuals with conditions listed in the <a href="#">Cautions</a> section, provide the additional recommended advice.</p> |

|                |   |
|----------------|---|
| <b>Records</b> | <p>Record:</p> <ul style="list-style-type: none"> <li>• whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the <a href="#">Mental Capacity Act 2005</a></li> <li>• 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)</li> <li>• name of member of staff who supplied the product</li> <li>• name and brand of the product</li> <li>• date of supply</li> <li>• dose, form and route of administration of the product</li> <li>• quantity supplied</li> <li>• batch number and expiry date</li> <li>• advice given; including advice given if the individual is excluded or declines treatment</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• that the product was supplied via PGD</li> </ul> <p>All records should be signed and dated (or password-controlled on records)</p> <p>All records should be clear, legible and contemporaneous</p> <p>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</p> <p>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</p> |
|----------------|---|



## 6. Key references

|                       |  |
|-----------------------|--|
| <b>Key references</b> | <ul style="list-style-type: none"><li>• <a href="#">Ciprofloxacin Summary of Product Characteristics</a> accessed 21 November 2024</li><li>• <a href="#">MHRA Fluoroquinolone Drug Safety Updates</a> accessed 21 November 2024</li><li>• <a href="#">British National Formulary</a> last updated 30 October 2024</li><li>• <a href="#">Chemical, biological, radiological and nuclear incidents: clinical management and health protection</a> May 2018</li><li>• <a href="#">NHS Medicines A-Z: Ciprofloxacin</a>. Accessed 21 November 2024</li><li>• <a href="#">NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions</a> updated 27 March 2017</li><li>• <a href="#">NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions</a> updated 4 January 2018</li><li>• <a href="#">Health Technical Memorandum 07-01: Safe and sustainable Management of Healthcare Waste</a>. 7 March 2023</li></ul> |
|-----------------------|--|



## 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 above-named 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.