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CYM-25002

Local reference:
PGD 0244A

Chemoprophylaxis medication: NHS Wales Chemical, Biological, Radiological and Nuclear (CBRN) emergency response following known or suspected exposure to **anthrax, plague or tularemia**

Patient Group Directions for the supply of antibiotics by healthcare practitioners responding to an incident following activation of the NHS Wales CBRN emergency planning procedures

in Powys Teaching Health Board (PTHB)

Operational from: 01 May 2025

Review date: 01 October 2027

Expiry date: 31 March 2028

Version number: v1.0

PGDs for the supply of antibiotics by healthcare practitioners responding to an incident following activation of the NHS Wales CBRN emergency planning procedures

Reference: Ciprofloxacin and doxycycline PGDs for anthrax, plague or tularemia
 Version no: 1.0
 Valid from: 01 May 2025
 Review date: 01 October 2027
 Expiry date: 31 March 2028

The UK Health Security Agency (UKHSA) Chemical, Biological, Radiological and Nuclear (CBRN) PGDs have been used by The Welsh Medicines Advice Service to develop these PGDs for adoption across NHS Wales.

Those using these PGDs must ensure that they are authorised by the Local Health Board/NHS Trust in which they are operating and signed in section 3 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. **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 such action will invalidate the *clinical sign-off* with which it is provided.

As operation of these PGDs is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGDs.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THESE PGDs BEFORE WORKING IN ACCORDANCE WITH THEM.

Practitioners and organisations must check that they are using the current version of these PGDs. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of a PGD should be addressed to: welshmedicines.information@wales.nhs.uk

Change history:

Version number	Change details	Date
1.0	Original combined PGD template booklet developed.	01 March 2025

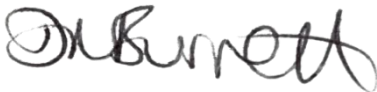

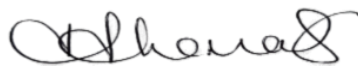
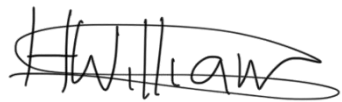
¹ this includes any relevant amendments to legislation (e.g. [2013 No.235](#), [2015 No.178](#), [2015 No.323](#) and [2024 No.729](#)).

1. PGD development

These PGDs have been developed by the following health care professionals on behalf of NHS Wales. The UKHSA PGDs for ciprofloxacin and doxycycline have been used to inform the clinical content.

This section MUST REMAIN when these PGDs are adopted by an organisation

PGD Development

Name	Designation	Signature
Main Author – Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB	
Expert Reviewer – Dr Laurence Gray	Consultant Clinical Pharmacologist, National Poisons Information Service.	
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These PGDs have been peer reviewed by the NHS Wales Countermeasures National Preparedness Group in accordance with the WMAS PGD Policy. They have been ratified by the All-Wales PGD Advisory Board.

Expert Panel – NHS Wales Countermeasures National Preparedness Group.

Name	Designation
David Goulding	Health Emergency Planning Advisor
Dianne Burnett	Pharmacist – Director of the Welsh Medicines Advice Service
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Date CNPG approval of PGDs: 18 April 2025

Date All Wales PGD Advisory Board ratification: 07 May 2025

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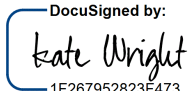


3. Organisational Authorisations

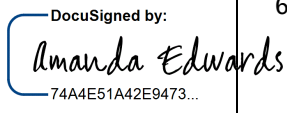
These PGDs are not legally valid until they have had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise PGDs, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of these PGDs.

Powys Teaching Health Board authorises these PGDs for use by healthcare professionals within its area that have been authorised / commissioned to provide the supply of medication for chemoprophylaxis following known or suspected exposure when the NHS Wales Chemical, Biological, Radiological and Nuclear (CBRN) emergency planning policy is activated. This authorisation is limited to the services or providers listed below:

Authorised for use by the following organisations and/or services
<p>Powys Teaching Health board</p> <p>Powys Teaching Health Board GP Practices: role, organisation, name, signature and date must be added to indicate adoption</p>
Limitations to authorisation
<p>Be employed by, or providing services on behalf of, Powys Teaching Health Board or a PTHB GP practice</p>

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Lead Doctor for PTHB (Medical Director)	Dr Kate Wright	DocuSigned by:  1F267952823F473...	5/21/2025
Senior Pharmacist for PTHB Head of Community Services Medicines Management/Pharmacy	Jayne Price	DocuSigned by:  A9AFDC3B15294CC...	5/30/2025
Executive Director of Nursing and Midwifery for PTHB	Claire Roche	DocuSigned by:  F07413E114E04B1...	6/6/2025

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date
Clinical Governance Lead for PTHB: Assistant Director for Innovation and Improvement	Amanda Edwards	 <p>DocuSigned by: <i>Amanda Edwards</i> 74A4E51A42E9473...</p>	6/11/2025

Local enquiries regarding the use of these PGDs may be directed to: Medicines Management on 01874 712641

[Appendix B](#) provides a practitioner listing sheet. Individual practitioners must be listed by name to work to these PGDs. Alternative practitioner listing sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner listing sheet as included at the end of these PGDs.

<p>Details of local policy or guidance that should be read in conjunction with this PGD</p> <p>Appendix C: PTHB Additional local appendix for CBRN PGD booklet (attached to the end of this PGD) must be read in conjunction with this PGD</p>
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Retention statement

<p>The final authorised copy of this PGD should be kept by the authorising organisation completing section 3 for 25 years after the PGD expires as the PGDs relate to adults and children.</p> <p>Provider organisations adopting authorised versions of this PGD should also retain copies for the period specified above.</p>

4. Characteristics of Staff

<p>Qualifications and professional registration</p>	<p>These PGDs are for use by registered practitioners with one of the following bodies:</p> <ul style="list-style-type: none"> ➤ nurses currently registered with the Nursing and Midwifery Council (NMC). ➤ pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC). ➤ paramedics currently registered with the Health and Care Professions Council (HCPC). ➤ additional registered healthcare professionals who can legally operate under a PGD according to the Human Medicines Regulations 2012. <p>Practitioners must also fulfill all the additional requirements.</p> <p>Check section 3 limitations to authorisation to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.</p>
<p>Additional requirements</p>	<p>Healthcare practitioners must:</p> <ul style="list-style-type: none"> ➤ be employed by or providing services on behalf of PTHB or a PTHB GP Practice. ➤ be authorised by name as an approved practitioner under the current terms of these Patient Group Directions before working to them. ➤ be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs) ➤ have undertaken appropriate training for working under PGDs for supply or administration of medicines. ➤ have undertaken training appropriate to these PGDs. ➤ be competent to assess the individual and discuss the treatment options. ➤ be familiar with the medicines and alert to changes in the British National Formulary (BNF), British National Formulary for Children (BNFC), and Summary of Product Characteristics (SmPC) entries for ciprofloxacin and doxycycline. ➤ have awareness of the adverse drug reactions associated with ciprofloxacin and doxycycline. ➤ practitioners must have access to the PGDs and associated online resources. ➤ practitioners should fulfil any additional requirements defined by local policy. <p>The healthcare practitioner must be listed by name, under the current version of this PGD before working according to it.</p>

Ongoing training and competency

Healthcare practitioners must:

- undertake regular Continuing Professional Development (CPD) and maintain their own level of competence and knowledge to provide the service, as outlined by their professional bodies, e.g. NMC and GPhC.
- be aware of any updates made to the products in its [SmPC](#) or [BNF](#) entries.
- be aware of any updates to relevant national and local guidelines.
- as registered professionals, be professionally accountable and must work within their competence. A record of training and competence must be maintained.

PGD for the initial supply of ciprofloxacin for post-exposure prophylaxis to anthrax in adults and children aged 12 years and over

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Initial chemoprophylaxis following exposure to a known or suspected deliberate release of anthrax.</p> <p>Notes:</p> <p>Doxycycline is also indicated for post-exposure prophylaxis to anthrax. See doxycycline initial supply PGD.</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on anthrax, including post exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Adults and children aged 12 years and over following exposure to a known or suspected deliberate release of anthrax</p> <p>AND</p> <p>are not showing symptoms compatible with anthrax infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance.</p> <p>Note: The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in growing adolescents, pregnant or breastfeeding individuals who should be given ciprofloxacin in the situation criteria set out above.</p>
<p>Exclusion criteria²</p> <p>(continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they have a known history of severe allergic reaction to ciprofloxacin, other fluoroquinolones or quinolones, or to any of the listed excipients see SmPC. ➤ they are under 12 years of age. ➤ they have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to a quinolone or fluoroquinolone antibiotic. ➤ they have a history of tendon disease / disorder related to ciprofloxacin or other fluoroquinolones or quinolones. ➤ they are taking an interacting medicine as listed in the drug interactions section of this PGD. ➤ they have known chronic kidney disease (CKD) stages 4 or 5 (eGFR <30 mL/min/1.73m²) or are on dialysis.

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 for supply will be required

<p>Exclusion criteria (continued)</p>	<p>➤ they have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained).</p> <p>See action to be taken if individual is excluded section of this PGD.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>Caution is advised for individuals with the following conditions or who are taking certain medicines.</p> <p>Note: Doxycycline is the preferred option for these individuals if it is not contraindicated and is available. See the doxycycline initial supply PGD.</p> <p>If doxycycline is contraindicated, or not available then ciprofloxacin can be supplied as the benefit of taking it to prevent infection outweighs the risk in the case of a deliberate release of anthrax. 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>1. At increased risk of tendinitis or tendon rupture:</p> <ul style="list-style-type: none"> ➤ over 60 years of age. ➤ have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD). ➤ are taking corticosteroids. ➤ have a solid organ transplant. <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>2. Conditions with risk factor for QT interval prolongation:</p> <ul style="list-style-type: none"> ➤ cardiac disease (for example, heart failure, myocardial infarction, bradycardia). ➤ congenital long QT syndrome. ➤ history of symptomatic arrhythmias. ➤ concomitant use of medicines known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics). ➤ electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia). <p>Advise to monitor for the exacerbation of or development of symptoms associated with QT interval prolongation. If symptoms develop, advise individuals to seek immediate medical advice for assessment and consideration of alternative antibiotics.</p> <p>3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:</p> <ul style="list-style-type: none"> ➤ a positive family history of aneurysm disease or congenital heart valve disease.

Cautions (including relevant actions to be taken)

(continued)

- pre-existing aortic aneurysm and/or aortic dissection or heart valve disease.
- presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation / incompetence, such as:
 - connective tissue disorders such as Marfan’s syndrome or Ehlers-Danlos syndrome.
 - Turner syndrome.
 - Behçet’s disease.
 - hypertension.
 - rheumatoid arthritis.
- presence of other risk factors or conditions for aortic aneurysm and dissection, such as:
 - vascular disorders including Takayasu arteritis or giant cell arteritis.
 - known atherosclerosis.
 - Sjögren’s syndrome.
- heart valve regurgitation / incompetence caused, for example, by infective endocarditis.

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.

Advise to seek immediate medical attention by dialling 111 or via a 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.

4. Epilepsy or conditions that predispose to seizures and/or those taking medication that may predispose to seizures (for example NSAIDs):

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.

5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):

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.

6. G6PD deficiency:

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.

(continued over page)

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>7. Myasthenia gravis: Advise to self-monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise individuals to seek urgent medical advice. Note: doxycycline is also cautioned for individuals with myasthenia gravis.</p> <p>8. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol): Advise individual to arrange for INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising. Note: INR also needs to be monitored with doxycycline.</p> <p>9. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine: Advise individuals 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. Refer to the SmPC for ciprofloxacin for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual, parent or their carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if they develop symptoms compatible with anthrax infection or signs or symptoms of sepsis. ➤ Symptoms of anthrax will depend on the type of exposure as follows: <ul style="list-style-type: none"> ○ Inhalational: flu-like illness (fever, malaise, nausea / vomiting, headache, non-productive cough) ○ Cutaneous: initial pimple / papule that enlarges, blisters, ulcerates over 2 to 6 days to form a black scab. ○ Gastrointestinal: severe abdominal pain, nausea, vomiting, bloody diarrhoea. ➤ See CRBN guidance for further information on symptoms. ➤ Document the advice given and the decision reached.
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ Consider supply of doxycycline (see doxycycline initial supply PGD). ➤ If doxycycline is contraindicated, refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics. ➤ Document reasons for exclusion and any referrals that have been made.

**Arrangements for
referral for medical
advice**

Follow local procedures for referral to the supervising doctor and / or other services.

2. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 500 mg tablets
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Yes</p> <p>Manipulating solid dosage forms</p> <p>Tablets (not suspension) are the preferred formulation for children aged 12 years and older unless they have medically confirmed swallowing difficulties.</p> <p>In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.</p> <p>Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.</p> <p>The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away.</p> <p>Pregnancy</p> <p>The manufacturers advise as a precautionary measure to avoid the use of ciprofloxacin during pregnancy. However, the data available on administration of ciprofloxacin to pregnant women indicates no malformative or fetoneonatal toxicity but the SmPC 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 the disease outweigh these potential risks in pregnancy. A patient information leaflet for ciprofloxacin in pregnancy is available here: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org)</p> <p>Breastfeeding</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>

(continued over page)

<p>Off-label use (continued)</p>	<p>Ciprofloxacin may cause some babies to have mild stomach upsets and oral candidiasis. See patient advice section.</p> <p>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.</p>
<p>Route / method of administration</p>	<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>
<p>Dose and frequency of administration</p>	<p>Adults and children aged 12 years or over</p> <p>ONE tablet (500 mg) to be taken TWICE a day</p> <p>Administration should begin as soon as possible after suspected or confirmed exposure.</p> <p>For individuals who are unable to swallow the tablets, refer to the off label section of the PGD.</p>
<p>Duration of treatment</p>	<p>10 days</p>
<p>Quantity to be supplied</p>	<p>20 (twenty) tablets OR</p> <p>supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the 10-day course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise the individual, parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>
<p>Storage</p>	<p>Store in original container below 25°C.</p>
<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>
<p>Drug interactions (continued over page)</p>	<p>Concurrent medications should be checked for interactions. This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p>

Drug interactions

(continued)

Contraindications

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 [doxycycline initial supply PGD](#)) refer individuals to the supervising doctor.

- agomelatine.
- domperidone.
- ergometrine, ergotamine or dihydroergotamine.
- fezolinetant.
- tizanidine.

The following medicines may require dose adjustments. If doxycycline is contraindicated (see [doxycycline initial supply PGD](#)), individuals should be referred to the supervising doctor:

- | | | |
|----------------|----------------|----------------|
| ➤ olanzapine | ➤ tolvaptan | ➤ ropinirole |
| ➤ capivasertib | ➤ daridorexant | ➤ guanfacine |
| ➤ elacestrant | ➤ venetoclax | ➤ pirfenidone |
| ➤ eliglustat | ➤ zanubrutinib | ➤ pomalidomide |
| ➤ ibrutinib | | |

Cautions

Individuals who have **received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days** should be advised to contact the clinic where the vaccine was administered or their GP for advice as ciprofloxacin may reduce the efficacy of these vaccines.

Ciprofloxacin may increase the likelihood of side effects when taken with some medicines (for example, **anagrelide, chlorpromazine, duloxetine, melatonin, rasagiline, riluzole, roflumilast, sildenafil**). Advise individuals to be alert to any increase in adverse effects and to speak to their usual healthcare provider as soon as possible if side effects occur.

Individuals taking **zolmitriptan** should be advised that a maximum dose of 5mg of zolmitriptan should be taken in any 24-hours.

See [cautions](#) 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.

Ciprofloxacin should be given 2 hours before, or 4 hours after **sevelamer, lanthanum, sucralfate, antacids** and any medicines or supplements containing **calcium, magnesium, aluminium, iron or zinc** that may reduce the absorption of ciprofloxacin.

(continued over page)

<p>Drug interactions (continued)</p>	<p>Oral contraceptives.</p> <p>Ciprofloxacin does not reduce their efficacy but if it makes them vomit or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).</p>
<p>Identification & management of adverse reactions</p>	<p>Although there are some potential and serious side effects, the benefit of using ciprofloxacin to prevent disease associated with anthrax exposure outweighs these risks.</p> <p>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"> ➤ anaphylaxis (delayed or immediate). ➤ sudden, severe pain in the stomach, chest or back. ➤ seizures. ➤ thoughts about harming themselves or ending their life. <p>Advise individuals to stop taking ciprofloxacin and seek immediate medical advice by calling 111 or a GP if any of the following rare effects occur:</p> <ul style="list-style-type: none"> ➤ changes to vision, taste, smell or hearing. ➤ signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach). ➤ symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking). ➤ diarrhoea that lasts more than 4 days or contains blood or mucus. ➤ sudden breathlessness, especially when lying down. ➤ new onset heart palpitations. ➤ swollen ankles, feet or stomach. ➤ 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). ➤ pain, swelling or inflammation of joints such as the shoulders, arms or legs or tendon pain or swelling. <p>A detailed list of adverse reactions is available in the SmPC.</p>

<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Alert the supervising doctor in the event of any serious adverse reaction to the medicine, document in the individual's record and inform the individual's GP.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p> <p>The additional information leaflet covering the use of ciprofloxacin in response to known or expected exposure to a biological agent should also be provided.</p> <p>Consider providing the MHRA information leaflet on side effects.</p>
<p>Advice / follow up treatment</p> <p>(continued over page)</p>	<p>Explain the treatment.</p> <p>Advise the individual, parent or carer to:</p> <ul style="list-style-type: none"> ➤ drink plenty of fluids. ➤ not take indigestion remedies, sevelamer, lanthanum, sucralfate or medicines containing calcium, magnesium, aluminium, iron or zinc 2 hours before or 4 hours after taking the medicine. ➤ not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice). ➤ 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. ➤ not chew the tablets. ➤ space the doses evenly throughout the day. ➤ keep taking the medicine until the course is finished, unless they are told to stop. ➤ not give the tablets to anyone else. ➤ return any unused tablets at the end of the course to a community pharmacy for destruction. <p>Inform the individual or their parent or carer:</p> <ul style="list-style-type: none"> ➤ of possible side effects and their management. ➤ 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.

<p>Records (continued)</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> <p>For pregnant women record the medicine supplied in the hand-held maternity record (if available).</p>
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PGD for the initial supply of ciprofloxacin for post-exposure prophylaxis to anthrax in children aged under 12 years

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Initial chemoprophylaxis following exposure to a known or suspected deliberate release of anthrax.</p> <p>Notes:</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on anthrax, including post exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Children aged from 4 weeks to less than 12 years of age, following exposure to a known or suspected deliberate release of anthrax</p> <p>AND</p> <p>are not showing symptoms compatible with anthrax infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance for symptoms.</p> <p>Note: The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in children, who should be given ciprofloxacin in the situation criteria set out above.</p>
<p>Exclusion criteria³ (continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they are aged 12 years or over (see ciprofloxacin initial supply PGD for over 12s). ➤ they are less than 4 weeks of age. ➤ they are known to be outside of weight range for age⁴. ➤ they have a known history of severe allergic reaction to ciprofloxacin, other quinolones or fluoroquinolones, or to any of the listed excipients. See SmPC. ➤ they have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to quinolone or fluoroquinolone antibiotic use. ➤ they have a history of tendon disease / disorder related to ciprofloxacin or other quinolone or fluoroquinolone antibiotic use. ➤ they are taking an interacting medicine as listed in the drug interactions section of this PGD.

³ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

⁴ See [British National Formulary for Children](#) (BNFC)

<p>Exclusion criteria (continued)</p>	<ul style="list-style-type: none"> ➤ they have known chronic kidney disease (CKD) stages 4 or 5 (eGFR <30 mL/min/1.73m²) or are on dialysis. ➤ their parent or carer has not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained). <p>See action to be taken if individual is excluded section of this PGD.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>Although caution is advised for individuals with the following conditions or who are taking certain medicines, the benefits of taking ciprofloxacin to prevent anthrax outweighs the risk following a suspected or known deliberate release of anthrax.</p> <p>Provide the child's parent or carer 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>1. At increased risk of tendinitis or tendon rupture:</p> <ul style="list-style-type: none"> ➤ have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD). ➤ are taking corticosteroids. ➤ have a solid organ transplant. <p>Advise parents or carers to monitor for tendinitis (for example, painful swelling, inflammation). In young children who may not be able to report pain, be alert to lack of use of limbs or signs of pain on movement. If signs of tendinitis occur, advise that the parent or carer stops giving ciprofloxacin and to seek immediate medical advice by dialling 111 or the child's GP for assessment.</p> <p>2. Conditions with risk factor for QT interval prolongation:</p> <ul style="list-style-type: none"> ➤ cardiac disease (for example, heart failure, myocardial infarction, bradycardia). ➤ congenital long QT syndrome. ➤ history of symptomatic arrhythmias. ➤ concomitant use of medicines known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics). ➤ electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia). <p>Advise parents or carers to monitor for the exacerbation of or development of symptoms associated with QT interval prolongation. If symptoms develop, advise parents or carers to stop giving ciprofloxacin and to seek immediate medical advice for assessment and consideration of alternative antibiotics.</p> <p>3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:</p> <ul style="list-style-type: none"> ➤ a positive family history of aneurysm disease or congenital heart valve disease.

Cautions (including relevant actions to be taken)

(continued)

- pre-existing aortic aneurysm and/or aortic dissection or heart valve disease.
- presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation / incompetence:
 - connective tissue disorders such as Marfan’s syndrome or Ehlers-Danlos syndrome.
 - Turner syndrome.
 - Behçet’s disease.
 - hypertension.
 - rheumatoid arthritis.
- presence of other risk factors or conditions for aortic aneurysm and dissection, such as:
 - vascular disorders including Takayasu arteritis or giant cell arteritis.
 - known atherosclerosis.
 - Sjögren’s syndrome.
- heart valve regurgitation / incompetence caused, for example, by infective endocarditis.

Advise parents or carers of the possibility of these rare events, and to seek urgent medical attention by dialling 999 if the child develops sudden-onset severe abdominal, chest or back pain.

Advise parents or carers to seek immediate medical attention by dialling 111 or via the GP if the child experiences 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.

4. Epilepsy or conditions that predispose to seizures and/or those taking medication that may predispose to seizures (for example NSAIDs):

Advise parents or carers to monitor for any increase in frequency or severity of seizures. If an increase in frequency or severity of seizures occurs, advise parents or carers to stop giving ciprofloxacin and seek urgent medical attention. Advise parents or carers to avoid giving an NSAID where possible (for example, ibuprofen) whilst taking ciprofloxacin.

5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):

Disturbances in blood glucose can occur. Advise parents or carers to carefully monitor blood glucose during treatment, to be alert to symptoms of hypoglycaemia and hyperglycaemia and to seek medical advice if required.

6. G6PD deficiency:

There is a risk of haemolysis when ciprofloxacin is given to individuals with G6PD deficiency. If ciprofloxacin must be used, advise the parent or carer to monitor for signs of haemolysis. If signs of haemolysis develop, advise to stop giving ciprofloxacin and to seek urgent medical advice.

(continued over page)

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>7. Myasthenia gravis: Advise parents or carers to monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise that they seek urgent medical advice. Note: doxycycline is also cautioned for individuals with myasthenia gravis.</p> <p>8. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol): Advise parents or carers to arrange for the child's INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising. Note: INR also needs to be monitored with doxycycline.</p> <p>9. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine: Advise parents or carers to 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. Refer to the SmPC for ciprofloxacin for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the parent or carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if children develop symptoms compatible with anthrax infection or signs or symptoms of sepsis. ➤ Symptoms of anthrax will depend on the type of exposure as follows: <ul style="list-style-type: none"> ○ Inhalational: flu-like illness (fever, malaise, nausea / vomiting, headache, non-productive cough). ○ Cutaneous: initial pimple / papule that enlarges, blisters, ulcerates over 2 to 6 days to form a black scab. ○ Gastrointestinal: severe abdominal pain, nausea, vomiting, bloody diarrhoea. ➤ See CRBN guidance for further information on symptoms. ➤ Document the advice given and the decision reached.
<p>Action to be taken if the individual is excluded (continued over page)</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ If they are aged 12 years or over, refer to the ciprofloxacin initial supply PGD. ➤ If excluded for other reasons, refer to the supervising doctor for assessment.

<p>Action to be taken if the individual is excluded (continued)</p>	<ul style="list-style-type: none"> ➤ If they are 8 years and over, consider doxycycline. See doxycycline initial supply PGD. ➤ If the child is under weight for their age range, refer to the supervising doctor. If a different dose of ciprofloxacin for their age range is required, a Patient Specific Direction (PSD) will be needed. ➤ Document reasons for exclusion and any referrals that have been made.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising doctor and / or other services.</p>

2. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 100 mg tablets, 250 mg tablets, 500 mg tablets, 250 mg in 5 mL suspension																			
Legal category	Prescription Only Medicine (POM)																			
Black triangle▼	No																			
Off-label use	<p>Yes.</p> <p>The SmPC states dosing is mg/kg, but UK national guidance recommends age banding as per the RCPH and UK-WHO growth charts.</p> <p>Manipulating solid dosage forms</p> <p>Tablets (not suspension) are the preferred formulation for children aged 2 years and older unless they have medically confirmed swallowing difficulties.</p> <p>In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.</p> <p>Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.</p> <p>The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away.</p> <p>Where a product is recommended off-label consider, as part of the consent process, informing the parent or carer that the product is being offered in accordance with national guidance but that this is outside the product licence.</p>																			
Route / method of administration	<p>Oral</p> <p>Tablets 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>																			
Dose and frequency of administration	<p>Doses to be taken TWICE a day – see dosage table below.</p> <table border="1"> <thead> <tr> <th>Age</th> <th>Dose (mg)</th> <th>Dose (volume or quantity)</th> </tr> </thead> <tbody> <tr> <td>Less than 4 weeks of age</td> <td colspan="2">Excluded</td> </tr> <tr> <td>4 weeks to less than 8 weeks of age</td> <td>50 mg TWICE a day</td> <td>1 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>8 weeks to less than 6 months of age</td> <td>75 mg TWICE a day</td> <td>1.5 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>6 months to less than 1 year of age</td> <td>100 mg TWICE a day</td> <td>2 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>1 year to less than 2 years of age</td> <td>150 mg TWICE a day</td> <td>3 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> </tbody> </table>		Age	Dose (mg)	Dose (volume or quantity)	Less than 4 weeks of age	Excluded		4 weeks to less than 8 weeks of age	50 mg TWICE a day	1 mL of 250 mg in 5 mL suspension TWICE a day	8 weeks to less than 6 months of age	75 mg TWICE a day	1.5 mL of 250 mg in 5 mL suspension TWICE a day	6 months to less than 1 year of age	100 mg TWICE a day	2 mL of 250 mg in 5 mL suspension TWICE a day	1 year to less than 2 years of age	150 mg TWICE a day	3 mL of 250 mg in 5 mL suspension TWICE a day
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<p>Duration of treatment</p>	<p># See off label section for advice on manipulating solid dose forms in swallowing difficulty.</p> <p>Ten (10) days</p>												
<p>Quantity to be supplied</p>	<p>Suspension: 1 x 100 mL suspension should be supplied per child irrespective of dose. A bottle of suspension must be discarded 14 days after reconstitution.</p> <p>100 mg tablets: Children aged 2 years to less than 4 years of age: 40 tablets.</p> <p>250 mg tablets: Children aged 4 years to less than 8 years: 20 tablets. Children aged 8 years to less than 12 years: 40 tablets.</p> <p>500 mg tablets: Children aged 8 years to less than 12 years: 20 tablets.</p> <p>OR</p> <p>supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the 10-day treatment course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise the parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>												

<p>Additional information</p>	<p>Tablets (not suspension) are the preferred formulation for children aged 2 years and older unless they have medically confirmed swallowing difficulties.</p> <p>The suspension must be reconstituted according to the manufacturer's instructions before handing to parent / carer or other responsible person.</p> <p>Supply an oral syringe with the suspension and instructions for using the syringe.</p> <p>The suspension should not be administered through a nasogastric tube because of the risk of blocking the tube. Refer to the supervising doctor.</p> <p>The suspension should not be given to individuals with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or saccharose-isomaltase deficiency. Refer to the supervising doctor.</p> <p>As the reconstituted suspension only lasts 14 days, any remaining solution should be taken to a community pharmacy for destruction.</p>															
<p>Storage</p>	<p>Store in original container below 25°C.</p> <p>Reconstituted suspension may either be stored at ambient temperatures up to 30°C or it can be stored in a refrigerator.</p>															
<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>															
<p>Drug interactions</p> <p>(continued over page)</p>	<p>Concurrent medications should be checked for interactions. This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p> <p>Contraindications</p> <p>Where it is known an individual is concurrently taking one of the following medicines, ciprofloxacin should not be supplied under this PGD. Refer individuals to the supervising doctor.</p> <ul style="list-style-type: none"> ➤ agomelatine. ➤ domperidone. ➤ ergometrine, ergotamine or dihydroergotamine. ➤ fezolinetant. ➤ tizanidine. <p>The following medicines may require dose adjustments. Individuals should be referred to the supervising doctor:</p> <table border="0" style="width: 100%;"> <tr> <td>➤ guanfacine</td> <td>➤ tolvaptan</td> <td>➤ ropinirole</td> </tr> <tr> <td>➤ olanzapine</td> <td>➤ daridorexant</td> <td>➤ capivasertib</td> </tr> <tr> <td>➤ elacestrant</td> <td>➤ venetoclax</td> <td>➤ pifrenidone</td> </tr> <tr> <td>➤ eliglustat</td> <td>➤ zanubrutinib</td> <td>➤ pomalidomide</td> </tr> <tr> <td>➤ ibrutinib</td> <td></td> <td></td> </tr> </table>	➤ guanfacine	➤ tolvaptan	➤ ropinirole	➤ olanzapine	➤ daridorexant	➤ capivasertib	➤ elacestrant	➤ venetoclax	➤ pifrenidone	➤ eliglustat	➤ zanubrutinib	➤ pomalidomide	➤ ibrutinib		
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➤ ibrutinib																

<p>Identification & management of adverse reactions (continued)</p>	<p>report specific joint pain, so parents and carers should be alert to other signs such as lack of use of limbs or pain on movement.</p> <ul style="list-style-type: none"> ➤ diarrhoea that lasts more than 4 days or contains blood or mucus. ➤ changes to vision, taste, smell or hearing. ➤ signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach). ➤ symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking). ➤ sudden breathlessness, especially when lying down. ➤ new onset heart palpitations. ➤ swollen ankles, feet or stomach. ➤ 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). <p>A detailed list of adverse reactions is available in the SmPC.</p>
<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Alert the supervising doctor in the event of any serious adverse reaction to the medicine, document in the individual's record and inform the individual's GP.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p> <p>The additional information leaflet covering the use of ciprofloxacin in response to known or expected exposure to a biological agent should also be provided.</p> <p>An information leaflet explaining how to use and clean the oral syringe.</p> <p>Consider providing the MHRA information leaflet on side effects.</p>
<p>Advice / follow up treatment (continued over page)</p>	<p>Explain the treatment.</p> <p>Advise the parent or carer the child should:</p> <ul style="list-style-type: none"> ➤ maintain adequate fluid intake. ➤ not take indigestion remedies or medicines containing calcium, magnesium, aluminium, iron or zinc 2 hours before or 4 hours after taking the medicine. ➤ not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice).

Advice / follow up treatment

(continued)

- space the doses evenly throughout the day.
- keep taking the medicine until the course is finished, unless they are told to stop.

For suspension: Inform the parent or carer:

- to shake the suspension bottle vigorously each time before use for approximately 15 seconds.
- although there may be suspension remaining after the initial ten-day course, a further supply will be needed if a follow-on course is recommended.
- to take any remaining unused suspension to a community pharmacy for disposal.

For tablets: Inform the parent or carer:

- these should 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.
- tablets should not be chewed.
- tablets can be crushed, if necessary (see [off-label section](#) of this PGD), parents and carers should be advised that the tablets are very bitter in taste, and to encourage their children to swallow the tablets whole where possible.
- any unused tablets should be taken to a community pharmacy for disposal.

Inform the parent or carer:

- for babies receiving milk feeds, to space the doses in the mid period between expected feed times.
- of possible side effects and their management.
- 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.
- the medicine can make the skin more sensitive to direct sunlight. Children should avoid exposure to excessive sunlight or use high SPF sunblock if prolonged exposure to the sun is unavoidable.
- the medicine may cause the child to feel tired or less alert. Children should take care when doing tasks that require coordination (for example, riding a bike) until they get used to the medicine.
- to seek immediate medical attention if the individual develops signs or symptoms compatible with anthrax or other serious adverse effects (see [identification and management of adverse reactions](#)).
- when subsequent supply is due and where they can obtain this further supply.

For individuals with conditions listed in the [cautions](#) section, provide the additional recommended advice.

Records

Record:

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

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

All records should be clear, legible and contemporaneous.

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

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

PGD for the further supply of ciprofloxacin for post-exposure prophylaxis to anthrax in adults and children aged 12 years and over

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Where continuing chemoprophylaxis is required following exposure to a known deliberate release of anthrax.</p> <p>Notes:</p> <p>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 anthrax, including post exposure prophylaxis, see CBRN guidance.</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p>
<p>Inclusion criteria</p>	<p>Adults and children aged 12 years and over following exposure to a known deliberate release of anthrax</p> <p>AND</p> <p>who have already received chemoprophylaxis for 10 days with ciprofloxacin or doxycycline</p> <p>AND</p> <p>are not showing symptoms compatible with anthrax infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance for symptoms.</p> <p>Note: The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in growing adolescents, pregnant or breastfeeding individuals who should be given ciprofloxacin in the situation criteria set out above.</p>
<p>Exclusion criteria⁵</p> <p>(continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they have a known history of severe allergic reaction to ciprofloxacin, other fluoroquinolones or quinolones, or to any of the listed excipients. See SmPC. ➤ they are under 12 years of age. ➤ they have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to a

⁵ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

<p>Exclusion criteria (continued)</p>	<p>quinolone or fluoroquinolone antibiotic.</p> <ul style="list-style-type: none"> ➤ they have a history of tendon disease / disorder related to ciprofloxacin or other fluoroquinolones or quinolones. ➤ they have experienced unacceptable side effects while taking the initial ten days' supply of ciprofloxacin. ➤ they are taking an interacting medicine as listed in the drug interactions section of this PGD. ➤ they have known chronic kidney disease (CKD) stages 4 or 5 (eGFR <30 mL/min/1.73m²) or are on dialysis. ➤ they have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained). <p>See action to be taken if individual is excluded section of this PGD.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>Caution is advised for individuals with the following conditions or who are taking certain medicines.</p> <p>Note: Doxycycline is the preferred option for these individuals if it is not contraindicated and is available. See the doxycycline further supply PGD.</p> <p>If doxycycline is contraindicated, or not available, then ciprofloxacin can be supplied as the benefit of taking it to prevent anthrax 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>1. At increased risk of tendinitis or tendon rupture:</p> <ul style="list-style-type: none"> ➤ over 60 years of age. ➤ have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD). ➤ are taking corticosteroids. ➤ have a solid organ transplant. <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>2. Conditions with risk factor for QT interval prolongation:</p> <ul style="list-style-type: none"> ➤ cardiac disease (for example, heart failure, myocardial infarction, bradycardia). ➤ congenital long QT syndrome. ➤ history of symptomatic arrhythmias. ➤ concomitant use of medicines known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics). <ul style="list-style-type: none"> ➤ electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia).



Cautions (including relevant actions to be taken)

(continued)

Advise to monitor for the exacerbation of or development of [symptoms associated with QT interval prolongation](#). If symptoms develop, advise individuals to seek immediate medical advice for assessment and consideration of alternative antibiotics.

3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:

- a positive family history of aneurysm disease or congenital heart valve disease.
- pre-existing aortic aneurysm and/or aortic dissection or heart valve disease.
- presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation / incompetence:
 - connective tissue disorders such as Marfan's syndrome or Ehlers-Danlos syndrome.
 - Turner syndrome.
 - Behçet's disease.
 - hypertension.
 - rheumatoid arthritis.
- presence of other risk factors or conditions for aortic aneurysm and dissection:
 - vascular disorders including Takayasu arteritis or giant cell arteritis.
 - known atherosclerosis.
 - Sjögren's syndrome.
- heart valve regurgitation / incompetence caused, for example, by infective endocarditis.

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.

Advise to seek immediate medical attention by dialling 111 or via a 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.

4. Epilepsy or conditions that predispose to seizures and/or those taking medication that may predispose to seizures (for example NSAIDs):

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.

5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):

Disturbances in blood glucose can occur. Advise individuals to carefully monitor blood glucose during treatment, and to be alert to symptoms of hypoglycaemia and hyperglycaemia and to seek medical advice if required.

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<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>6. G6PD deficiency: 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>7. Myasthenia gravis: Advise to self-monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise individuals to seek urgent medical advice. Note: doxycycline is also cautioned for individuals with myasthenia gravis.</p> <p>8. Severely immunocompromised individuals: Individuals who are severely immunocompromised (as defined in chapter 28a Green book) should be advised to arrange an appointment with a GP or specialist before the end of the course to determine whether they need to continue treatment beyond the course outlined in this PGD.</p> <p>9. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol): Advise individual to arrange for INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising. Note: INR also needs to be monitored with doxycycline.</p> <p>10. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine: Advise individuals 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. Refer to the SmPC for ciprofloxacin for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual, parent or carer declines prophylaxis (continued over page)</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual, parent or their carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if they develop symptoms compatible with anthrax infection or signs or symptoms of sepsis. ➤ Symptoms of anthrax will depend on the type of exposure as follows: <ul style="list-style-type: none"> ○ Inhalational: flu-like illness (fever, malaise, nausea / vomiting, headache, non-productive cough).

<p>Action to be taken if the individual, parent or carer declines prophylaxis (continued)</p>	<ul style="list-style-type: none"> ○ Cutaneous: initial pimple / papule that enlarges, blisters, ulcerates over 2 to 6 days to form a black scab. ○ Gastrointestinal: severe abdominal pain, nausea, vomiting, bloody diarrhoea. <p>➤ See CRBN guidance for further information on symptoms. Document the advice given and the decision reached.</p>
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ Consider supply of doxycycline (see doxycycline further supply PGD). ➤ Where doxycycline is contraindicated, refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics. ➤ Document reasons for exclusion and any referrals that have been made.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising doctor and / or other services.</p>



2. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 500mg tablets.
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Yes – the SmPC states a treatment duration of 60 days but UK national guidance states a shorter period may be recommended. See duration of treatment section.</p> <p>Manipulating solid dosage forms</p> <p>Tablets (not suspension) are the preferred formulation for children aged 12 years and older unless they have medically confirmed swallowing difficulties.</p> <p>In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.</p> <p>Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.</p> <p>The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away.</p> <p>Pregnancy</p> <p>The manufacturers advise as a precautionary measure to avoid the use of ciprofloxacin during pregnancy. However, the data available on administration of ciprofloxacin to pregnant women indicates no malformative or feto/neonatal toxicity but the SmPC 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 the disease outweigh these potential risks in pregnancy. A patient information leaflet for ciprofloxacin in pregnancy is available here: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org)</p> <p>Breastfeeding</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</p> <p>(continued over page)</p>

<p>Off-label use (continued)</p>	<p>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. See patient advice section.</p> <p>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.</p>
<p>Route / method of administration</p>	<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>
<p>Dose and frequency of administration</p>	<p>Adults and children aged 12 years or over</p> <p>ONE tablet (500 mg) to be taken TWICE a day</p> <p>For individuals who are unable to swallow the tablets, refer to the off-label section of the PGD.</p>
<p>Duration of treatment</p>	<p>20 days (total length of course 30 days)</p> <p>Note: these individuals have previously received an initial ten-day supply of an antibiotic.</p>
<p>Quantity to be supplied</p>	<p>40 (forty) tablets OR</p> <p>supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the 20-day course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise the individual or their parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>
<p>Storage</p>	<p>Store in original container below 25°C.</p>
<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>



Drug interactions

Concurrent medications should be checked for interactions. This list is not exhaustive. A detailed list of drug interactions can be found in the [SmPC](#) or the [BNF](#).

Contraindications

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 [doxycycline further supply PGD](#)) refer individuals to the supervising doctor.

- agomelatine.
- domperidone.
- ergometrine, ergotamine or dihydroergotamine.
- fezolinetant.
- tizanidine.

The following medicines may require dose adjustments. If doxycycline is contraindicated (see [doxycycline further supply PGD](#)), individuals should be referred to the supervising doctor:

- | | | |
|----------------|----------------|----------------|
| ➤ olanzapine | ➤ tolvaptan | ➤ ropinirole |
| ➤ capivasertib | ➤ daridorexant | ➤ guanfacine |
| ➤ elacestrant | ➤ venetoclax | ➤ pirfenidone |
| ➤ eliglustat | ➤ zanubrutinib | ➤ pomalidomide |
| ➤ ibrutinib | | |

Cautions

Individuals who have **received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days** should be referred to the supervising doctor for assessment and advice as ciprofloxacin may reduce the efficacy of these vaccines.

Ciprofloxacin may increase the likelihood of side effects when taken with some medicines (for example, **anagrelide, chlorpromazine, duloxetine, melatonin, rasagiline, riluzole, roflumilast, sildenafil**). Advise individuals to be alert to any increase in adverse effects and to speak to their usual healthcare provider as soon as possible if side effects occur.

Individuals taking **zolmitriptan** should be advised that a maximum dose of 5mg of zolmitriptan should be taken in any 24-hours.

See [cautions](#) 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.

Ciprofloxacin should be given 2 hours before, or 4 hours after **sevelamer, lanthanum, sucralfate, antacids** and any medicines or supplements containing **calcium, magnesium, aluminium, iron or zinc** that may reduce the absorption of ciprofloxacin.

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<p>Drug interactions (continued)</p>	<p>Oral contraceptives.</p> <p>Ciprofloxacin does not reduce their efficacy but if it makes them vomit or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).</p>
<p>Identification & management of adverse reactions</p>	<p>Although there are some potential and serious side effects, the benefit of using ciprofloxacin to prevent disease associated with anthrax exposure outweighs these risks.</p> <p>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"> ➤ anaphylaxis (delayed or immediate). ➤ sudden, severe pain in the stomach, chest or back. ➤ seizures. ➤ thoughts about harming themselves or ending their life. <p>Advise individuals to stop taking ciprofloxacin and seek immediate medical advice by calling 111 or a GP if any of the following rare effects occur:</p> <ul style="list-style-type: none"> ➤ changes to vision, taste, smell or hearing. ➤ signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach). ➤ symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking). ➤ diarrhoea that lasts more than 4 days or contains blood or mucus. ➤ sudden breathlessness, especially when lying down. ➤ new onset heart palpitations. ➤ swollen ankles, feet or stomach. ➤ 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). ➤ pain, swelling or inflammation of joints such as the shoulders, arms or legs or tendon pain or swelling. <p>A detailed list of adverse reactions is available in the SmPC.</p>

<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Alert the supervising doctor in the event of any serious adverse reaction to the medicine, document in the individual's record and inform the individual's GP.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p> <p>The additional information leaflet covering the use of ciprofloxacin in response to known or expected exposure to a biological agent should also be provided.</p> <p>Consider providing the MHRA information leaflet on side effects.</p>
<p>Advice / follow up treatment</p> <p>(continued over page)</p>	<p>Explain the treatment.</p> <p>Advise the individual, parent or carer to:</p> <ul style="list-style-type: none"> ➤ drink plenty of fluids. ➤ not take indigestion remedies, sevelamer, lanthanum, sucralfate or medicines containing calcium, magnesium, aluminium, iron or zinc 2 hours before or 4 hours after taking the medicine. ➤ not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice). ➤ 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. ➤ not chew the tablets. ➤ space the doses evenly throughout the day. ➤ keep taking the medicine until the course is finished, unless they are told to stop. ➤ not give the tablets to anyone else. ➤ return any unused tablets at the end of the course to a community pharmacy for destruction. <p>Inform individual, parent or carer:</p> <ul style="list-style-type: none"> ➤ of possible side effects and their management. ➤ 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.

<p>Records (continued)</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> <p>For pregnant women record the medicine supplied in the hand-held maternity record (if available).</p>
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PGD for the further supply of ciprofloxacin for post-exposure prophylaxis to anthrax in children aged under 12 years

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Where continuing chemoprophylaxis is required following exposure to a known deliberate release of anthrax.</p> <p>Notes:</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on anthrax, including post exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Children aged from 4 weeks to less than 12 years of age, following exposure to a known deliberate release of anthrax who have already received ten days' supply of antibiotics for the exposure</p> <p>AND</p> <p>are not showing symptoms compatible with anthrax infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance for symptoms compatible with anthrax infection.</p> <p>Note: The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in children, who should be given ciprofloxacin in the situation criteria set out above.</p>
<p>Exclusion criteria⁶</p> <p>(continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they are aged 12 years or over (see ciprofloxacin further supply PGD for over 12s). ➤ they are less than 4 weeks of age. ➤ they are known to be outside of weight range for age⁷. ➤ they have a known history of severe allergic reaction to ciprofloxacin, other quinolones or fluoroquinolones, or to any of the listed excipients. See SmPC. ➤ they have experienced unacceptable side effects while taking the initial ten days' supply of ciprofloxacin. ➤ they have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to quinolone or fluoroquinolone antibiotic use. ➤ they have a history of tendon disease / disorder related to ciprofloxacin or other quinolone or fluoroquinolone antibiotic use.

⁶ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

⁷ See [British National Formulary for Children](#) (BNFC)

<p>Exclusion criteria (continued)</p>	<ul style="list-style-type: none"> ➤ they are taking an interacting medicine as listed in the drug interactions section of this PGD. ➤ they have known chronic kidney disease (CKD) stages 4 or 5 (eGFR <30 mL/min/1.73m²) or are on dialysis. ➤ their parent or carer has not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained). <p>See action to be taken if individual is excluded section of this PGD.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>Although caution is advised for individuals with the following conditions or who are taking certain medicines, the benefits of taking ciprofloxacin to prevent anthrax outweighs the risk following a known deliberate release of anthrax.</p> <p>Provide the child’s parent or carer 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>1. At increased risk of tendinitis or tendon rupture:</p> <ul style="list-style-type: none"> ➤ have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD). ➤ are taking corticosteroids. ➤ have a solid organ transplant. <p>Advise parents or carers to monitor for tendinitis (for example, painful swelling, inflammation). In young children who may not be able to report pain, be alert to lack of use of limbs or signs of pain on movement. If signs of tendinitis occur, advise that the parent or carer stops giving ciprofloxacin and to seek immediate medical advice by dialling 111 or the child’s GP for assessment.</p> <p>2. Conditions with risk factor for QT interval prolongation:</p> <ul style="list-style-type: none"> ➤ cardiac disease (for example, heart failure, myocardial infarction, bradycardia). ➤ congenital long QT syndrome. ➤ history of symptomatic arrhythmias. ➤ concomitant use of medicines known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics). ➤ electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia). <p>Advise parents or carers to monitor for the exacerbation of or development of symptoms associated with QT interval prolongation. If symptoms develop, advise parents or carers to stop giving ciprofloxacin and to seek immediate medical advice for assessment and consideration of alternative antibiotics.</p>

Cautions (including relevant actions to be taken)

(continued)

3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:

- a positive family history of aneurysm disease or congenital heart valve disease.
- pre-existing aortic aneurysm and/or aortic dissection or heart valve disease.
- presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation / incompetence:
 - connective tissue disorders such as Marfan’s syndrome or Ehlers-Danlos syndrome.
 - Turner syndrome.
 - Behçet’s disease.
 - hypertension.
 - rheumatoid arthritis.
- presence of other risk factors or conditions for aortic aneurysm and dissection:
 - vascular disorders including Takayasu arteritis or giant cell arteritis.
 - known atherosclerosis.
 - Sjögren’s syndrome.
- heart valve regurgitation / incompetence caused, for example, by infective endocarditis.

Advise parents or carers of the possibility of these rare events, and that they should seek urgent medical attention by dialling 999 if the child develops sudden-onset severe abdominal, chest or back pain.

Advise parents or carers to seek immediate medical attention by dialling 111 or via the GP if the child experiences 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.

4. Epilepsy or conditions that predispose to seizures and/or those taking medication that may predispose to seizures (for example NSAIDs):

Advise parents or carers to monitor for any increase in frequency or severity of seizures. If an increase in frequency or severity of seizures occurs, advise parents or carers to stop giving ciprofloxacin and seek urgent medical attention. Advise parents or carers to avoid giving an NSAID where possible (for example, ibuprofen) whilst taking ciprofloxacin.

5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):

Disturbances in blood glucose can occur. Advise parents or carers to carefully monitor blood glucose during treatment, to be alert to symptoms of hypoglycaemia and hyperglycaemia and to seek medical advice if required.

(continued over page)

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>6. G6PD deficiency:</p> <p>There is a risk of haemolysis when ciprofloxacin is given to individuals with G6PD deficiency. If ciprofloxacin must be used, advise the parent or carer to monitor for signs of haemolysis. If signs of haemolysis develop, advise to stop giving ciprofloxacin and seek urgent medical advice.</p> <p>7. Myasthenia gravis:</p> <p>Advise parents or carers to monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise that they seek urgent medical advice.</p> <p>8. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol):</p> <p>Advise parents or carers to arrange for the child's INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising.</p> <p>9. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine:</p> <p>Advise parents or carers to 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>10. Severely immunocompromised individuals:</p> <p>Parents and carers of individuals who are severely immunocompromised (as defined in chapter 28a Green book) should be advised to arrange an appointment with their specialist or GP to determine whether they need to continue treatment beyond the course outlined in this PGD.</p> <p>Refer to the SmPC for ciprofloxacin for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the parent or carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if children develop symptoms compatible with anthrax infection or signs or symptoms of sepsis. ➤ Symptoms of anthrax will depend on the type of exposure as follows: <ul style="list-style-type: none"> ○ Inhalational: flu-like illness (fever, malaise, nausea / vomiting, headache, non-productive cough). ○ Cutaneous: initial pimple / papule that enlarges, blisters, ulcerates over 2 to 6 days to form a black scab. ○ Gastrointestinal: severe abdominal pain, nausea, vomiting, bloody diarrhoea.

<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ See CRBN guidance for further information on symptoms. ➤ Document the advice given and the decision reached. ➤ Explain why they have been excluded. ➤ If they are aged 12 years or over, refer to the ciprofloxacin further supply PGD. ➤ If excluded for other reasons, refer to the supervising doctor for assessment. ➤ If the child is under weight for their age range, refer to the supervising doctor. If a different dose of ciprofloxacin for their age range is required, a Patient Specific Direction (PSD) will be needed. ➤ Document reasons for exclusion and any referrals that have been made.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising doctor and / or other services.</p>

2. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 100 mg tablets, 250 mg tablets, 500 mg tablets, 250 mg in 5 mL suspension.																	
Legal category	Prescription Only Medicine (POM)																	
Black triangle▼	No																	
Off-label use	<p>Yes.</p> <ul style="list-style-type: none"> ➤ The SmPC states a treatment duration of 60 days but UK national guidance states a shorter period may be recommended. See duration of treatment section. ➤ The SmPC states dosing is mg/kg, but UK national guidance recommends age banding as per the RCPH and UK-WHO growth charts. <p>Manipulating solid dosage forms</p> <p>Tablets (not suspension) are the preferred formulation for children aged 2 years and older unless they have medically confirmed swallowing difficulties.</p> <p>In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.</p> <p>Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.</p> <p>The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away.</p> <p>Where a product is recommended off-label consider, as part of the consent process, informing the parent or carer that the product is being offered in accordance with national guidance but that this is outside the product licence.</p>																	
Route / method of administration	<p>Oral</p> <p>Tablets 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>																	
Dose and frequency of administration	<p>Doses to be taken TWICE a day – see dosage table below.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Age</th> <th style="width: 25%;">Dose (mg)</th> <th style="width: 50%;">Dose (volume or quantity)</th> </tr> </thead> <tbody> <tr> <td>Less than 4 weeks of age</td> <td colspan="2" style="text-align: center;">Excluded</td> </tr> <tr> <td>4 weeks to less than 8 weeks of age</td> <td style="text-align: center;">50 mg TWICE a day</td> <td>1 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>8 weeks to less than 6 months of age</td> <td style="text-align: center;">75 mg TWICE a day</td> <td>1.5 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>6 months to less than 1 year of age</td> <td style="text-align: center;">100 mg TWICE a day</td> <td>2 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> </tbody> </table> <p>(continued over page)</p>			Age	Dose (mg)	Dose (volume or quantity)	Less than 4 weeks of age	Excluded		4 weeks to less than 8 weeks of age	50 mg TWICE a day	1 mL of 250 mg in 5 mL suspension TWICE a day	8 weeks to less than 6 months of age	75 mg TWICE a day	1.5 mL of 250 mg in 5 mL suspension TWICE a day	6 months to less than 1 year of age	100 mg TWICE a day	2 mL of 250 mg in 5 mL suspension TWICE a day
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<p># See off label section for advice on manipulating solid dose forms in swallowing difficulty.</p>																
<p>Duration of treatment</p> <p>Twenty (20) days (total length of course 30 days).</p> <p>Note: these individuals have previously received an initial ten-day supply.</p>																
<p>Quantity to be supplied</p> <p>NOTE: reconstituted ciprofloxacin suspension has a 14-day shelf life. Each bottle of suspension must be discarded 14 days after reconstitution.</p> <p>Suspension:</p> <p>Supply 1 x 100 mL suspension on 2 separate occasions.</p> <p>It is the responsibility of the organisation distributing the antibiotic to determine the frequency at which an individual returns for further supplies, as no more than a 14-day supply can be provided at any one time. Parents or carers will have to return every 14 days for further supplies of suspension.</p> <p>100 mg tablets:</p> <p>Children aged 2 years to less than 4 years of age: 80 tablets</p> <p>250 mg tablets:</p> <p>Children aged 4 years to less than 8 years: 40 tablets. Children aged 8 years to less than 12 years: 80 tablets</p> <p>500 mg tablets:</p> <p>Children aged 8 years to less than 12 years: 40 tablets.</p> <p>OR</p> <p>supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the treatment course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. 																
<p>(continued over page)</p>																

<p>Quantity to be supplied (continued)</p>	<ul style="list-style-type: none"> ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual’s name, the date and additional instructions must be written on the label at the time of supply. <p>Advise the individuals parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>
<p>Additional information</p>	<p>Tablets (not suspension) are the preferred formulation for children aged 2 years and older unless they have medically confirmed swallowing difficulties.</p> <p>The suspension must be reconstituted according to the manufacturer’s instructions before handing to parent / carer or other responsible person.</p> <p>Supply an oral syringe with the suspension and instructions for using the syringe.</p> <p>The suspension should not be administered through a nasogastric tube because of the risk of blocking the tube. Refer to the supervising doctor.</p> <p>The suspension should not be given to individuals with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or saccharose-isomaltase deficiency. Refer to the supervising doctor.</p> <p>As the reconstituted suspension only lasts 14 days, any remaining solution should be taken to a community pharmacy for destruction.</p>
<p>Storage</p>	<p>Store in original container below 25°C.</p> <p>Reconstituted suspension may either be stored at ambient temperatures up to 30°C or it can be stored in a refrigerator.</p>
<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>
<p>Drug interactions (continued over page)</p>	<p>Concurrent medications should be checked for interactions. This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p> <p>Contraindications</p> <p>Where it is known an individual is concurrently taking one of the following medicines, ciprofloxacin should not be supplied under this PGD. Refer individuals to the supervising doctor.</p> <ul style="list-style-type: none"> ➤ agomelatine. ➤ domperidone. ➤ ergometrine, ergotamine or dihydroergotamine. ➤ fezolinetant. ➤ tizanidine.

<p>Drug interactions (continued)</p>	<p>The following medicines may require dose adjustments. Individuals should be referred to the supervising doctor:</p> <ul style="list-style-type: none"> ➤ guanfacine ➤ olanzapine ➤ elacestrant ➤ eliglustat ➤ ibrutinib ➤ tolvaptan ➤ daridorexant ➤ venetoclax ➤ zanubrutinib ➤ ropinirole ➤ capivasertib ➤ pirfenidone ➤ pomalidomide <p>Cautions</p> <p>Individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be referred to the supervising doctor for assessment and 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, anagrelide, chlorpromazine, duloxetine, melatonin, rasagiline, riluzole, roflumilast, sildenafil). Advise parents or carers to be alert to any increase in adverse effects and to speak to the child's usual healthcare provider as soon as possible if adverse effects occur.</p> <p>Individuals taking zolmitriptan should be advised that a maximum dose of 5mg of zolmitriptan should be taken in any 24-hours.</p> <p>See cautions 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 sevelamer, lanthanum, sucralfate, antacids and any medicines or supplements containing calcium, magnesium, aluminium, iron or zinc that may reduce the absorption of ciprofloxacin.</p>
<p>Identification & management of adverse reactions (continued over page)</p>	<p>Ciprofloxacin is licensed in children for inhalational anthrax and although there are potential and serious side effects, the benefit of using ciprofloxacin to prevent disease associated with anthrax exposure outweighs these risks.</p> <p>Commonly reported adverse reactions are nausea, diarrhoea and joint pain and joint inflammation in children. Nausea may be relieved by taking ciprofloxacin after food. Parents and carers should be alert to the possibility of joint pain and inflammation, and follow the advice outlined below.</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 parents or carers to stop giving ciprofloxacin to their child immediately and seek urgent medical advice by dialling 999 if the following severe adverse effects occur:</p> <ul style="list-style-type: none"> ➤ anaphylaxis (delayed or immediate). ➤ sudden, severe pain in the stomach, chest or back.

<p>Identification & management of adverse reactions</p> <p>(continued)</p>	<ul style="list-style-type: none"> ➤ seizures. ➤ thoughts about harming themselves or ending their life. <p>Advise parents or carers to be alert to the possibility of the following rare effects, and to stop giving ciprofloxacin to their child immediately and seek urgent medical advice by calling a GP or 111 if the child experiences any of the following:</p> <ul style="list-style-type: none"> ➤ pain, swelling or inflammation of joints such as the shoulders, arms or legs or tendon pain or swelling. Very young children may not be able to report specific joint pain, so parents and carers should be alert to other signs such as lack of use of limbs or pain on movement. ➤ diarrhoea that lasts more than 4 days or contains blood or mucus. ➤ changes to vision, taste, smell or hearing. ➤ signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach). ➤ symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking). ➤ sudden breathlessness, especially when lying down. ➤ new onset heart palpitations. ➤ swollen ankles, feet or stomach. ➤ 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). <p>A detailed list of adverse reactions is available in the SmPC.</p>
<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Alert the supervising doctor in the event of a serious adverse reaction, document in the individual's record and inform the individual's GP.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p> <p>The additional information leaflet covering the use of ciprofloxacin in response to known or suspected exposure to a biological agent should also be provided.</p> <p>An information leaflet explaining how to use and clean the oral syringe.</p> <p>Consider providing the MHRA information leaflet on side effects.</p>

Advice / follow up treatment

Explain the treatment.

Advise the parent or carer the child should:

- maintain adequate fluid intake.
- not take indigestion remedies or medicines containing calcium, magnesium, aluminium, iron or zinc 2 hours before or 4 hours after taking the medicine.
- not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice).
- space the doses evenly throughout the day.
- keep taking the medicine until the course is finished, unless they are told to stop.

For suspension: Inform the parent or carer:

- to shake the suspension bottle vigorously each time before use for approximately 15 seconds.
- when to return for a second bottle.
- any suspension remaining 14 days after being reconstituted needs to be returned to a community pharmacy for destruction.

For tablets: Inform the parent or carer:

- these should 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.
- tablets should not be chewed.
- tablets can be crushed, if necessary (see [off-label section](#) of this PGD), parents and carers should be advised that the tablets are very bitter in taste, and to encourage their children to swallow the tablets whole where possible.
- any unused tablets should be taken to a community pharmacy for disposal.

Inform the parent or carer:

- for babies receiving milk feeds, to space the doses in the mid period between expected feed times.
- of possible side effects and their management.
- 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.
- the medicine can make the skin more sensitive to direct sunlight. Children should avoid exposure to excessive sunlight or use high SPF sunblock if prolonged exposure to the sun is unavoidable.
- to seek immediate medical attention if the child develops signs or symptoms compatible with anthrax or other serious adverse effects (see [identification and management of adverse reactions](#)).

(continued over page)

<p>Advice / follow up treatment (continued)</p>	<ul style="list-style-type: none"> ➤ the medicine may cause the child to feel tired or less alert. Children should take care when doing tasks that require coordination (for example riding a bike) until they get used to the medicine. <p>For individuals with conditions listed in the cautions section, provide the additional recommended advice.</p>
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> ➤ whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005. ➤ name of individual, address, date of birth, weight if known, allergies, and GP with whom the individual is registered (or record where an individual is not registered with a GP). ➤ name of member of staff who supplied the product. ➤ name and brand of the product. ➤ date of supply. ➤ dose, form and route of administration of the product. ➤ quantity supplied. ➤ batch number and expiry date. ➤ advice given; including advice given if the child is excluded or the parent/carer declines treatment. ➤ details of any adverse drug reactions and actions taken. ➤ that the product was supplied via PGD. <p>All records should be signed and dated (or password-controlled on records). 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>

PGD for the initial supply of doxycycline for post-exposure prophylaxis to anthrax in adults and children aged 8 years and over

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Initial chemoprophylaxis following exposure to a known or suspected deliberate release of anthrax.</p> <p>Notes:</p> <p>Ciprofloxacin is also indicated for post exposure prophylaxis to anthrax. See ciprofloxacin initial supply PGD for 12 years and over or for under 12 years.</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on anthrax, including post-exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Adults and children aged 8 years and over following exposure to a known or suspected deliberate release of anthrax</p> <p>AND</p> <p>are not showing symptoms compatible with anthrax infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance for symptoms.</p>
<p>Exclusion criteria⁸</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they are under 8 years of age. ➤ they are pregnant or suspected to be pregnant as doxycycline affects teeth and bone growth in the baby, notably in the second and third trimester. ➤ they are currently breastfeeding. ➤ they have known severe hepatic impairment. ➤ they have a known history of severe allergic reaction to doxycycline, other tetracyclines or to any of the listed excipients. See SmPC. ➤ they are receiving systemic retinoid treatment (for example acitretin, alitretinoin, isotretinoin, tretinoin) due to possible increased risk of benign intracranial hypertension when tetracyclines are given with retinoids. ➤ they are taking enzyme inducing anti-epileptic medicines (carbamazepine, fosphenytoin, phenobarbitone / phenobarbital, primidone, phenytoin) as effectiveness of doxycycline may be reduced. ➤ they have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained). <p>See action to be taken if individual is excluded section of this PGD.</p>

⁸ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Cautions (including relevant actions to be taken)

For individuals where the following cautions apply, supply doxycycline unless there are life-threatening contraindications as benefit outweighs risk in the case of a suspected or deliberate release of anthrax. Individuals should be provided with the advice outlined below.

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

1. Myasthenia gravis:

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

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

2. Systemic lupus erythematosus (SLE):

Consider supply of ciprofloxacin ([see ciprofloxacin initial supply PGD](#)) if no contra-indications or advise to self-monitor for any increase in severity of SLE. If increase in severity of SLE occurs, advise individuals to seek urgent medical advice.

3. Liver impairment:

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

4. Chronic alcohol dependence:

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

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

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

Note: INR also needs to be monitored with ciprofloxacin.

6. Taking penicillin:

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

7. Taking ciclosporin or lithium:

Consider supply of ciprofloxacin ([see ciprofloxacin initial supply PGD](#)) if appropriate or advise individual to contact the service who prescribe / monitor the affected medicines to arrange monitoring and any dose adjustments.

Advise to be aware of any signs of toxicity.

(continued over page)

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>8. Already taking doxycycline or other tetracycline for another condition:</p> <p>Advise individual to stop their existing course. They should now take doxycycline at the dose and frequency outlined in this PGD. If doxycycline or another tetracycline has previously been prescribed for ongoing treatment, the individual can be advised to continue at the previous dose once the course for anthrax post-exposure prophylaxis is complete.</p> <p>If unclear, seek advice from the supervising doctor.</p> <p>Refer to the SmPC for doxycycline for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ Consider supply of ciprofloxacin (see ciprofloxacin initial supply PGD). ➤ Where ciprofloxacin is contraindicated refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics. ➤ Document reasons for exclusion and any referrals that have been made.
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual, parent or their carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if they develop symptoms compatible with anthrax infection or signs and symptoms of sepsis. ➤ Symptoms of anthrax will depend on the type of exposure as follows: <ul style="list-style-type: none"> ○ Inhalational: flu-like illness (fever, malaise, nausea / vomiting, headache, non-productive cough) ○ Cutaneous: initial pimple / papule that enlarges, blisters, ulcerates over 2 to 6 days to form a black scab. ○ Gastrointestinal: severe abdominal pain, nausea, vomiting, bloody diarrhoea. ➤ See CRBN guidance for further information on symptoms. Document the advice given and the decision reached.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising doctor and / or other services.</p>



2. Description of Treatment

Name, strength & formulation of drug	Doxycycline 100 mg capsules
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Anthrax post exposure prophylaxis is not included under the therapeutic indications in the SmPC but is recommended in the guidance on CBRN incidents.</p> <p>The dose for 8-12 years is higher than in the SmPC but follows the recommendations in the guidance on CBRN incidents.</p> <p>Where a product is recommended off-label consider, as part of the consent process, informing the individual, parent or carer the product is being offered in accordance with national guidance, but this is outside the product licence.</p>
Route / method of administration	<p>Oral</p> <p>To be swallowed whole with a full glass of water, in either the sitting or standing position. It can be taken with food or milk to reduce the risk of gastric irritation.</p>
Dose and frequency of administration	<p>ONE capsule (100 mg) to be taken TWICE a day</p> <p>For individuals who are unable to swallow the capsules, refer to the supervising doctor for assessment and consideration of alternative antibiotics or formulation.</p>
Duration of treatment	10 days
Quantity to be supplied	<p>20 (twenty) capsules OR</p> <p>supply a sufficient number of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for a 10-day course and instruct individual to take one capsule twice daily for 10 days only.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise individual or their parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>

<p>Storage</p>	<p>Store in original container below 25°C.</p>
<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>
<p>Drug interactions</p>	<p>This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p> <p>Contraindications</p> <ul style="list-style-type: none"> ➤ individuals taking systemic retinoids and enzyme-inducing anti-epileptics are excluded from this PGD (see exclusion criteria). <p>Cautions</p> <ul style="list-style-type: none"> ➤ anticoagulants, vitamin K antagonists, ciclosporin, lithium penicillin, alcohol: see cautions for advice to be given. ➤ individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be advised to contact the administering clinic or GP as soon as possible for advice as doxycycline may reduce the efficacy of these vaccines. ➤ antacids, aluminium, calcium, iron, magnesium, bismuth and zinc salts: greatly decrease the absorption of doxycycline. Administration should be separated by 2 to 3 hours. <p>Oral contraceptives.</p> <p>Doxycycline does not reduce their efficacy but if it makes them vomit or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).</p>
<p>Identification & management of adverse reactions</p> <p>(continued over page)</p>	<p>A detailed list of adverse reactions is available in the SmPC.</p> <p>Advise the individual that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999:</p> <ul style="list-style-type: none"> ➤ allergic reactions such as sudden difficulty with breathing, speaking and swallowing. ➤ extreme dizziness or fainting. ➤ severe itchy skin rash especially if blistering, soreness of the eyes, mouth or genital organs. <p>Commonly reported side effects include:</p> <ul style="list-style-type: none"> ➤ nausea, vomiting and headache ➤ hypersensitivity reactions ➤ photosensitivity and rash including maculopapular and erythematous rashes.

<p>Identification & management of adverse reactions (continued)</p>	<p>Advise individuals to take doxycycline after food or with a drink of milk instead of water to help with nausea.</p> <p>To help with photosensitivity, advise individuals to wear clothes that cover them up and a hat and sunglasses when going outside. Advise they use a high SPF sunscreen of at least 30 to prevent any sunburn.</p> <p>If individuals are concerned about other side effects, they should be advised to continue with treatment and contact a GP or pharmacist.</p>
<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Any serious adverse reaction to the medicine should be documented in the individual's record and the individual's GP informed.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p>
<p>Advice / follow up treatment (continued over page)</p>	<p>Provide the individual, parent or carer with the following advice:</p> <ul style="list-style-type: none"> ➤ the dose, frequency and method of administration. ➤ to swallow the capsules whole with plenty of fluid during meals in either the sitting or standing position. ➤ to not take on an empty stomach because of the risk of oesophagitis. ➤ to not lie down within an hour of taking the medication, so not to take at bedtime. ➤ to not take indigestion remedies or medicines containing aluminium, calcium, iron, magnesium zinc or bismuth, 2 to 3 hours before or after taking the medicine. ➤ if gastric irritation occurs, the capsules may be taken with milk. ➤ if a dose is missed, advise to refer to the PIL supplied with the product. ➤ to space the doses evenly throughout the day. ➤ to avoid exposure to direct sunlight or ultraviolet light including sunbeds and sun lamps. If unavoidable, advise to cover up and use high SPF sun cream. ➤ to avoid alcohol. ➤ to keep taking this medicine until the course is finished, unless they are told to stop. ➤ to return any unused medication at the end of the course to a community pharmacy for destruction.

<p>Advice / follow up treatment (continued)</p>	<p>For individuals with conditions listed in the cautions section, provide the additional recommended advice.</p> <p>Inform the individual, parent or carer:</p> <ul style="list-style-type: none"> ➤ to read the PIL provided with the medicine. ➤ of possible side effects and their management. ➤ to seek medical advice if side effects or any other unexplained effects on health are experienced. ➤ if side effects become serious, severe or prolonged, or if the individual notices any side effects not listed in the PIL to contact a GP or pharmacist immediately. ➤ if symptoms compatible with anthrax infection develop to seek medical advice immediately. ➤ when the subsequent supply is due and where they can get the supply.
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> ➤ whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005. ➤ name of individual, address, date of birth, allergies, and GP with whom the individual is registered (or record where an individual is not registered with a GP). ➤ name of member of staff who supplied the product. ➤ name and brand of the product. ➤ date of supply. ➤ dose, form and route of administration of the product. ➤ quantity supplied. ➤ batch number and expiry date. ➤ advice given; including advice given if the individual is excluded or the individual or the parent or carer declines treatment. ➤ details of any adverse drug reactions and actions taken. ➤ that the product was supplied via PGD. <p>All records should be signed and dated (or password-controlled on records). 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 doxycycline or an alternative antibiotic, where appropriate.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

PGD for the further supply of doxycycline for post-exposure prophylaxis to anthrax in adults and children aged 12 years and above

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Where continuing chemoprophylaxis is required following a known exposure to a deliberate release of anthrax.</p> <p>Notes:</p> <p>Use doxycycline wherever possible, reserving continuity of prophylaxis with ciprofloxacin for children under 12 years of age.</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on anthrax, including post-exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Adults and children aged 12 years and over following exposure to a known deliberate release of anthrax</p> <p>AND</p> <p>who have already received chemoprophylaxis for 10 days with doxycycline or ciprofloxacin</p> <p>AND</p> <p>are not showing symptoms compatible with anthrax infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below and the chemical, biological, radiological and nuclear (CBRN) incident guidance for symptoms.</p>
<p>Exclusion criteria⁹ (continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they are under 12 years of age. ➤ they are pregnant or suspected to be pregnant as doxycycline affects teeth and bone growth in the baby, notably in the second and third trimester. ➤ they are currently breastfeeding. ➤ they have known severe liver impairment. ➤ they have a known history of severe allergic reaction to doxycycline or other tetracyclines or to any of the listed excipients. See SmPC ➤ they have experienced unacceptable side effects while taking the initial ten days' supply of doxycycline. ➤ they are receiving systemic retinoid treatment (for example acitretin, alitretinoin, isotretinoin, tretinoin) due to possible increased risk of benign intracranial hypertension when tetracyclines are given with retinoids.

⁹ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

<p>Exclusion criteria (continued)</p>	<ul style="list-style-type: none"> ➤ they are taking enzyme inducing anti-epileptic medicines (carbamazepine, fosphenytoin, phenobarbitone / phenobarbital, primidone, phenytoin) as effectiveness of doxycycline may be reduced. ➤ they have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained). <p>See action to be taken if the individual is excluded section.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>For individuals where the following cautions apply, supply doxycycline unless there are life-threatening contraindications as benefit outweighs risk in the case of a deliberate release of anthrax. 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>1. Myasthenia gravis:</p> <p>Advise to self-monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise individuals to seek urgent medical attention.</p> <p>Note: ciprofloxacin is also cautioned for individuals with myasthenia gravis.</p> <p>2. Systemic lupus erythematosus (SLE):</p> <p>Consider supply of ciprofloxacin (see ciprofloxacin further supply PGD) if no contra-indications or advise to self-monitor for any increase in severity of SLE. If increase in severity of SLE occurs advise individual to seek medical advice.</p> <p>3. Liver impairment:</p> <p>Doxycycline has been associated with rare incidents of hepatic injury. Manufacturers advise caution in those with liver impairment or those receiving potentially hepatotoxic medicines. Those with known severe liver impairment are excluded from this PGD (see exclusion criteria).</p> <p>4. Chronic alcohol dependence:</p> <p>Alcohol may reduce the half-life of doxycycline, particularly for individuals with chronic alcohol dependence. Twice daily dosing may reduce the significance of this interaction. If ciprofloxacin is contraindicated, advise of risk and to seek immediate medical advice if symptoms compatible with anthrax infection develop.</p> <p>5. Severely immunocompromised individuals:</p> <p>Individuals who are severely immunocompromised (as defined in chapter 28a Green book) should be advised to arrange an appointment with a GP or specialist to determine whether they need to continue treatment beyond the course outlined in this PGD.</p> <p>6. Taking vitamin K antagonists (for example, warfarin, phenindione and acenocoumarol):</p> <p>Advise individual to arrange for INR to be monitored 3-5 days after starting</p>

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained/excessive bruising.</p> <p>Note: INR also needs to be monitored with ciprofloxacin.</p> <p>7. Taking penicillin: Doxycycline may reduce the effect of penicillin. For individuals taking penicillin for a serious infection, seek advice from the supervising doctor.</p> <p>8. Taking ciclosporin or lithium: Consider supply of ciprofloxacin (see ciprofloxacin further supply PGD) if appropriate or advise individual to contact the service who prescribe / monitor the affected medicines to arrange monitoring and any dose adjustments. Advise to be aware of any signs of toxicity.</p> <p>9. Already taking doxycycline or other tetracycline for another condition: Advise individual to stop their existing course. They should now take doxycycline at the dose and frequency outlined in this PGD. If doxycycline or another tetracycline has previously been prescribed for ongoing treatment, the individual can be advised to continue at the previous dose once the course for anthrax post-exposure prophylaxis is complete.</p> <p>Refer to the SmPC for doxycycline for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ Consider supply of ciprofloxacin (see ciprofloxacin further supply PGD). ➤ Where ciprofloxacin is contraindicated refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics. ➤ Document reasons for exclusion and any referrals that have been made.
<p>Action to be taken if the individual, parent or carer declines prophylaxis (continued over page)</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual, parent or their carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if they develop symptoms compatible with anthrax infection or signs or symptoms of sepsis. ➤ Symptoms of anthrax will depend on the type of exposure as follows: <ul style="list-style-type: none"> ○ Inhalational: flu-like illness (fever, malaise, nausea / vomiting, headache, non-productive cough). ○ Cutaneous: initial pimple / pauple that enlarges, blisters, ulcerates over 2 to 6 days to form a black scab. ○ Gastrointestinal: severe abdominal pain, nausea, vomiting, bloody diarrhoea.

<p>Action to be taken if the individual, parent or carer declines prophylaxis (continued)</p>	<ul style="list-style-type: none"> ➤ See CRBN guidance for further information on symptoms to be aware of depending on the type of exposure. ➤ Document the advice given and the decision reached.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising doctor and / or other services.</p>



2. Description of treatment

Name, strength & formulation of drug	Doxycycline 100 mg capsules
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Anthrax post exposure prophylaxis is not included under the therapeutic indications in the SmPC but is recommended in the guidance on CBRN incidents.</p> <p>Where a product is recommended off-label consider, as part of the consent process, informing the individual, parent or carer the product is being offered in accordance with national guidance, but this is outside the product licence.</p>
Route / method of administration	<p>Oral</p> <p>To be swallowed whole with a full glass of water, in either the sitting or standing position. It can be taken with food or milk to reduce the risk of gastric irritation.</p>
Dose and frequency of administration	<p>ONE capsule (100 mg) to be taken TWICE a day</p> <p>For individuals who are unable to swallow the capsules, refer to the supervising doctor for assessment and consideration of alternative antibiotics or formulation.</p>
Duration of treatment	20 days following an initial 10-day supply of antibiotics.
Quantity to be supplied	<p>40 (forty) capsules OR</p> <p>supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise the individual or their parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>
Storage	Store in original container below 25°C.

<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>
<p>Drug interactions</p>	<p>This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNE.</p> <p>Contraindications</p> <ul style="list-style-type: none"> ➤ individuals taking systemic retinoids and enzyme-inducing anti-epileptics are excluded from this PGD (see exclusion criteria). <p>Cautions</p> <ul style="list-style-type: none"> ➤ individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be advised to contact the administering clinic or GP as soon as possible for advice as doxycycline may reduce the efficacy of these vaccines. ➤ anticoagulants, vitamin K antagonists, ciclosporin, lithium penicillin, alcohol: see cautions for advice to be given. ➤ antacids, aluminium, calcium, iron, magnesium, bismuth and zinc salts: greatly decrease the absorption of doxycycline. Administration should be separated by 2 to 3 hours. <p>Oral contraceptives.</p> <p>Doxycycline does not reduce their efficacy but if it makes them vomit or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).</p>
<p>Identification & management of adverse reactions</p> <p>(continued over page)</p>	<p>A detailed list of adverse reactions is available in the SmPC.</p> <p>Advise the individual that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999:</p> <ul style="list-style-type: none"> ➤ allergic reactions such as sudden difficulty with breathing, speaking and swallowing. ➤ extreme dizziness or fainting. ➤ severe itchy skin rash especially if blistering, soreness of the eyes, mouth or genital organs. <p>Commonly reported side effects include:</p> <ul style="list-style-type: none"> ➤ nausea, vomiting and headache. ➤ hypersensitivity reactions. ➤ photosensitivity and rash including maculopapular and erythematous rashes. <p>Advise individuals to take doxycycline after food or with a drink of milk instead of water to help with nausea.</p>

<p>Identification & management of adverse reactions</p> <p>(continued)</p>	<p>To help with photosensitivity, advise individuals to wear clothes that cover them up and a hat and sunglasses when going outside. Advise they use a high SPF sunscreen of at least 30 to prevent any sunburn.</p> <p>If individuals are concerned about other side effects, they should be advised to continue with treatment and contact a GP or pharmacist.</p>
<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Any serious adverse reaction to the medicine should be documented in the individual's record and the individual's GP informed.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p>
<p>Advice / follow up treatment</p> <p>(continued over page)</p>	<p>Provide the individual, parent or carer with the following advice:</p> <ul style="list-style-type: none"> ➤ the dose, frequency and method of administration. ➤ to swallow the capsules whole with plenty of fluid during meals in either the sitting or standing position. ➤ to not take on an empty stomach because of the risk of oesophagitis. ➤ to not lie down within an hour of taking the medication, so not to take at bedtime. ➤ to not take indigestion remedies or medicines containing aluminium, calcium, iron, magnesium, zinc or bismuth, 2 to 3 hours before or after taking the medicine. ➤ if gastric irritation occurs, the capsules may be taken with milk. ➤ if a dose is missed, advise to refer to the PIL supplied with the product. ➤ to space the doses evenly throughout the day. ➤ to avoid exposure to direct sunlight or ultraviolet light including sunbeds and sun lamps. If unavoidable, advise to cover up and use high SPF sun cream. ➤ to avoid alcohol. ➤ to keep taking this medicine until the course is finished, unless they are told to stop. ➤ to return any unused medication at the end of the course to a community pharmacy for destruction. <p>For individuals with conditions listed in the cautions section, provide the additional recommended advice.</p>

<p>Advice / follow up treatment (continued)</p>	<p>Inform the individual, parent or carer:</p> <ul style="list-style-type: none"> ➤ to read the PIL provided with the medicine. ➤ of possible side effects and their management. ➤ to seek medical advice if side effects or any other unexplained effects on health are experienced. ➤ if side effects become serious, severe or prolonged, or if the individual notices any side effects not listed in the PIL to contact a GP or pharmacist immediately. ➤ if symptoms compatible with anthrax infection develop to seek medical advice immediately. ➤ to return any unused medicine to a pharmacy.
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> ➤ whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005. ➤ name of individual, address, date of birth, allergies, and GP with whom the individual is registered (or record where an individual is not registered with a GP). ➤ name of member of staff who supplied the product. ➤ name and brand of the product. ➤ date of supply. ➤ dose, form and route of administration of the product. ➤ quantity supplied. ➤ batch number and expiry date. ➤ advice given; including advice given if the individual is excluded or the individual, parent or carer declines treatment. ➤ details of any adverse drug reactions and actions taken. ➤ that the product was supplied via PGD. <p>All records should be signed and dated (or password-controlled on records). 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 or an alternative antibiotic, where appropriate.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

PGD for the supply of ciprofloxacin for post-exposure prophylaxis to plague in adults and children aged 12 years and over

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Chemoprophylaxis following exposure to a known or suspected deliberate release of plague (<i>Yersinia pestis</i>).</p> <p>Notes:</p> <p>No follow-on course (further supply) for plague is required.</p> <p>Doxycycline is also indicated for post-exposure prophylaxis to plague. See doxycycline PGD.</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on plague, including post exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Adults and children aged 12 years and over following exposure to a known or suspected deliberate release of plague (<i>Yersinia pestis</i>)</p> <p>AND</p> <p>are not showing symptoms compatible with plague infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance.</p> <p>Note: The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in growing adolescents, pregnant or breastfeeding individuals who should be given ciprofloxacin in the situation criteria set out above.</p>
<p>Exclusion criteria¹⁰</p> <p>(continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they have a known history of severe allergic reaction to ciprofloxacin, other fluoroquinolones or quinolones, or to any of the listed excipients. See SmPC. ➤ they are under 12 years of age. ➤ they have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to a quinolone or fluoroquinolone antibiotic. ➤ they have a history of tendon disorders related to ciprofloxacin or other fluoroquinolones or quinolones. ➤ they are taking an interacting medicine as listed in the drug interactions section of this PGD. ➤ they have known chronic kidney disease (CKD) stages 4 or 5 (eGFR <30 mL/min/1.73m²) or are on dialysis.

¹⁰ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

<p>Exclusion criteria (continued)</p>	<p>➤ they have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained).</p> <p>See action to be taken if individual is excluded section of this PGD.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>Caution is advised for individuals with the following conditions or who are taking certain medicines.</p> <p>Note: Doxycycline is the preferred option for these individuals if it is not contraindicated and is available. See the doxycycline PGD.</p> <p>If doxycycline is contraindicated, or not available then ciprofloxacin can be supplied as the benefit of taking it to prevent plague infection outweighs the risk in the case of a deliberate release of plague. 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>1. At increased risk of tendinitis or tendon rupture:</p> <ul style="list-style-type: none"> ➤ over 60 years of age. ➤ have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD). ➤ are taking corticosteroids. ➤ have a solid organ transplant. <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>2. Conditions with risk factor for QT interval prolongation:</p> <ul style="list-style-type: none"> ➤ cardiac disease (for example, heart failure, myocardial infarction, bradycardia). ➤ congenital long QT syndrome. ➤ history of symptomatic arrhythmias. ➤ concomitant use of medicines known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics). ➤ electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia). <p>Advise to monitor for the exacerbation of or development of symptoms associated with QT interval prolongation. If symptoms develop, advise individuals to seek immediate medical advice for assessment and consideration of alternative antibiotics.</p> <p>3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:</p> <ul style="list-style-type: none"> ➤ a positive family history of aneurysm disease or congenital heart valve disease. ➤ pre-existing aortic aneurysm and/or aortic dissection or heart valve disease.

Cautions (including relevant actions to be taken)

(continued)

- presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation / incompetence, such as:
 - connective tissue disorders such as Marfan’s syndrome or Ehlers-Danlos syndrome.
 - Turner syndrome.
 - Behçet’s disease.
 - hypertension.
 - rheumatoid arthritis.
- presence of other risk factors or conditions for aortic aneurysm and dissection, such as:
 - vascular disorders including Takayasu arteritis or giant cell arteritis.
 - known atherosclerosis.
 - Sjögren’s syndrome.
- heart valve regurgitation / incompetence caused, for example, by infective endocarditis.

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.

Advise to seek immediate medical attention by dialling 111 or via a 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.

4. Epilepsy or conditions that predispose to seizures and/or those taking medication that may predispose to seizures (for example NSAIDs):

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.

5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):

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.

6. G6PD deficiency:

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.

(continued over page)

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>7. Myasthenia gravis: Advise to self-monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise individuals to seek urgent medical advice. Note: doxycycline is also cautioned for individuals with myasthenia gravis.</p> <p>8. Severely immunocompromised individuals: Individuals who are severely immunocompromised (as defined in chapter 28a Green book) should be advised to arrange an appointment with a GP or specialist before the end of the course to determine whether they need to continue treatment beyond the course outlined in this PGD.</p> <p>9. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol): Advise individual to arrange for INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising. Note: INR also needs to be monitored with doxycycline.</p> <p>10. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine: Advise individuals 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. Refer to the SmPC for ciprofloxacin for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual, parent or their carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if they develop symptoms of plague and any signs or symptoms of sepsis. ➤ Symptoms of pneumonic plague include: <ul style="list-style-type: none"> ○ fever, chills, sweats, headache, severe malaise, vomiting, diarrhoea, cough, increasing dyspnoea, watery sputum (may be bloody), associated chest pain. ➤ See CRBN guidance for further information on symptoms. ➤ Document the advice given and the decision reached.

<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ Consider supply of doxycycline (see doxycycline PGD). ➤ If doxycycline is contraindicated, refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics. ➤ Document reasons for exclusion and any referrals that have been made.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising doctor and / or other services.</p>



2. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 500mg tablets
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Yes: Ciprofloxacin tablets are not licensed for use in plague. UK national guidance recommends its use.</p> <p>Manipulating solid dosage forms</p> <p>Tablets (not suspension) are the preferred formulation for children aged 12 years and older unless they have medically confirmed swallowing difficulties.</p> <p>In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.</p> <p>Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.</p> <p>The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away.</p> <p>Pregnancy</p> <p>The manufacturers advise as a precautionary measure to avoid the use of ciprofloxacin during pregnancy. However, the data available suggests administration of ciprofloxacin to pregnant women indicates no malformative or fetoneonatal toxicity but the SmPC 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 the disease outweigh these potential risks in pregnancy. A patient information leaflet for ciprofloxacin in pregnancy is available here: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org).</p> <p>Breastfeeding</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</p>

(continued over page)

<p>Off-label use (continued)</p>	<p>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. See patient advice section</p> <p>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.</p>
<p>Route / method of administration</p>	<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>
<p>Dose and frequency of administration</p>	<p>Adults and children aged 12 years or over</p> <p>ONE tablet (500 mg) to be taken TWICE a day</p> <p>Administration should begin as soon as possible after suspected or confirmed exposure.</p> <p>For individuals who are unable to swallow the tablets, refer to the off-label section of the PGD.</p>
<p>Duration of treatment</p>	<p>7 days</p>
<p>Quantity to be supplied</p>	<p>14 (fourteen) tablets.</p> <p>Instruct the individual to take ONE tablet TWICE daily for 7 days only (that is 14 tablets in total).</p> <p>Note: No follow-on course for plague is required.</p> <p>OR</p> <p>supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the 7-day course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise individual or their parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>

<p>Storage</p>	<p>Store in original container below 25°C.</p>															
<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>															
<p>Drug interactions</p>	<p>Concurrent medications should be checked for interactions. This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p> <p>Contraindications</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 doxycycline PGD) refer individuals to the supervising doctor.</p> <ul style="list-style-type: none"> ➤ agomelatine. ➤ domperidone. ➤ ergometrine, ergotamine or dihydroergotamine. ➤ fezolinetant. ➤ tizanidine. <p>The following medicines may require dose adjustments. If doxycycline is contraindicated (see doxycycline PGD), individuals should be referred to the supervising doctor:</p> <table border="0"> <tr> <td>➤ olanzapine</td> <td>➤ tolvaptan</td> <td>➤ ropinirole</td> </tr> <tr> <td>➤ capivasertib</td> <td>➤ daridorexant</td> <td>➤ guanfacine</td> </tr> <tr> <td>➤ elacestrant</td> <td>➤ venetoclax</td> <td>➤ pifenidone</td> </tr> <tr> <td>➤ eliglustat</td> <td>➤ zanubrutinib</td> <td>➤ pomalidomide</td> </tr> <tr> <td>➤ ibrutinib</td> <td></td> <td></td> </tr> </table> <p>Cautions</p> <p>Individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be referred to the supervising doctor for assessment and 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, anagrelide, chlorpromazine, duloxetine, melatonin, rasagiline, riluzole, roflumilast, sildenafil). Advise individuals to be alert to any increase in adverse effects and to speak to their usual healthcare provider as soon as possible if side effects occur.</p> <p>Individuals taking zolmitriptan should be advised that a maximum dose of 5mg of zolmitriptan should be taken in any 24-hours.</p> <p>See cautions 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>(continued over page)</p>	➤ olanzapine	➤ tolvaptan	➤ ropinirole	➤ capivasertib	➤ daridorexant	➤ guanfacine	➤ elacestrant	➤ venetoclax	➤ pifenidone	➤ eliglustat	➤ zanubrutinib	➤ pomalidomide	➤ ibrutinib		
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➤ ibrutinib																

<p>Drug interactions (continued)</p>	<p>Ciprofloxacin should be given 2 hours before, or 4 hours after sevelamer, lanthanum, sucralfate, antacids and any medicines or supplements containing calcium, magnesium, aluminium, iron or zinc that may reduce the absorption of ciprofloxacin.</p> <p>Oral contraceptives.</p> <p>Ciprofloxacin does not reduce their efficacy but if it makes them vomit or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).</p>
<p>Identification & management of adverse reactions</p>	<p>Although there are some potential and serious side effects, the benefit of using ciprofloxacin to prevent disease associated with plague 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"> ➤ anaphylaxis (delayed or immediate). ➤ sudden, severe pain in the stomach, chest or back. ➤ seizures. ➤ thoughts about harming themselves or ending their life. <p>Advise individuals to stop taking ciprofloxacin immediately and seek urgent medical advice by calling a GP or 111 if any of the following rare effects occur:</p> <ul style="list-style-type: none"> ➤ changes to vision, taste, smell or hearing. ➤ signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach). ➤ symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking). ➤ diarrhoea that lasts more than 4 days or contains blood or mucus. ➤ sudden breathlessness, especially when lying down. ➤ new onset heart palpitations. ➤ swollen ankles, feet or stomach. ➤ 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). ➤ pain, swelling or inflammation of joints such as the shoulders, arms or legs or tendon pain or swelling. <p>A detailed list of adverse reactions is available in the SmPC.</p>

<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Alert the supervising doctor in the event of a serious adverse reaction to the medicine, document in the individual's record and inform the individual's GP.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p> <p>Consider providing the MHRA information leaflet on side effects.</p>
<p>Advice / follow up treatment</p> <p>(continued over page)</p>	<p>Explain the treatment.</p> <p>Advise the individual, parent or carer to:</p> <ul style="list-style-type: none"> ➤ drink plenty of fluids. ➤ not take indigestion remedies, sevelamer, lanthanum, sucralfate or medicines containing calcium, magnesium, aluminium, iron or zinc 2 hours before or 4 hours after taking the medicine. ➤ not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice). ➤ 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. ➤ not chew the tablets. ➤ space the doses evenly throughout the day. ➤ keep taking the medicine until the course is finished, unless they are told to stop. ➤ not give the tablets to anyone else. ➤ return any unused tablets at the end of the course to a community pharmacy for destruction. <p>Inform individual, parent or carer:</p> <ul style="list-style-type: none"> ➤ of possible side effects and their management. ➤ 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. ➤ 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.

<p>Records (continued)</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> <p>For pregnant women record the medicine supplied in the hand-held maternity record (if available).</p>
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PGD for the supply of ciprofloxacin for post-exposure prophylaxis to plague in children aged under 12 years

1. Clinical Condition

Clinical condition or situation to which this PGD applies	<p>Chemoprophylaxis following exposure to a known or suspected deliberate release of plague (<i>Yersinia pestis</i>).</p> <p>Notes:</p> <p>No follow-on course (further supply) for plague is required.</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on plague, including post exposure prophylaxis, see CBRN guidance.</p>
Inclusion criteria	<p>Children aged from 4 weeks to less than 12 years of age, following exposure to a known or suspected deliberate release of plague (<i>Yersinia pestis</i>)</p> <p>AND</p> <p>are not showing symptoms compatible with plague infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance.</p> <p>Note: The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in children, who should be given ciprofloxacin in the situation criteria set out above.</p>
Exclusion criteria¹¹	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they are aged 12 years or over (see ciprofloxacin supply PGD for over 12s). ➤ they are less than 4 weeks of age. ➤ they are known to be outside of weight range for age¹². ➤ they have a known history of severe allergic reaction to ciprofloxacin, other quinolones or fluoroquinolones, or to any of the listed excipients. See SmPC. ➤ they have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to quinolone or fluoroquinolone antibiotic use. ➤ they have a history of tendon disease / disorder related to ciprofloxacin or other quinolone or fluoroquinolone antibiotic use. ➤ they are taking an interacting medicine as listed in the drug interactions section of this PGD. <p>(continued over page)</p>
Exclusion criteria	<ul style="list-style-type: none"> ➤ they have known chronic kidney disease (CKD) stages 4 or 5 (eGFR

¹¹ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

¹² See [British National Formulary for Children](#) (BNFC)

<p>(continued)</p>	<p><30 mL/min/1.73m²) or are on dialysis.</p> <ul style="list-style-type: none"> ➤ their parent or carer has not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained). <p>See action to be taken if individual is excluded section of this PGD.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>Although caution is advised for individuals with the following conditions or who are taking certain medicines, the benefits of taking ciprofloxacin to prevent plague outweighs the risk following a suspected or known deliberate release of plague.</p> <p>Provide the child’s parent or carer 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>1. At increased risk of tendinitis or tendon rupture:</p> <ul style="list-style-type: none"> ➤ have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD). ➤ are taking corticosteroids. ➤ have a solid organ transplant. <p>Advise parents or carers to monitor for tendinitis (for example, painful swelling, inflammation). In young children who may not be able to report pain, be alert to lack of use of limbs or signs of pain on movement. If signs of tendinitis occur, advise that the parent or carer stops giving ciprofloxacin and to seek immediate medical advice by dialling 111 or the child’s GP for assessment.</p> <p>2. Conditions with risk factor for QT interval prolongation:</p> <ul style="list-style-type: none"> ➤ cardiac disease (for example, heart failure, myocardial infarction, bradycardia). ➤ congenital long QT syndrome. ➤ history of symptomatic arrhythmias. ➤ concomitant use of medicines known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics). ➤ electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia). <p>Advise parents or carers to monitor for the exacerbation of or development of symptoms associated with QT interval prolongation. If symptoms develop, advise parents or carers to stop giving ciprofloxacin and to seek immediate medical advice for assessment and consideration of alternative antibiotics.</p> <p>3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:</p> <ul style="list-style-type: none"> ➤ a positive family history of aneurysm disease or congenital heart valve disease.

Cautions (including relevant actions to be taken)

(continued)

- pre-existing aortic aneurysm and/or aortic dissection or heart valve disease.
- presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation / incompetence:
 - connective tissue disorders such as Marfan's syndrome or Ehlers-Danlos syndrome.
 - Turner syndrome.
 - Behçet's disease.
 - hypertension.
 - rheumatoid arthritis.
- presence of other risk factors or conditions for aortic aneurysm and dissection:
 - vascular disorders including Takayasu arteritis or giant cell arteritis.
 - known atherosclerosis.
 - Sjögren's syndrome.
- heart valve regurgitation / incompetence caused, for example, by infective endocarditis

Advise parents or carers of the possibility of these rare events, and to seek urgent medical attention by dialling 999 if the child develops sudden-onset severe abdominal, chest or back pain.

Advise parents or carers to seek immediate medical attention by dialling 111 or via the GP if the child experiences 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.

4. Epilepsy or conditions that predispose to seizures and/or those taking medication that may predispose to seizures (for example NSAIDs):

Advise parents or carers to monitor for any increase in frequency or severity of seizures. If an increase in frequency or severity of seizures occurs, advise parents or carers to stop giving ciprofloxacin and seek urgent medical attention. Advise parents or carers to avoid giving an NSAID where possible (for example, ibuprofen) whilst taking ciprofloxacin.

5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):

Disturbances in blood glucose can occur. Advise parents or carers to carefully monitor blood glucose during treatment, to be alert to symptoms of hypoglycaemia and hyperglycaemia and to seek medical advice if required.

6. G6PD deficiency:

There is a risk of haemolysis when ciprofloxacin is given to individuals with G6PD deficiency. If ciprofloxacin must be used, advise the parent or carer to monitor for signs of haemolysis. If signs of haemolysis develop, advise to stop giving ciprofloxacin and to seek urgent medical advice.

(continued over page)

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>7. Myasthenia gravis:</p> <p>Advise parents or carers to monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise that they seek urgent medical advice.</p> <p>Note: doxycycline is also cautioned for individuals with myasthenia gravis.</p> <p>8. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol):</p> <p>Advise parents or carers to arrange for the child’s INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising.</p> <p>Note: INR also needs to be monitored with doxycycline.</p> <p>9. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine:</p> <p>Advise parents or carers to 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>10. Severely immunocompromised individuals:</p> <p>Individuals who are severely immunocompromised (as defined in chapter 28a Green Book) should be advised to arrange an appointment with the child’s GP or specialist before the end of the course to determine whether they need to continue treatment beyond the course outlined in this PGD.</p> <p>Refer to the SmPC for ciprofloxacin for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the parent or carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if children develop symptoms compatible with plague or signs or symptoms of sepsis. ➤ Symptoms of pneumonic plague include: <ul style="list-style-type: none"> ○ fever, chills, sweats, headache, severe malaise, vomiting, diarrhoea, cough, increasing dyspnoea, watery sputum (may be bloody), associated chest pain. ➤ See CRBN guidance for further information on symptoms. ➤ Document the advice given and the decision reached.

<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ If they are aged 12 years or over, refer to the ciprofloxacin PGD for adults and children 12 years and over. ➤ If excluded for other reasons, refer to the supervising doctor for assessment. ➤ If they are 8 years and over, consider doxycycline. See doxycycline PGD. ➤ If the child is under weight for their age range, refer to the supervising doctor. If a different dose of ciprofloxacin for their age range is required, a Patient Specific Direction (PSD) will be needed. ➤ Document reasons for exclusion and any referrals that have been made.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising doctor and / or other services.</p>

2. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 100 mg tablets, 250 mg tablets, 500 mg tablets, 250 mg in 5 mL suspension																
Legal category	Prescription Only Medicine (POM)																
Black triangle▼	No																
Off-label use	<p>Yes</p> <p>Ciprofloxacin tablets are not licensed for use in plague. UK national guidance recommends its use.</p> <p>The SmPC states dosing is mg/kg, but UK national guidance recommends age banding as per the RCPH and UK-WHO growth charts.</p> <p>Manipulating solid dosage forms</p> <p>Tablets (not suspension) are the preferred formulation for children aged 2 years and older unless they have medically confirmed swallowing difficulties.</p> <p>In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.</p> <p>Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.</p> <p>The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away.</p> <p>Where a product is recommended off-label consider, as part of the consent process, informing the parent or carer that the product is being offered in accordance with national guidance but that this is outside the product licence.</p>																
Route / method of administration	<p>Oral</p> <p>Tablets 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>																
Dose and frequency of administration	<p>Doses to be taken TWICE a day – see dosage table below.</p> <table border="1"> <thead> <tr> <th>Age</th> <th>Dose (mg)</th> <th>Dose (volume or quantity)</th> </tr> </thead> <tbody> <tr> <td>Less than 4 weeks of age</td> <td colspan="2">Excluded</td> </tr> <tr> <td>4 weeks to less than 8 weeks of age</td> <td>50 mg TWICE a day</td> <td>1 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>8 weeks to less than 6 months of age</td> <td>75 mg TWICE a day</td> <td>1.5 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>6 months to less than 1 year of age</td> <td>100 mg TWICE a day</td> <td>2 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> </tbody> </table> <p>(continued over page)</p>		Age	Dose (mg)	Dose (volume or quantity)	Less than 4 weeks of age	Excluded		4 weeks to less than 8 weeks of age	50 mg TWICE a day	1 mL of 250 mg in 5 mL suspension TWICE a day	8 weeks to less than 6 months of age	75 mg TWICE a day	1.5 mL of 250 mg in 5 mL suspension TWICE a day	6 months to less than 1 year of age	100 mg TWICE a day	2 mL of 250 mg in 5 mL suspension TWICE a day
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<p>Dose and frequency of administration (continued)</p>	<table border="1"> <thead> <tr> <th>Age</th> <th>Dose (mg)</th> <th>Dose (volume or quantity)</th> </tr> </thead> <tbody> <tr> <td>1 year to less than 2 years of age</td> <td>150 mg TWICE a day</td> <td>3 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>2 years to less than 4 years of age</td> <td>200 mg TWICE a day</td> <td>4 mL of 250 mg in 5 mL suspension TWICE a day or TWO 100mg tablets TWICE a day</td> </tr> <tr> <td>4 years to less than 8 years of age</td> <td>250 mg TWICE a day</td> <td>5 mL of 250 mg in 5 mL suspension TWICE a day or ONE 250 mg tablet TWICE a day</td> </tr> <tr> <td>8 years to less than 12 years of age</td> <td>500 mg TWICE a day</td> <td># TWO 250 mg tablets TWICE a day or ONE 500 mg tablet TWICE a day</td> </tr> </tbody> </table>	Age	Dose (mg)	Dose (volume or quantity)	1 year to less than 2 years of age	150 mg TWICE a day	3 mL of 250 mg in 5 mL suspension TWICE a day	2 years to less than 4 years of age	200 mg TWICE a day	4 mL of 250 mg in 5 mL suspension TWICE a day or TWO 100mg tablets TWICE a day	4 years to less than 8 years of age	250 mg TWICE a day	5 mL of 250 mg in 5 mL suspension TWICE a day or ONE 250 mg tablet TWICE a day	8 years to less than 12 years of age	500 mg TWICE a day	# TWO 250 mg tablets TWICE a day or ONE 500 mg tablet TWICE a day
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<p># See off label section for advice on manipulating solid dose forms in swallowing difficulty.</p>																
<p>Duration of treatment</p>																
<p>Seven (7) days</p>																
<p>Quantity to be supplied</p>																
<p>Suspension:</p> <p>1 x 100 mL suspension should be supplied per child irrespective of dose A bottle of suspension must be discarded 14 days after reconstitution.</p> <p>100 mg tablets:</p> <p>Children aged 2 years to less than 4 years of age: 40 tablets</p> <p>Instruct the parent or carer to give TWO tablets TWICE daily for 7 days only (that is 28 tablets in total) and to take the remaining tablets to a community pharmacy for disposal.</p> <p>250 mg tablets:</p> <p>Children aged 4 years to less than 8 years: 20 tablets Children aged 8 years to less than 12 years: 30 tablets</p> <p>Instruct the parent or carer to give the appropriate dose for 7 days only and to take the remaining tablets to a community pharmacy for disposal.</p> <p>500 mg tablets:</p> <p>Children aged 8 years to less than 12 years: 20 tablets</p> <p>Instruct the parent or carer to give ONE tablet TWICE daily for 7 days only (that is 14 tablets in total) and to take the remaining tablets to a community pharmacy for disposal.</p> <p>Note: No follow-on course for plague is required.</p> <p>OR</p> <p>Supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the 7-day course.</p> <p>➤ Pack sizes may vary subject to availability. Original packs should not be split.</p>																
<p>(continued over page)</p>																

<p>Quantity to be supplied (continued)</p>	<ul style="list-style-type: none"> ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual’s name, the date and additional instructions must be written on the label at the time of supply. <p>Advise the parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>
<p>Additional information</p>	<p>Tablets (not suspension) are the preferred formulation for children aged 2 years and older unless they have medically confirmed swallowing difficulties.</p> <p>The suspension must be reconstituted according to the manufacturer’s instructions before handing to parent / carer or other responsible person.</p> <p>Supply an oral syringe with the suspension and instructions for using the syringe.</p> <p>The suspension should not be administered through a nasogastric tube because of the risk of blocking the tube. Refer to the supervising doctor.</p> <p>The suspension should not be given to individuals with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or saccharose-isomaltase deficiency. Refer to the supervising doctor.</p> <p>As the reconstituted suspension only lasts 14 days, any remaining solution should be taken to a community pharmacy for destruction.</p>
<p>Storage</p>	<p>Store in original container below 25°C.</p> <p>Reconstituted suspension may either be stored at ambient temperatures up to 30°C or it can be stored in a refrigerator.</p>
<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant <u>local policy or guidance</u>.</p>
<p>Drug interactions (continued over page)</p>	<p>Concurrent medications should be checked for interactions. This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p> <p>Contraindications</p> <p>Where it is known an individual is concurrently taking one of the following medicines, ciprofloxacin should not be supplied under this PGD. Refer individuals to the supervising doctor.</p> <ul style="list-style-type: none"> ➤ agomelatine. ➤ domperidone. ➤ ergometrine, ergotamine or dihydroergotamine. ➤ fezolinetant. ➤ tizanidine.



<p>Identification & management of adverse reactions (continued)</p>	<p>Advise parents or carers to be alert to the possibility of the following rare effects, and to stop giving ciprofloxacin to their child immediately and seek urgent medical advice by calling a GP or 111 if the child experiences any of the following:</p> <ul style="list-style-type: none"> ➤ pain, swelling or inflammation of joints such as the shoulders, arms or legs or tendon pain or swelling. Very young children may not be able to report specific joint pain, so parents and carers should be alert to other signs such as lack of use of limbs or pain on movement. ➤ diarrhoea that lasts more than 4 days or contains blood or mucus. ➤ changes to vision, taste, smell or hearing. ➤ signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach). ➤ symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking). ➤ sudden breathlessness, especially when lying down. ➤ new onset heart palpitations. ➤ swollen ankles, feet or stomach. ➤ 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). <p>A detailed list of adverse reactions is available in the SmPC.</p>
<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Alert the supervising doctor in the event of a serious adverse reaction to the medicine, document in the individual's record and inform the individual's GP.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p> <p>An information leaflet explaining how to use and clean the oral syringe.</p> <p>Consider providing the MHRA information leaflet on side effects.</p>
<p>Advice / follow up treatment (continued over page)</p>	<p>Explain the treatment.</p> <p>Advise the parent or carer the child should:</p> <ul style="list-style-type: none"> ➤ maintain adequate fluid intake. ➤ not take indigestion remedies or medicines containing calcium, magnesium, aluminium, iron or zinc 2 hours before or 4 hours after taking the medicine.

Advice / follow up treatment

(continued)

- not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice).
- space the doses evenly throughout the day.
- keep taking the medicine until the course is finished, unless they are told to stop.

For suspension: Inform the parent or carer:

- to shake the suspension bottle vigorously each time before use for approximately 15 seconds.
- there may be suspension remaining after the initial seven-day course, and to take any remaining unused suspension to a community pharmacy for disposal.

For tablets: Inform the parent or carer:

- these should 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.
- tablets should not be chewed.
- tablets can be crushed if necessary (see [off-label section](#) of this PGD) parents and carers should be advised that the tablets are very bitter in taste, and to encourage their children to swallow the tablets whole where possible.
- any unused tablets should be taken to a community pharmacy for disposal.

Inform the parent or carer:

- for babies receiving milk feeds, to space the doses in the mid period between expected feed times.
- of possible side effects and their management.
- 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.
- the medicine can make the skin more sensitive to direct sunlight. Children should avoid exposure to excessive sunlight or use high SPF sunblock if prolonged exposure to the sun is unavoidable.
- the medicine may cause the child to feel tired or less alert. Children should take care when doing tasks that require coordination (for example, riding a bike) until they get used to the medicine.
- to seek immediate medical attention if the individual develops signs or symptoms compatible with plague or other serious adverse effects (see [identification and management of adverse reactions](#)).

For individuals with conditions listed in the [cautions](#) section, provide the additional recommended advice.

Records

Record:

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

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

All records should be clear, legible and contemporaneous.

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

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

PGD for the supply of doxycycline for post-exposure prophylaxis to plague in adults and children aged 8 years and over

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Chemoprophylaxis following exposure to a known or suspected deliberate release of plague.</p> <p>Notes:</p> <p>Ciprofloxacin is also indicated for post exposure prophylaxis to plague. See supply of ciprofloxacin (12 years and above and under 12s) plague PGDs.</p> <p>For additional information on plague, including post-exposure prophylaxis, see CBRN guidance.</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>No follow-on course (further supply) for plague is required after this initial course.</p>
<p>Inclusion criteria</p>	<p>Adults and children aged 8 years and over following exposure to a known or suspected deliberate release of plague.</p> <p>AND</p> <p>are not showing symptoms compatible with plague infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance for symptoms.</p>
<p>Exclusion criteria¹³</p> <p>(continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they are under 8 years of age. ➤ they are pregnant or suspected to be pregnant as doxycycline affects teeth and bone growth in the baby, notably in the second and third trimester. ➤ they are currently breastfeeding. ➤ they have known severe liver impairment. ➤ they have a known history of severe allergic reaction to doxycycline, other tetracyclines or to any of the listed excipients. See SmPC. ➤ they are receiving systemic retinoid treatment (for example, acitretin, alitretinoin, isotretinoin, tretinoin) due to possible increased risk of benign intracranial hypertension when tetracyclines are given with retinoids. ➤ they are taking enzyme inducing anti-epileptic medicines (carbamazepine, fosphenytoin, phenobarbitone / phenobarbital, primidone, phenytoin) as effectiveness of doxycycline may be reduced.

¹³ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

<p>Exclusion criteria (continued)</p>	<p>➤ they have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained).</p> <p>See action to be taken if the individual is excluded section.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>For individuals where the following cautions apply, supply doxycycline unless there are life-threatening contraindications as benefit outweighs risk in the case of a suspected or deliberate release of plague. Provide affected individuals with the advice given below.</p> <p>Refer to the supervising doctor if concerned about an individual’s risk for assessment and consideration of alternative antibiotics.</p> <p>1. Myasthenia gravis:</p> <p>Advise to self-monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise individuals to seek urgent medical advice.</p> <p>Note: ciprofloxacin is also cautioned for individuals with myasthenia gravis.</p> <p>2. Systemic lupus erythematosus (SLE):</p> <p>Consider supply of ciprofloxacin (see ciprofloxacin initial supply PGD) if no contra-indications or advise to self-monitor for any increase in severity of SLE. If increase in severity of SLE occurs, advise individuals to seek urgent medical advice.</p> <p>3. Liver impairment:</p> <p>Doxycycline has been associated with rare incidents of hepatic injury. Manufacturers advise caution in those with liver impairment or those receiving potentially hepatotoxic medicines. Those with known severe liver impairment are excluded from this PGD (see exclusion criteria).</p> <p>4. Chronic alcohol dependence:</p> <p>Alcohol may reduce the half-life of doxycycline, particularly for individuals with chronic alcohol dependence. Twice daily dosing may reduce the significance of this interaction. If ciprofloxacin is contraindicated, advise of risk and to seek immediate medical advice if symptoms compatible with plague infection develop.</p> <p>5. Severely immunocompromised individuals:</p> <p>Individuals who are severely immunocompromised (as defined in chapter 28a Green book) should be advised to arrange an appointment with their GP or specialist to determine whether they need to continue treatment beyond the course outlined in this PGD.</p> <p>6. Taking vitamin K antagonists (for example, warfarin, phenindione and acenocoumarol):</p> <p>Advise individual to arrange for INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained/excessive bruising.</p> <p>Note: INR also needs to be monitored with ciprofloxacin.</p>

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>7. Taking penicillin: Doxycycline may reduce the effect of penicillin. For individuals taking penicillin for a serious infection, seek advice from the supervising doctor.</p> <p>8. Taking ciclosporin or lithium: Consider supply of ciprofloxacin (see ciprofloxacin initial supply PGD) if appropriate or advise individual to contact the service who prescribe / monitor the affected medicines to arrange monitoring and any dose adjustments. Advise to be aware of any signs of toxicity.</p> <p>9. Already taking doxycycline or other tetracycline for another condition: Advise individual to stop their existing course. They should now take doxycycline at the dose and frequency outlined in this PGD. If doxycycline or another tetracycline has previously been prescribed for ongoing treatment, the individual can be advised to continue at the previous dose once the course for plague post-exposure prophylaxis is complete. If unclear, seek advice from the supervising doctor.</p> <p>Refer to the SmPC for doxycycline for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ Consider supply of ciprofloxacin (see ciprofloxacin supply PGD). ➤ Where ciprofloxacin is contraindicated refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics. ➤ Document reasons for exclusion and any referrals that have been made.
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual, parent or their carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if they develop symptoms compatible with plague infection or signs and symptoms of sepsis, Symptoms of pneumonic plague include: <ul style="list-style-type: none"> ○ fever, chills, sweats, headache, severe malaise, vomiting, diarrhoea, cough, increasing dyspnoea, watery sputum (may be bloody), associated chest pain. ➤ See CRBN guidance for further information on symptoms. ➤ Document the advice given and the decision reached.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising doctor and / or other services.</p>



2. Description of Treatment

Name, strength & formulation of drug	Doxycycline 100 mg capsules
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Plague post-exposure prophylaxis is not included under the therapeutic indications in the SmPC but is recommended in the guidance on CBRN incidents.</p> <p>The dose for 8-12 years is higher than in the SmPC but follows the recommendations in the guidance on CBRN incidents.</p> <p>Where a product is recommended off-label consider, as part of the consent process, informing the individual, parent or carer the product is being offered in accordance with national guidance, but this is outside the product licence.</p>
Route / method of administration	<p>Oral</p> <p>To be swallowed whole with a full glass of water, in either the sitting or standing position. It can be taken with food or milk to reduce the risk of gastric irritation.</p>
Dose and frequency of administration	<p>ONE capsule (100 mg) to be taken TWICE a day</p> <p>For individuals who are unable to swallow the capsules, refer to the supervising doctor for assessment and consideration of alternative antibiotics or formulation.</p>
Duration of treatment	7 (seven) days
Quantity to be supplied	<p>14 (fourteen) capsules OR</p> <p>supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the 7-day course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise individual or their parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>
Storage	Store in original container below 25°C.

<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>
<p>Drug interactions</p>	<p>This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p> <p>Contraindications</p> <ul style="list-style-type: none"> ➤ individuals taking systemic retinoids and enzyme-inducing anti-epileptics are excluded from this PGD (see exclusion criteria). <p>Cautions</p> <ul style="list-style-type: none"> ➤ anticoagulants, vitamin K antagonists, ciclosporin, lithium, penicillin, alcohol: see cautions for advice to be given. ➤ individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be advised to contact the administering clinic or GP as soon as possible for advice as doxycycline may reduce the efficacy of these vaccines. ➤ antacids, aluminium, calcium, iron, magnesium, bismuth and zinc salts: greatly decrease the absorption of doxycycline. Administration should be separated by 2 to 3 hours. <p>Oral contraceptives</p> <p>Doxycycline does not reduce their efficacy but if it makes them vomit or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).</p>
<p>Identification & management of adverse reactions</p> <p>(continued over page)</p>	<p>A detailed list of adverse reactions is available in the SmPC.</p> <p>Advise the individual that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999:</p> <ul style="list-style-type: none"> ➤ allergic reactions such as sudden difficulty with breathing, speaking and swallowing. ➤ extreme dizziness or fainting. ➤ severe itchy skin rash especially if blistering, soreness of the eyes, mouth or genital organs. <p>Commonly reported side effects include:</p> <ul style="list-style-type: none"> ➤ nausea, vomiting and headache. ➤ hypersensitivity reactions. ➤ photosensitivity and rash including maculopapular and erythematous rashes.

<p>Advice / follow up treatment (continued)</p>	<p>Inform the individual, parent or carer:</p> <ul style="list-style-type: none"> ➤ to read the PIL provided with the medicine. ➤ of possible side effects and their management. ➤ to seek medical advice if side effects or any other unexplained effects on health are experienced. ➤ if side effects become serious, severe or prolonged, or if the individual notices any side effects not listed in the PIL to contact a GP or pharmacist immediately. ➤ to only take the medicine for 7 days and return the excess to a community pharmacy for destruction. ➤ if symptoms compatible with plague develop, to seek medical advice immediately.
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> ➤ whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005. ➤ name of individual, address, date of birth, allergies, and GP with whom the individual is registered (or record where an individual is not registered with a GP). ➤ name of member of staff who supplied the product. ➤ name and brand of the product. ➤ date of supply. ➤ dose, form and route of administration of the product. ➤ quantity supplied. ➤ batch number and expiry date. ➤ advice given; including advice given if the individual is excluded or the individual or the parent or carer declines treatment. ➤ details of any adverse drug reactions and actions taken. ➤ that the product was supplied via PGD. <p>All records should be signed and dated (or password-controlled on records). 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 or an alternative antibiotic, where appropriate.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

PGD for the initial supply of ciprofloxacin for post-exposure prophylaxis to tularemia in adults and children aged 12 years and over

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Initial chemoprophylaxis following exposure to a known or suspected deliberate release of tularemia.</p> <p>Notes:</p> <p>Doxycycline is also indicated for post-exposure prophylaxis to tularemia. See doxycycline initial supply PGD.</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on tularemia, including post exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Adults and children aged 12 years and over following exposure to a known or suspected deliberate release of tularemia</p> <p>AND</p> <p>are not showing symptoms compatible with tularemia infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance.</p> <p>Note: The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in growing adolescents, pregnant or breastfeeding individuals who should be given ciprofloxacin in the situation criteria set out above.</p>
<p>Exclusion criteria¹⁴</p> <p>(continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they have a known history of severe allergic reaction to ciprofloxacin, other fluoroquinolones or quinolones, or to any of the listed excipients. See SmPC. ➤ they are under 12 years of age. ➤ they have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to a quinolone or fluoroquinolone antibiotic. ➤ they have a history of tendon disease / disorder related to ciprofloxacin or other fluoroquinolones or quinolones. ➤ they are taking an interacting medicine as listed in the drug interactions section of this PGD. ➤ they have known chronic kidney disease (CKD) stages 4 or 5 (eGFR <30 mL/min/1.73m²) or are on dialysis.

¹⁴ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

<p>Exclusion criteria (continued)</p>	<p>➤ they have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained).</p> <p>See action to be taken if individual is excluded section of this PGD.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>Caution is advised for individuals with the following conditions or who are taking certain medicines.</p> <p>Note: Doxycycline is the preferred option for these individuals if it is not contraindicated and is available. See the doxycycline initial supply PGD.</p> <p>If doxycycline is contraindicated, or not available then ciprofloxacin can be supplied as the benefit of taking it to prevent tularemia infection outweighs the risk in the case of a deliberate release of tularemia. 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>1. At increased risk of tendinitis or tendon rupture:</p> <ul style="list-style-type: none"> ➤ over 60 years of age. ➤ have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD). ➤ are taking corticosteroids. ➤ have a solid organ transplant. <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>2. Conditions with risk factor for QT interval prolongation:</p> <ul style="list-style-type: none"> ➤ cardiac disease (for example, heart failure with reduced left ventricular ejection fraction, myocardial infarction, bradycardia). ➤ congenital long QT syndrome. ➤ history of symptomatic arrhythmias. ➤ concomitant use of medicines known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics). ➤ electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia). <p>Advise to monitor for the exacerbation of or development of symptoms associated with QT interval prolongation. If symptoms develop, advise individuals to seek immediate medical advice for assessment and consideration of alternative antibiotics.</p> <p>3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:</p> <ul style="list-style-type: none"> ➤ a positive family history of aneurysm disease or congenital heart valve disease.

Cautions (including relevant actions to be taken)

(continued)

- pre-existing aortic aneurysm and/or aortic dissection or heart valve disease.
- presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation / incompetence, such as:
 - connective tissue disorders such as Marfan’s syndrome or Ehlers-Danlos syndrome.
 - Turner syndrome.
 - Behçet’s disease.
 - hypertension.
 - rheumatoid arthritis.
- presence of other risk factors or conditions for aortic aneurysm and dissection, such as:
 - vascular disorders including Takayasu arteritis or giant cell arteritis.
 - known atherosclerosis.
 - Sjögren’s syndrome.
- heart valve regurgitation / incompetence caused, for example, by infective endocarditis.

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.

Advise to seek immediate medical attention by dialling 111 or via a 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.

4. Epilepsy or conditions that predispose to seizures and/or those taking medication that may predispose to seizures (for example NSAIDs):

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.

5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):

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.

6. G6PD deficiency:

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.

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<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>7. Myasthenia gravis: Advise to self-monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise individuals to seek urgent medical advice. Note: doxycycline is also cautioned for individuals with myasthenia gravis.</p> <p>8. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol): Advise individual to arrange for INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising. Note: INR also needs to be monitored with doxycycline.</p> <p>9. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine: Advise individuals 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. Refer to the SmPC for ciprofloxacin for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual, parent or their carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise individuals to seek urgent medical attention if they develop symptoms compatible with tularemia infection or signs or symptoms of sepsis. ➤ Symptoms of pneumonic tularemia include: <ul style="list-style-type: none"> ○ fever, chills, headache, myalgia, sore throat, dry cough, pleuritic chest pain, dyspnoea. ➤ See CRBN guidance for further information on symptoms. ➤ Document the advice given and the decision reached.
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ Consider supply of doxycycline (see doxycycline initial supply PGD). ➤ If doxycycline is contraindicated, refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics. ➤ Note: Tularemia is not sensitive to penicillins such as amoxicillin or co-amoxiclav. ➤ Document reasons for exclusion and any referrals that have been made.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising doctor and / or other services.</p>

2. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 500 mg tablets
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Yes – ciprofloxacin tablets are not licensed for use in tularemia. UK national guidance recommends its use.</p> <p>Manipulating solid dosage forms</p> <p>Tablets (not suspension) are the preferred formulation for children aged 12 years and older unless they have medically confirmed swallowing difficulties.</p> <p>In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.</p> <p>Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.</p> <p>The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away.</p> <p>Pregnancy</p> <p>The manufacturers advise as a precautionary measure to avoid the use of ciprofloxacin during pregnancy. However, the data available suggests administration of ciprofloxacin to pregnant women indicates no malformative or fetoneonatal toxicity but the SmPC 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 the disease outweigh these potential risks in pregnancy. A patient information leaflet for ciprofloxacin in pregnancy is available here: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org).</p> <p>Breastfeeding</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</p>

(continued over page)

Off-label use (continued)	<p>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. See patient advice section.</p> <p>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.</p>
Route / method of administration	<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>
Dose and frequency of administration	<p>Adults and children aged 12 years or over</p> <p>ONE tablet (500 mg) to be taken TWICE a day</p> <p>Administration should begin as soon as possible after suspected or confirmed exposure.</p> <p>For individuals who are unable to swallow the tablets, refer to the off-label section of the PGD.</p>
Duration of treatment	<p>10 days</p>
Quantity to be supplied	<p>20 (twenty) tablets OR</p> <p>supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the 10-day course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise the individual or their parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>
Storage	<p>Store in original container below 25°C.</p>
Disposal	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>



Drug interactions

Concurrent medications should be checked for interactions. This list is not exhaustive. A detailed list of drug interactions can be found in the [SmPC](#) or the [BNF](#).

Contraindications

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 [doxycycline initial supply PGD](#)) refer individuals to the supervising doctor.

- agomelatine.
- domperidone.
- ergometrine, ergotamine or dihydroergotamine.
- fezolinetant.
- tizanidine.

The following medicines may require dose adjustments. If doxycycline is contraindicated (see [doxycycline initial supply PGD](#)), individuals should be referred to the supervising doctor:

- | | | |
|----------------|----------------|----------------|
| ➤ olanzapine | ➤ tolvaptan | ➤ ropinirole |
| ➤ capivasertib | ➤ daridorexant | ➤ guanfacine |
| ➤ elacestrant | ➤ venetoclax | ➤ pirlfenidone |
| ➤ eliglustat | ➤ zanubrutinib | ➤ pomalidomide |
| ➤ ibrutinib | | |

Cautions

Individuals who have **received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days** should be referred to the supervising doctor for assessment and advice as ciprofloxacin may reduce the efficacy of these vaccines.

Ciprofloxacin may increase the likelihood of side effects when taken with some medicines (for example, **anagrelide, chlorpromazine, duloxetine, melatonin, rasagiline, riluzole, roflumilast, sildenafil**). Advise individuals to be alert to any increase in adverse effects and to speak to their usual healthcare provider as soon as possible if side effects occur.

Individuals taking **zolmitriptan** should be advised that a maximum dose of 5mg should be taken in any 24-hours.

See [cautions](#) 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.

Ciprofloxacin should be given 2 hours before, or 4 hours after **sevelamer, lanthanum, sucralfate, antacids** and any medicines or supplements containing **calcium, magnesium, aluminium, iron or zinc** that may reduce the absorption of ciprofloxacin.

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<p>Drug interactions (continued)</p>	<p>Oral contraceptives.</p> <p>Ciprofloxacin does not reduce their efficacy but if it makes them vomit or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).</p>
<p>Identification & management of adverse reactions</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>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"> ➤ anaphylaxis (delayed or immediate). ➤ sudden, severe pain in the stomach, chest or back. ➤ seizures. ➤ thoughts about harming themselves or ending their life. <p>Advise individuals to stop taking ciprofloxacin and seek immediate medical advice by calling 111 or a GP if any of the following rare effects occur:</p> <ul style="list-style-type: none"> ➤ changes to vision, taste, smell or hearing. ➤ signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach). ➤ symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking). ➤ diarrhoea that lasts more than 4 days or contains blood or mucus. ➤ sudden breathlessness, especially when lying down. ➤ new onset heart palpitations. ➤ swollen ankles, feet or stomach. ➤ 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). ➤ pain, swelling or inflammation of joints such as the shoulders, arms or legs or tendon pain or swelling. <p>A detailed list of adverse reactions is available in the SmPC.</p>

<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Alert the supervising doctor in the event of a serious adverse reaction to the medicine, document in the individual's record and inform the individual's GP.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p> <p>Consider providing the MHRA information leaflet on side effects.</p>
<p>Advice / follow up treatment</p> <p>(continued over page)</p>	<p>Explain the treatment.</p> <p>Advise the individual, parent or carer to:</p> <ul style="list-style-type: none"> ➤ drink plenty of fluids. ➤ not take indigestion remedies, or medicines containing calcium, magnesium, aluminium, iron or zinc 1-2 hours before or 4 hours after taking the medicine. ➤ not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice). ➤ 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. ➤ not chew the tablets. ➤ space the doses evenly throughout the day. ➤ keep taking the medicine until the course is finished, unless they are told to stop. ➤ not give the tablets to anyone else. ➤ return any unused tablets at the end of the course to a community pharmacy for destruction. <p>Inform individual, parent or carer:</p> <ul style="list-style-type: none"> ➤ of possible side effects and their management. ➤ 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. ➤ 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.

<p>Advice / follow up treatment</p> <p>(continued)</p>	<ul style="list-style-type: none"> ➤ ciprofloxacin may affect reaction times. If affected, they should avoid driving or operating machinery. ➤ to seek immediate medical attention if the individual develops signs or symptoms compatible with tularemia or other serious adverse effects (see identification and management of adverse reactions). ➤ if they are pregnant, a patient information leaflet for ciprofloxacin in pregnancy is available here: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org). ➤ if they are breastfeeding, they can continue; ciprofloxacin can cause some babies to have mild stomach upsets. If their baby is not feeding as well as usual or they are unsettled after feeding, if they have diarrhoea and or vomiting, if they develop a rash or are unusually sleepy, if they have oral thrush, or any concerns, they should contact their health visitor, midwife or general practitioner. <p>For individuals with conditions listed in the cautions section, provide the additional recommended advice.</p> <p>When applicable, advise individual, parent or carer when the subsequent supply is due and where they can obtain this further supply.</p>
<p>Records</p> <p>(continued over page)</p>	<p>Record:</p> <ul style="list-style-type: none"> ➤ whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005. ➤ name of individual, address, date of birth, allergies, and GP with whom the individual is registered (or record where an individual is not registered with a GP). ➤ name of member of staff who supplied the product. ➤ name and brand of the product. ➤ date of supply. ➤ dose, form and route of administration of the product. ➤ quantity supplied. ➤ batch number and expiry date. ➤ advice given; including advice given if the individual is excluded or the individual, parent or carer declines treatment. ➤ details of any adverse drug reactions and actions taken. ➤ that the product was supplied via PGD. <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>Records (continued)</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> <p>For pregnant women record the medicine supplied in the hand-held maternity record (if available).</p>
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PGD for the initial supply of ciprofloxacin for post-exposure prophylaxis to tularemia in children aged under 12 years

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Initial chemoprophylaxis following exposure to a known or suspected deliberate release of tularemia.</p> <p>Notes:</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on tularemia, including post exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Children aged from 4 weeks to less than 12 years of age, following exposure to a known or suspected deliberate release of tularemia</p> <p>AND</p> <p>are not showing symptoms compatible with tularemia infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance.</p> <p>Note: The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in children, who should be given ciprofloxacin in the situation criteria set out above.</p>
<p>Exclusion criteria¹⁵</p> <p>(continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they are aged 12 years or over (see ciprofloxacin initial supply PGD). ➤ they are less than 4 weeks of age. ➤ they are known to be outside of weight range for age¹⁶. ➤ they have a known history of severe allergic reaction to ciprofloxacin, other quinolones or fluoroquinolones, or to any of the listed excipients. See SmPC. ➤ they have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction related to quinolone or fluoroquinolone antibiotic use. ➤ they have a history of tendon disease / disorder related to ciprofloxacin or other quinolone or fluoroquinolone antibiotic use. ➤ they are taking an interacting medicine as listed in the drug interactions section of this PGD.

¹⁵ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

¹⁶ See [British National Formulary for Children](#) (BNFC)

<p>Exclusion criteria (continued)</p>	<ul style="list-style-type: none"> ➤ they have known chronic kidney disease (CKD) stages 4 or 5 (eGFR <30 mL/min/1.73m²) or are on dialysis. ➤ their parent or carer has not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained). <p>See action to be taken if individual is excluded section of this PGD.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>Although caution is advised for individuals with the following conditions or who are taking certain medicines, the benefits of taking ciprofloxacin to prevent tularemia outweighs the risk following a suspected or know deliberate release of tularemia.</p> <p>Provide the child’s parent or carer 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>1. At increased risk of tendinitis or tendon rupture:</p> <ul style="list-style-type: none"> ➤ have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD). ➤ are taking corticosteroids. ➤ have a solid organ transplant. <p>Advise parents or carers to monitor for tendinitis (for example, painful swelling, inflammation). In young children who may not be able to report pain, be alert to lack of use of limbs or signs of pain on movement. If signs of tendinitis occur, advise that the parent or carer stops giving ciprofloxacin and to seek immediate medical advice by dialling 111 or the child’s GP for assessment.</p> <p>2. Conditions with risk factor for QT interval prolongation:</p> <ul style="list-style-type: none"> ➤ cardiac disease (for example, heart failure, myocardial infarction, bradycardia). ➤ congenital long QT syndrome. ➤ history of symptomatic arrhythmias. ➤ concomitant use of medicines known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics). ➤ electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia). <p>Advise parents or carers to monitor for the exacerbation of or development of symptoms associated with QT interval prolongation. If symptoms develop, advise parents or carers to stop giving ciprofloxacin and to seek immediate medical advice for assessment and consideration of alternative antibiotics.</p> <p>3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:</p> <ul style="list-style-type: none"> ➤ a positive family history of aneurysm disease or congenital heart valve disease.

Cautions (including relevant actions to be taken)

(continued)

- pre-existing aortic aneurysm and/or aortic dissection or heart valve disease.
- presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation / incompetence:
 - connective tissue disorders such as Marfan’s syndrome or Ehlers-Danlos syndrome.
 - Turner syndrome.
 - Behçet’s disease.
 - hypertension.
 - rheumatoid arthritis.
- presence of other risk factors or conditions for aortic aneurysm and dissection:
 - vascular disorders including Takayasu arteritis or giant cell arteritis.
 - known atherosclerosis.
 - Sjögren’s syndrome.
- heart valve regurgitation / incompetence caused, for example, by infective endocarditis.

Advise parents or carers of the possibility of these rare events, and to seek urgent medical attention by dialling 999 if the child develops sudden-onset severe abdominal, chest or back pain.

Advise parents or carers to seek immediate medical attention by dialling 111 or via the GP if the child experiences 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.

4. Epilepsy or conditions that predispose to seizures and/or those taking medication that may predispose to seizures (for example NSAIDs):

Advise parents or carers to monitor for any increase in frequency or severity of seizures. If an increase in frequency or severity of seizures occurs, advise parents or carers to stop giving ciprofloxacin and seek urgent medical attention. Advise parents or carers to avoid giving an NSAID where possible (for example, ibuprofen) whilst taking ciprofloxacin.

5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):

Disturbances in blood glucose can occur. Advise parents or carers to carefully monitor blood glucose during treatment, to be alert to symptoms of hypoglycaemia and hyperglycaemia and to seek medical advice if required.

6. G6PD deficiency:

There is a risk of haemolysis when ciprofloxacin is given to individuals with G6PD deficiency. If ciprofloxacin must be used, advise the parent or carer to monitor for signs of haemolysis. If signs of haemolysis develop, advise to stop giving ciprofloxacin and to seek urgent medical advice.

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<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>7. Myasthenia gravis: Advise parents or carers to monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise that they seek urgent medical advice. Note: doxycycline is also cautioned for individuals with myasthenia gravis.</p> <p>8. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol): Advise parents or carers to arrange for the child's INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising. Note: INR also needs to be monitored with doxycycline.</p> <p>9. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine: Advise parents or carers to 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. Refer to the SmPC for ciprofloxacin for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the parent or carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if children develop symptoms compatible with tularemia or signs or symptoms of sepsis. ➤ Symptoms of pneumonic tularemia include: <ul style="list-style-type: none"> ○ fever, chills, headache, myalgia, sore throat, dry cough, pleuritic chest pain, dyspnoea. ➤ See CRBN guidance for further information on symptoms to be aware of depending on the type of exposure. ➤ Document the advice given and the decision reached.
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ If they are aged 12 years or over, refer to the ciprofloxacin initial supply PGD. ➤ If excluded for other reasons, refer to the supervising doctor for assessment. ➤ If they are 8 years and over, consider doxycycline. See doxycycline initial supply PGD. ➤ If the child is under weight for their age range, refer to the supervising doctor. If a different dose of ciprofloxacin for their age range is required, a Patient Specific Direction (PSD) will be needed. ➤ Document reasons for exclusion and any referrals that have been made.

**Arrangements for
referral for medical
advice**

Follow local procedures for referral to the supervising doctor and / or other services.

2. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 100 mg tablets, 250 mg tablets, 500 mg tablets, 250 mg in 5 mL suspension																	
Legal category	Prescription Only Medicine (POM)																	
Black triangle▼	No																	
Off-label use	<p>Yes</p> <p>Ciprofloxacin tablets are not licensed for use in tularemia. UK national guidance recommends its use.</p> <p>The SmPC states dosing is mg/kg, but UK national guidance recommends age banding as per the RCPH and UK-WHO growth charts.</p> <p>Manipulating solid dosage forms</p> <p>Tablets (not suspension) are the preferred formulation for children aged 2 years and older unless they have medically confirmed swallowing difficulties.</p> <p>In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.</p> <p>Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.</p> <p>The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away.</p> <p>Where a product is recommended off-label consider, as part of the consent process, informing the parent or carer that the product is being offered in accordance with national guidance but that this is outside the product licence.</p>																	
Route / method of administration	<p>Oral</p> <p>Tablets 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>																	
Dose and frequency of administration	<p>Doses to be taken TWICE a day – see dosage table below.</p> <table border="1"> <thead> <tr> <th>Age</th> <th>Dose (mg)</th> <th>Dose (volume or quantity)</th> </tr> </thead> <tbody> <tr> <td>Less than 4 weeks of age</td> <td colspan="2">Excluded</td> </tr> <tr> <td>4 weeks to less than 8 weeks of age</td> <td>50 mg TWICE a day</td> <td>1 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>8 weeks to less than 6 months of age</td> <td>75 mg TWICE a day</td> <td>1.5 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>6 months to less than 1 year of age</td> <td>100 mg TWICE a day</td> <td>2 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> </tbody> </table> <p>(continued over page)</p>			Age	Dose (mg)	Dose (volume or quantity)	Less than 4 weeks of age	Excluded		4 weeks to less than 8 weeks of age	50 mg TWICE a day	1 mL of 250 mg in 5 mL suspension TWICE a day	8 weeks to less than 6 months of age	75 mg TWICE a day	1.5 mL of 250 mg in 5 mL suspension TWICE a day	6 months to less than 1 year of age	100 mg TWICE a day	2 mL of 250 mg in 5 mL suspension TWICE a day
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6 months to less than 1 year of age	100 mg TWICE a day	2 mL of 250 mg in 5 mL suspension TWICE a day																

<p>Dose and frequency of administration (continued)</p>	<table border="1"> <thead> <tr> <th>Age</th> <th>Dose (mg)</th> <th>Dose (volume or quantity)</th> </tr> </thead> <tbody> <tr> <td>1 year to less than 2 years of age</td> <td>150 mg TWICE a day</td> <td>3 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>2 years to less than 4 years of age</td> <td>200 mg TWICE a day</td> <td>4 mL of 250 mg in 5 mL suspension TWICE a day or TWO 100mg tablets TWICE a day</td> </tr> <tr> <td>4 years to less than 8 years of age</td> <td>250 mg TWICE a day</td> <td>5 mL of 250 mg in 5 mL suspension TWICE a day or ONE 250 mg tablet TWICE a day</td> </tr> <tr> <td>8 years to less than 12 years of age</td> <td>500 mg TWICE a day</td> <td># TWO 250 mg tablets TWICE a day or ONE 500 mg tablet TWICE a day</td> </tr> </tbody> </table>	Age	Dose (mg)	Dose (volume or quantity)	1 year to less than 2 years of age	150 mg TWICE a day	3 mL of 250 mg in 5 mL suspension TWICE a day	2 years to less than 4 years of age	200 mg TWICE a day	4 mL of 250 mg in 5 mL suspension TWICE a day or TWO 100mg tablets TWICE a day	4 years to less than 8 years of age	250 mg TWICE a day	5 mL of 250 mg in 5 mL suspension TWICE a day or ONE 250 mg tablet TWICE a day	8 years to less than 12 years of age	500 mg TWICE a day	# TWO 250 mg tablets TWICE a day or ONE 500 mg tablet TWICE a day
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<p># See off label section for advice on manipulating solid dose forms in swallowing difficulty.</p>																
<p>Duration of treatment</p> <p>Ten (10) days</p>																
<p>Quantity to be supplied</p> <p>Suspension: 1 x 100 mL suspension should be supplied per child irrespective of dose A bottle of suspension must be discarded 14 days after reconstitution.</p> <p>100 mg tablets: Children aged 2 years to less than 4 years of age: 40 tablets</p> <p>250 mg tablets: Children aged 4 years to less than 8 years: 20 tablets Children aged 8 years to less than 12 years: 40 tablets</p> <p>500 mg tablets: Children aged 8 years to less than 12 years: 20 tablets</p> <p>OR</p> <p>supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the 10-day course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise individual or their parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>																

<p>Additional information</p>	<p>Tablets (not suspension) are the preferred formulation for children aged 2 years and older unless they have medically confirmed swallowing difficulties.</p> <p>The suspension must be reconstituted according to the manufacturer's instructions before handing to parent / carer or other responsible person.</p> <p>Supply an oral syringe with the suspension and instructions for using the syringe.</p> <p>The suspension should not be administered through a nasogastric tube because of the risk of blocking the tube. Refer to the supervising doctor.</p> <p>The suspension should not be given to individuals with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or saccharose-isomaltase deficiency. Refer to the supervising doctor.</p> <p>As the reconstituted suspension only lasts 14 days, any remaining solution should be taken to a community pharmacy for destruction.</p>															
<p>Storage</p>	<p>Store in original container below 25°C.</p> <p>Reconstituted suspension may either be stored at ambient temperatures up to 30°C or it can be stored in a refrigerator.</p>															
<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>															
<p>Drug interactions</p> <p>(continued over page)</p>	<p>Concurrent medications should be checked for interactions. This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p> <p>Contraindications</p> <p>Where it is known an individual is concurrently taking one of the following medicines, ciprofloxacin should not be supplied under this PGD. Refer individuals to the supervising doctor.</p> <ul style="list-style-type: none"> ➤ agomelatine. ➤ domperidone. ➤ ergometrine, ergotamine or dihydroergotamine. ➤ fezolinetant. ➤ tizanidine. <p>The following medicines may require dose adjustments. Individuals should be referred to the supervising doctor:</p> <table border="0"> <tr> <td>➤ guanfacine</td> <td>➤ tolvaptan</td> <td>➤ ropinirole</td> </tr> <tr> <td>➤ olanzapine</td> <td>➤ daridorexant</td> <td>➤ capivasertib</td> </tr> <tr> <td>➤ elacestrant</td> <td>➤ venetoclax</td> <td>➤ pifenidone</td> </tr> <tr> <td>➤ eliglustat</td> <td>➤ zanubrutinib</td> <td>➤ pomalidomide</td> </tr> <tr> <td>➤ ibrutinib</td> <td></td> <td></td> </tr> </table> <p>Cautions</p> <p>Individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be referred to the</p>	➤ guanfacine	➤ tolvaptan	➤ ropinirole	➤ olanzapine	➤ daridorexant	➤ capivasertib	➤ elacestrant	➤ venetoclax	➤ pifenidone	➤ eliglustat	➤ zanubrutinib	➤ pomalidomide	➤ ibrutinib		
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<p>Identification & management of adverse reactions (continued)</p>	<ul style="list-style-type: none"> ➤ changes to vision, taste, smell or hearing. ➤ signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach). ➤ symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking). ➤ sudden breathlessness, especially when lying down. ➤ new onset heart palpitations. ➤ swollen ankles, feet or stomach. ➤ 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). <p>A detailed list of adverse reactions is available in the SmPC.</p>
<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Alert the supervising doctor in the event of a serious adverse reaction to the medicine, document in the individual's record and inform the individual's GP.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p> <p>An information leaflet explaining how to use and clean the oral syringe.</p> <p>Consider providing the MHRA information leaflet on side effects.</p>
<p>Advice / follow up treatment (continued over page)</p>	<p>Explain the treatment.</p> <p>Advise the parent or carer the child should:</p> <ul style="list-style-type: none"> ➤ maintain adequate fluid intake. ➤ not take indigestion remedies or medicines containing calcium, magnesium, aluminium, iron or zinc 2 hours before or 4 hours after taking the medicine. ➤ not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice). ➤ space the doses evenly throughout the day. ➤ keep taking the medicine until the course is finished, unless they are told to stop. <p>For suspension: Inform the parent or carer:</p> <ul style="list-style-type: none"> ➤ to shake the suspension bottle vigorously each time before use for approximately 15 seconds.

<p>Advice / follow up treatment (continued)</p>	<ul style="list-style-type: none"> ➤ although there may be suspension remaining after the initial ten-day course, a further supply will be needed if a follow-on course is recommended ➤ to take any remaining unused suspension to a community pharmacy for disposal. <p>For tablets: Inform the parent or carer:</p> <ul style="list-style-type: none"> ➤ these should 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. ➤ tablets should not be chewed. ➤ tablets can be crushed, if necessary (see off-label section of this PGD), parents and carers should be advised that the tablets are very bitter in taste, and to encourage their children to swallow the tablets whole where possible. ➤ any unused tablets should be taken to a community pharmacy for disposal. <p>Inform the parent or carer:</p> <ul style="list-style-type: none"> ➤ for babies receiving milk feeds, to space the doses in the mid period between expected feed times. ➤ of possible side effects and their management. ➤ 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. ➤ the medicine can make the skin more sensitive to direct sunlight. Children should avoid exposure to excessive sunlight or use high SPF sunblock if prolonged exposure to the sun is unavoidable. ➤ the medicine may cause the child to feel tired or less alert. Children should take care when doing tasks that require coordination (for example, riding a bike) until they get used to the medicine. ➤ to seek immediate medical attention if the individual develops signs or symptoms compatible with tularemia or other serious adverse effects (see identification and management of adverse reactions). ➤ when the subsequent supply is due and where they can obtain this. <p>For individuals with conditions listed in the cautions section, provide the additional recommended advice.</p>
<p>Records (continued over page)</p>	<p>Record:</p> <ul style="list-style-type: none"> ➤ whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005. ➤ name of individual, address, date of birth, weight if known, allergies, and GP with whom the individual is registered (or record where an individual is not registered with a GP).

Records

(continued)

- name of member of staff who supplied the product.
- name and brand of the product.
- date of supply.
- dose, form and route of administration of the product.
- quantity supplied.
- batch number and expiry date.
- advice given; including advice given if the child is excluded or parent or carer declines treatment.
- details of any adverse drug reactions and actions taken.
- that the product was supplied via PGD.

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

All records should be clear, legible and contemporaneous.

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

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

PGD for the further supply of ciprofloxacin for post-exposure prophylaxis to tularemia in adults and children aged 12 years and over

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Where continuing chemoprophylaxis is required following exposure to a known deliberate release of tularemia.</p> <p>Notes:</p> <p>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> <p>Incident specific advice should be followed to support choice of antimicrobial.</p>
<p>Inclusion criteria</p>	<p>Adults and children aged 12 years and over following exposure to a known deliberate release of tularemia</p> <p>AND</p> <p>who have already received chemoprophylaxis for 10 days with ciprofloxacin or doxycycline</p> <p>AND</p> <p>are not showing symptoms compatible with tularemia infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance for symptoms.</p> <p>Note: The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in growing adolescents, pregnant or breastfeeding individuals who should be given ciprofloxacin in the situation criteria set out above.</p>
<p>Exclusion criteria¹⁷</p> <p>(continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they have a known history of severe allergic reaction to ciprofloxacin, other fluoroquinolones or quinolones, or to any of the listed excipients. See SmPC. ➤ they are under 12 years of age. ➤ they have experienced unacceptable side effects while taking the initial ten days' supply of ciprofloxacin. ➤ they have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to a quinolone or fluoroquinolone antibiotic.

¹⁷ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Cautions (including relevant actions to be taken)

(continued)

3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:

- a positive family history of aneurysm disease or congenital heart valve disease.
- pre-existing aortic aneurysm and/or aortic dissection or heart valve disease.
- presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation / incompetence:
 - connective tissue disorders such as Marfan's syndrome or Ehlers-Danlos syndrome.
 - Turner syndrome.
 - Behçet's disease.
 - hypertension.
 - rheumatoid arthritis.
- presence of other risk factors or conditions for aortic aneurysm and dissection:
 - vascular disorders including Takayasu arteritis or giant cell arteritis.
 - known atherosclerosis.
 - Sjögren's syndrome.
- heart valve regurgitation / incompetence caused, for example, by infective endocarditis

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.

Advise to seek immediate medical attention by dialling 111 or via a 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.

4. Epilepsy or conditions that predispose to seizures and/or those taking medication that may predispose to seizures (for example NSAIDs):

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.

5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):

Disturbances in blood glucose can occur. Advise individuals to carefully monitor blood glucose during treatment, and to be alert to symptoms of hypoglycaemia and hyperglycaemia and to seek medical advice if required.

6. G6PD deficiency:

There is a risk of haemolysis when ciprofloxacin is given to individuals with G6PD deficiency. If other antibiotics are not suitable and ciprofloxacin must

(continued over page)

<p>Cautions (including relevant actions to be taken)</p> <p>(continued)</p>	<p>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>7. Myasthenia gravis:</p> <p>Advise to self-monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise individuals to seek urgent medical advice.</p> <p>Note: doxycycline is also cautioned for individuals with myasthenia gravis.</p> <p>8. Severely immunocompromised individuals:</p> <p>Individuals who are severely immunocompromised (as defined in chapter 28a Green book) should be advised to arrange an appointment with a GP or specialist to determine whether they need to continue treatment beyond the course outlined in this PGD.</p> <p>9. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol):</p> <p>Advise individual to arrange for INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising.</p> <p>Note: INR also needs to be monitored with doxycycline.</p> <p>10. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine:</p> <p>Advise individuals 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 SmPC for ciprofloxacin for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual, parent or their carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise individuals to seek urgent medical attention if they develop symptoms compatible with tularemia infection and any signs or symptoms of sepsis. ➤ Symptoms of pneumonic tularemia include: <ul style="list-style-type: none"> ○ fever, chills, headache, myalgia, sore throat, dry cough, pleuritic chest pain, dyspnoea. ➤ See CRBN guidance for further information on symptoms. ➤ Document the advice given and the decision reached.

<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ Consider supply of doxycycline (see doxycycline further supply PGD). ➤ Where doxycycline is contraindicated, refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics. ➤ Note: Tularemia is not sensitive to penicillins such as amoxicillin or co-amoxiclav. ➤ Document reasons for exclusion and any referrals that have been made.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising doctor and / or other services.</p>

2. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 500 mg tablets
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Yes – ciprofloxacin tablets are not licensed for use in tularemia. UK national guidance recommends its use.</p> <p>Manipulating solid dosage forms</p> <p>Tablets (not suspension) are the preferred formulation for children aged 12 years and older unless they have medically confirmed swallowing difficulties.</p> <p>In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.</p> <p>Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.</p> <p>The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away.</p> <p>Pregnancy</p> <p>The manufacturers advise as a precautionary measure to avoid the use of ciprofloxacin during pregnancy. However, the data available suggests administration of ciprofloxacin to pregnant women indicates no malformative or fetoneonatal toxicity but the SmPC 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 the disease outweigh these potential risks in pregnancy. A patient information leaflet for ciprofloxacin in pregnancy is available here: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org).</p> <p>Breastfeeding</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</p>

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<p>Off-label use (continued)</p>	<p>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. See patient advice section.</p> <p>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.</p>
<p>Route / method of administration</p>	<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>
<p>Dose and frequency of administration</p>	<p>Adults and children aged 12 years or over</p> <p>ONE tablet (500 mg) to be taken TWICE a day</p> <p>For individuals who are unable to swallow the tablets, refer to the off-label section of the PGD.</p>
<p>Duration of treatment</p>	<p>4 days (total length of course 14 days)</p> <p>Note: these individuals have previously received an initial ten-day supply of an antibiotic.</p>
<p>Quantity to be supplied</p>	<p>10 (ten) tablets.</p> <p>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.</p> <p>OR</p> <p>supply a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise individual or their parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>
<p>Storage</p>	<p>Store in original container below 25°C.</p>

<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>															
<p>Drug interactions</p>	<p>Concurrent medications should be checked for interactions. This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p> <p>Contraindications</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 doxycycline further supply PGD) refer individuals to the supervising doctor.</p> <ul style="list-style-type: none"> ➤ agomelatine. ➤ domperidone. ➤ ergometrine, ergotamine or dihydroergotamine. ➤ fezolinetant. ➤ tizanidine. <p>The following medicines may require dose adjustments. If doxycycline is contraindicated (see doxycycline further supply PGD), individuals should be referred to the supervising doctor:</p> <table border="0"> <tr> <td>➤ olanzapine</td> <td>➤ tolvaptan</td> <td>➤ ropinirole</td> </tr> <tr> <td>➤ capivasertib</td> <td>➤ daridorexant</td> <td>➤ guanfacine</td> </tr> <tr> <td>➤ elacestrant</td> <td>➤ venetoclax</td> <td>➤ pifenidone</td> </tr> <tr> <td>➤ eliglustat</td> <td>➤ zanubrutinib</td> <td>➤ pomalidomide</td> </tr> <tr> <td>➤ ibrutinib</td> <td></td> <td></td> </tr> </table> <p>Cautions</p> <p>Individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be referred to the supervising doctor for assessment and 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, anagrelide, chlorpromazine, duloxetine, melatonin, rasagiline, riluzole, roflumilast, sildenafil). Advise individuals to be alert to any increase in adverse effects and to speak to their usual healthcare provider as soon as possible if side effects occur.</p> <p>Individuals taking zolmitriptan should be advised that a maximum dose of 5mg of zolmitriptan should be taken in any 24-hours.</p> <p>See cautions 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 sevelamer, lanthanum, sucralfate, antacids and any medicines or supplements</p>	➤ olanzapine	➤ tolvaptan	➤ ropinirole	➤ capivasertib	➤ daridorexant	➤ guanfacine	➤ elacestrant	➤ venetoclax	➤ pifenidone	➤ eliglustat	➤ zanubrutinib	➤ pomalidomide	➤ ibrutinib		
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<p>Drug interactions (continued)</p>	<p>containing calcium, magnesium, aluminium, iron or zinc that may reduce the absorption of ciprofloxacin.</p> <p>Oral contraceptives.</p> <p>Ciprofloxacin does not reduce their efficacy but if it makes them vomit or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).</p>
<p>Identification & management of adverse reactions</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>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"> ➤ anaphylaxis (delayed or immediate). ➤ sudden, severe pain in the stomach, chest or back. ➤ seizures. ➤ thoughts about harming themselves or ending their life. <p>Advise individuals to stop taking ciprofloxacin and seek immediate medical advice by calling 111 or a GP if any of the following rare effects occur:</p> <ul style="list-style-type: none"> ➤ changes to vision, taste, smell or hearing. ➤ signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach). ➤ symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking). ➤ diarrhoea that lasts more than 4 days or contains blood or mucus. ➤ sudden breathlessness, especially when lying down. ➤ new onset heart palpitations. ➤ swollen ankles, feet or stomach. ➤ 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). ➤ pain, swelling or inflammation of joints such as the shoulders, arms or legs or tendon pain or swelling. <p>A detailed list of adverse reactions is available in the SmPC.</p>

<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Alert the supervising doctor in the event of a serious adverse reaction to the medicine, document in the individual's record and inform the individual's GP.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p> <p>Consider providing the MHRA information leaflet on side effects.</p>
<p>Advice / follow up treatment</p> <p>(continued over page)</p>	<p>Explain the treatment.</p> <p>Advise the individual, parent or carer to:</p> <ul style="list-style-type: none"> ➤ drink plenty of fluids. ➤ not take indigestion remedies, sevelamer, lanthanum, sucralfate or medicines containing calcium, magnesium, aluminium, iron or zinc 2 hours before or 4 hours after taking the medicine. ➤ not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice). ➤ 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. ➤ not chew the tablets. ➤ space the doses evenly throughout the day. ➤ keep taking the medicine until the course is finished, unless they are told to stop. ➤ not give the tablets to anyone else. ➤ return any unused tablets at the end of the course to a community pharmacy for destruction. <p>Inform individual, parent or carer:</p> <ul style="list-style-type: none"> ➤ of possible side effects and their management. ➤ 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. ➤ 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.

<p>Advice / follow up treatment</p> <p>(continued)</p>	<ul style="list-style-type: none"> ➤ ciprofloxacin may affect reaction times; the ability to drive or operate machinery may be impaired. ➤ to seek immediate medical attention if the individual develops signs or symptoms compatible with tularemia or other serious adverse effects (see identification and management of adverse reactions). ➤ if they are pregnant, a patient information leaflet for ciprofloxacin in pregnancy is available here: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org). ➤ if they are breastfeeding, they can continue; ciprofloxacin can cause some babies to have mild stomach upsets. If their baby is not feeding as well as usual or they are unsettled after feeding, if they have diarrhoea and or vomiting, if they develop a rash or are unusually sleepy, if they have oral thrush, or any concerns, they should contact their health visitor, midwife or general practitioner. ➤ to only take the medicine for 4 days and to return the excess tablets to a community pharmacy for destruction. <p>For individuals with conditions listed in the cautions section, provide the additional recommended advice.</p>
<p>Records</p> <p>(continued over page)</p>	<p>Record:</p> <ul style="list-style-type: none"> ➤ whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005. ➤ name of individual, address, date of birth, allergies, and GP with whom the individual is registered (or record where an individual is not registered with a GP). ➤ name of member of staff who supplied the product. ➤ name and brand of the product. ➤ date of supply. ➤ dose, form and route of administration of the product. ➤ quantity supplied. ➤ batch number and expiry date. ➤ advice given; including advice given if the individual is excluded or the individual, parent or carer declines treatment. ➤ details of any adverse drug reactions and actions taken. ➤ that the product was supplied via PGD. <p>All records should be signed and dated (or password-controlled on records). 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>Records (continued)</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> <p>For pregnant women record the medicine supplied in the hand-held maternity record (if available).</p>
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PGD for the further supply of ciprofloxacin for post-exposure prophylaxis to tularemia in children aged under 12 years

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Where continuing chemoprophylaxis is required following exposure to a known deliberate release of tularemia.</p> <p>Notes:</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on tularemia, including post exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Children aged from 4 weeks to less than 12 years of age, following exposure to a known deliberate release of tularemia who have already received ten days' supply of antibiotics for the exposure</p> <p>AND</p> <p>are not showing symptoms compatible with tularemia infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance for symptoms compatible with tularemia infection.</p> <p>Note: The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in children, who should be given ciprofloxacin in the situation criteria set out above.</p>
<p>Exclusion criteria¹⁸</p> <p>(continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they are aged 12 years or over (see ciprofloxacin further supply PGD). ➤ they are less than 4 weeks of age. ➤ they are known to be outside of weight range for age¹⁹. ➤ they have a known history of severe allergic reaction to ciprofloxacin, other quinolones or fluoroquinolones, or to any of the listed excipients. ➤ they have experienced unacceptable side effects while taking the initial ten days' supply of ciprofloxacin. ➤ they have had a previous known severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to quinolone or fluoroquinolone antibiotic use. ➤ they have a history of tendon disease / disorder related to ciprofloxacin or other quinolone or fluoroquinolone antibiotic use. ➤ they are taking an interacting medicine as listed in the drug interactions section of this PGD.

¹⁸ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

¹⁹ See [British National Formulary for Children](#) (BNFC)

<p>Exclusion criteria (continued)</p>	<ul style="list-style-type: none"> ➤ they have known chronic kidney disease (CKD) stages 4 or 5 (eGFR <30 mL/min/1.73m²) or are on dialysis. ➤ their parent or carer has not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained). <p>See action to be taken if individual is excluded section of this PGD.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>Although caution is advised for individuals with the following conditions or who are taking certain medicines, the benefits of taking ciprofloxacin to prevent tularemia outweighs the risk following a known deliberate release of tularemia.</p> <p>Provide the child's parent or carer 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>1. At increased risk of tendinitis or tendon rupture:</p> <ul style="list-style-type: none"> ➤ have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD). ➤ are taking corticosteroids. ➤ have a solid organ transplant. <p>Advise parents or carers to monitor for tendinitis (for example, painful swelling, inflammation). In young children who may not be able to report pain, be alert to lack of use of limbs or signs of pain on movement. If signs of tendinitis occur, advise that the parent or carer stops giving ciprofloxacin and to seek immediate medical advice by dialling 111 or the child's GP for assessment.</p> <p>2. Conditions with risk factor for QT interval prolongation:</p> <ul style="list-style-type: none"> ➤ cardiac disease (for example, heart failure, myocardial infarction, bradycardia). ➤ congenital long QT syndrome. ➤ history of symptomatic arrhythmias. ➤ concomitant use of medicines known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics). ➤ electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia). <p>Advise parents or carers to monitor for the exacerbation of or development of symptoms associated with QT interval prolongation. If symptoms develop, advise parents or carers to stop giving ciprofloxacin and to seek immediate medical advice for assessment and consideration of alternative antibiotics.</p> <p>3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:</p> <ul style="list-style-type: none"> ➤ a positive family history of aneurysm disease or congenital heart valve disease.

Cautions (including relevant actions to be taken)

(continued)

- pre-existing aortic aneurysm and/or aortic dissection or heart valve disease.
- presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation / incompetence:
 - connective tissue disorders such as Marfan’s syndrome or Ehlers-Danlos syndrome.
 - Turner syndrome.
 - Behçet’s disease.
 - hypertension.
 - rheumatoid arthritis.
- presence of other risk factors or conditions for aortic aneurysm and dissection:
 - vascular disorders including Takayasu arteritis or giant cell arteritis.
 - known atherosclerosis.
 - Sjögren’s syndrome.
- heart valve regurgitation / incompetence caused, for example, by infective endocarditis.

Advise parents or carers of the possibility of these rare events, and that they should seek urgent medical attention by dialling 999 if the child develops sudden-onset severe abdominal, chest or back pain.

Advise parents or carers to seek immediate medical attention by dialling 111 or via the GP if the child experiences 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.

4. Epilepsy or conditions that predispose to seizures and/or those taking medication that may predispose to seizures (for example NSAIDs):

Advise parents or carers to monitor for any increase in frequency or severity of seizures. If an increase in frequency or severity of seizures occurs, advise parents or carers to stop giving ciprofloxacin and seek urgent medical attention. Advise parents or carers to avoid giving an NSAID where possible (for example, ibuprofen) whilst taking ciprofloxacin.

5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):

Disturbances in blood glucose can occur. Advise parents or carers to carefully monitor blood glucose during treatment, to be alert to symptoms of hypoglycaemia and hyperglycaemia and to seek medical advice if required.

6. G6PD deficiency:

There is a risk of haemolysis when ciprofloxacin is given to individuals with G6PD deficiency. If ciprofloxacin must be used, advise the parent or carer to monitor for signs of haemolysis. If signs of haemolysis develop, advise to stop giving ciprofloxacin and seek urgent medical advice.

(continued over page)

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>7. Myasthenia gravis: Advise parents or carers to monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise that they seek urgent medical advice.</p> <p>8. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol): Advise parents or carers to arrange for the child's INR to be monitored 3-5 days after starting treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising.</p> <p>9. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine: Advise parents or carers to 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>10. Severely immunocompromised individuals: Parents and carers of individuals who are severely immunocompromised (as defined in chapter 28a Green book) should be advised to arrange an appointment with their specialist or GP to determine whether they need to continue treatment beyond the course outlined in this PGD.</p>
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual or their parent or carer of the possible consequences of not receiving prophylaxis and of alternative options. ➤ Advise about the protective effects of the prophylaxis, risks of infection, and disease complications. ➤ Advise to seek urgent medical attention if children develop symptoms compatible with tularemia or signs or symptoms of sepsis. ➤ Symptoms of pneumonic tularemia include: <ul style="list-style-type: none"> ○ fever, chills, headache, myalgia, sore throat, dry cough, pleuritic chest pain, dyspnoea. ➤ See CRBN guidance for further information on symptoms to be aware of depending on the type of exposure. ➤ Document the advice given and the decision reached.
<p>Action to be taken if the individual is excluded (continued over page)</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ If they are aged 12 years or over, refer to the ciprofloxacin further supply 500mg tablet PGD. ➤ If excluded for other reasons, refer to the supervising doctor for assessment.
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ If the child is under weight for their age range, refer to the supervising doctor. If a different dose of ciprofloxacin for their age range is required, a Patient Specific Direction (PSD) will be needed.

(continued)	<ul style="list-style-type: none"> ➤ Note: Tularemia is not sensitive to penicillins such as amoxicillin or co-amoxiclav. ➤ Document reasons for exclusion and any referrals that have been made.
Arrangements for referral for medical advice	Follow local procedures for referral to the supervising doctor and / or other services.



2. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 100 mg tablets, 250 mg tablets, 500 mg tablets, 250 mg in 5 mL suspension																						
Legal category	Prescription Only Medicine (POM)																						
Black triangle▼	No																						
Off-label use	<p>Yes – ciprofloxacin is not licensed for use in tularemia. UK national guidance recommends its use.</p> <p>Manipulating solid dosage forms</p> <p>Tablets (not suspension) are the preferred formulation for children aged 2 years and older unless they have medically confirmed swallowing difficulties.</p> <p>In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.</p> <p>Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.</p> <p>The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away.</p> <p>Where a product is recommended off-label consider, as part of the consent process, informing the parent or carer that the product is being offered in accordance with national guidance but that this is outside the product licence.</p>																						
Route / method of administration	<p>Oral</p> <p>Tablets 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>																						
Dose and frequency of administration	<p>Doses to be taken TWICE a day – see dosage table below.</p> <table border="1"> <thead> <tr> <th>Age</th> <th>Dose (mg)</th> <th>Dose (volume or quantity)</th> </tr> </thead> <tbody> <tr> <td>Less than 4 weeks of age</td> <td colspan="2">Excluded</td> </tr> <tr> <td>4 weeks to less than 8 weeks of age</td> <td>50 mg TWICE a day</td> <td>1 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>8 weeks to less than 6 months of age</td> <td>75 mg TWICE a day</td> <td>1.5 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>6 months to less than 1 year of age</td> <td>100 mg TWICE a day</td> <td>2 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>1 year to less than 2 years of age</td> <td>150 mg TWICE a day</td> <td>3 mL of 250 mg in 5 mL suspension TWICE a day</td> </tr> <tr> <td>2 years to less than 4 years of age</td> <td>200 mg TWICE a day</td> <td>4 mL of 250 mg in 5 mL suspension TWICE a day or TWO 100mg tablets TWICE a day</td> </tr> </tbody> </table> <p>(continued over page)</p>		Age	Dose (mg)	Dose (volume or quantity)	Less than 4 weeks of age	Excluded		4 weeks to less than 8 weeks of age	50 mg TWICE a day	1 mL of 250 mg in 5 mL suspension TWICE a day	8 weeks to less than 6 months of age	75 mg TWICE a day	1.5 mL of 250 mg in 5 mL suspension TWICE a day	6 months to less than 1 year of age	100 mg TWICE a day	2 mL of 250 mg in 5 mL suspension TWICE a day	1 year to less than 2 years of age	150 mg TWICE a day	3 mL of 250 mg in 5 mL suspension TWICE a day	2 years to less than 4 years of age	200 mg TWICE a day	4 mL of 250 mg in 5 mL suspension TWICE a day or TWO 100mg tablets TWICE a day
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<p>Drug interactions (continued)</p>	<ul style="list-style-type: none"> ➤ eliglustat ➤ ibrutinib ➤ zanubrutinib ➤ pomalidomide <p>Cautions</p> <p>Individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be referred to the supervising doctor for assessment and 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, anagrelide, chlorpromazine, duloxetine, melatonin, rasagiline, riluzole, roflumilast, sildenafil). Advise parents or carers to be alert to any increase in adverse effects and to speak to the child's usual healthcare provider as soon as possible if adverse effects occur.</p> <p>Individuals taking zolmitriptan should be advised that a maximum dose of 5mg of zolmitriptan should be taken in any 24-hours.</p> <p>See cautions 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 sevelamer, lanthanum, sucralfate, antacids and any medicines or supplements containing calcium, magnesium, aluminium, iron or zinc that may reduce the absorption of ciprofloxacin.</p>
<p>Identification & management of adverse reactions (continued over page)</p>	<p>Although there are potential and serious side effects, the benefit of using ciprofloxacin to prevent disease associated with tularemia exposure outweighs these risks.</p> <p>Commonly reported adverse reactions are nausea, diarrhoea and joint pain and joint inflammation in children. Nausea may be relieved by taking ciprofloxacin after food. Parents and carers should be alert to the possibility of joint pain and inflammation, and follow the advice outlined below.</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 parents or carers to stop giving ciprofloxacin to their child immediately and seek urgent medical advice by dialling 999 if the following severe adverse effects occur:</p> <ul style="list-style-type: none"> ➤ anaphylaxis (delayed or immediate). ➤ sudden, severe pain in the stomach, chest or back. ➤ seizures. ➤ thoughts about self-harm or ending their life.

<p>Identification & management of adverse reactions (continued)</p>	<p>Advise parents or carers to be alert to the possibility of the following rare effects, and to stop giving ciprofloxacin to their child immediately and seek urgent medical advice by calling a GP or 111 if the child experiences any of the following:</p> <ul style="list-style-type: none"> ➤ pain, swelling or inflammation of joints such as the shoulders, arms or legs or tendon pain or swelling. Very young children may not be able to report specific joint pain, so parents and carers should be alert to other signs such as lack of use of limbs or pain on movement. ➤ diarrhoea that lasts more than 4 days or contains blood or mucus. ➤ changes to vision, taste, smell or hearing. ➤ signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach). ➤ symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking). ➤ sudden breathlessness, especially when lying down. ➤ new onset heart palpitations. ➤ swollen ankles, feet or stomach. ➤ 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). <p>A detailed list of adverse reactions is available in the SmPC.</p>
<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Alert the supervising doctor in the event of a serious adverse reaction to the medicine, document in the individual's record and inform the individual's GP.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p> <p>An information leaflet explaining how to use and clean the oral syringe.</p> <p>Consider providing the MHRA information leaflet on side effects.</p>
<p>Advice / follow up treatment (continued over page)</p>	<p>Explain the treatment.</p> <p>Advise the parent or carer the child should:</p> <ul style="list-style-type: none"> ➤ maintain adequate fluid intake. ➤ not take indigestion remedies or medicines containing calcium, magnesium, aluminium, iron or zinc 2 hours before or 4 hours after taking the medicine.

Advice / follow up treatment

(continued)

- not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice).
- space the doses evenly throughout the day.
- keep taking the medicine until the course is finished, unless they are told to stop.

For suspension: Inform the parent or carer:

- to shake the suspension bottle vigorously each time before use for approximately 15 seconds.
- there will be suspension remaining after the 4 days and to take the remaining unused suspension after the 4 days to a community pharmacy for disposal.

For tablets: Inform the parent or carer:

- these should 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.
- tablets should not be chewed.
- tablets can be crushed, if necessary (see [off-label section](#) of this PGD), parents and carers should be advised that the tablets are very bitter in taste, and to encourage their children to swallow the tablets whole where possible.
- any unused tablets should be taken to a community pharmacy for disposal.

Inform the parent or carer:

- for babies receiving milk feeds, to space the doses in the mid period between expected feed times.
- of possible side effects and their management.
- 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.
- the medicine can make the skin more sensitive to direct sunlight. Children should avoid exposure to excessive sunlight or use high SPF sunblock if prolonged exposure to the sun is unavoidable.
- to seek immediate medical attention if the child develops signs or symptoms compatible with anthrax or other serious adverse effects (see [identification and management of adverse reactions](#)).
- the medicine may cause the child to feel tired or less alert. Children should take care when doing tasks that require coordination (for example riding a bike) until they get used to the medicine.

For individuals with conditions listed in the [cautions](#) section, provide the additional recommended advice.



Records

Record:

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

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

All records should be clear, legible and contemporaneous.

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

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

PGD for the initial supply of doxycycline for post-exposure prophylaxis to tularemia in adults and children aged 8 years and over

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Initial chemoprophylaxis following exposure to a known or suspected deliberate release of tularemia.</p> <p>Notes:</p> <p>Ciprofloxacin is also indicated for post exposure prophylaxis to tularemia. See ciprofloxacin initial supply PGD for 12 years and over and under 12 years.</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on tularemia, including post-exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Adults and children aged 8 years and over following exposure to a known or suspected deliberate release of tularemia.</p> <p>AND</p> <p>are not showing symptoms compatible with tularemia infection. Individuals with symptoms should be referred urgently to the supervising clinician. See action to be taken if individual, parent or carer declines prophylaxis below, and the chemical, biological, radiological and nuclear (CBRN) incident guidance for symptoms.</p>
<p>Exclusion criteria²⁰</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they are under 8 years of age. ➤ they are pregnant or suspected to be pregnant as doxycycline affects teeth and bone growth in the baby, notably in the second and third trimester. ➤ they are currently breastfeeding. ➤ they have known severe hepatic impairment. ➤ they have a known history of severe allergic reaction to doxycycline, other tetracyclines or to any of the listed excipients. See SmPC. ➤ they are receiving systemic retinoid treatment (for example, acitretin, alitretinoin, isotretinoin, tretinoin) due to possible increased risk of benign intracranial hypertension when tetracyclines are given with retinoids. ➤ they are taking enzyme inducing anti-epileptic medications (carbamazepine, fosphenytoin, phenobarbital / phenobarbitone (barbiturates), primidone, phenytoin) as effectiveness of doxycycline may be reduced. ➤ they have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained). <p>See action to be taken if individual is excluded section of this PGD.</p>

²⁰ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Cautions (including relevant actions to be taken)

For individuals where the following cautions apply, supply doxycycline unless there are life-threatening contraindications as benefit outweighs risk in the case of a suspected or deliberate release of tularemia. Individuals should be provided with the advice outlined below.

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

1. Myasthenia gravis:

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

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

2. Systemic lupus erythematosus (SLE):

Consider supply of ciprofloxacin ([see ciprofloxacin initial supply PGD](#)) if no contra-indications or advise to self-monitor for any increase in severity of SLE. If increase in severity of SLE occurs, advise individual to seek urgent medical advice.

3. Liver impairment:

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

4. Chronic alcohol dependence:

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

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

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

Note: INR also needs to be monitored with ciprofloxacin.

6. Taking penicillin:

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

7. Taking ciclosporin or lithium:

Consider supply of ciprofloxacin ([see ciprofloxacin initial supply PGD](#)) if appropriate or advise individual to contact the service who prescribe / monitor the affected medicines to arrange monitoring and any dose adjustments.

Advise to be aware of any signs of toxicity.

(continued over page)

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>8. Already taking doxycycline or other tetracycline for another condition:</p> <p>Advise individual to stop their existing course. They should now take doxycycline at the dose and frequency outlined in this PGD. If doxycycline or another tetracycline has previously been prescribed for ongoing treatment, the individual can be advised to continue at the previous dose once the course for tularemia post-exposure prophylaxis is complete.</p> <p>Refer to the SmPC for doxycycline for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ Consider supply of ciprofloxacin (see ciprofloxacin initial supply PGD). ➤ Where ciprofloxacin is contraindicated refer the individual to the supervising clinician for assessment and consideration of alternative antibiotics. ➤ Document reasons for exclusion and any referrals that have been made. ➤ Note: tularemia is not sensitive to penicillins such as amoxicillin or co-amoxiclav.
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual, parent 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 to seek urgent medical attention if they develop symptoms compatible with tularemia infection or signs and symptoms of sepsis. Symptoms of pneumonic tularemia include: <ul style="list-style-type: none"> ○ fever, chills, headache, myalgia, sore throat, dry cough, pleuritic chest pain, dyspnoea. ➤ See CRBN guidance for information on other symptoms to be aware of depending on the type of exposure. ➤ Document the advice given and the decision reached.
<p>Arrangements for referral for medical advice</p>	<p>Follow local procedures for referral to the supervising clinician and / or other services.</p>



2. Description of Treatment

Name, strength & formulation of drug	Doxycycline 100 mg capsules
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Tularemia post exposure prophylaxis is not included under the therapeutic indications in the SmPC but is recommended in the guidance on CBRN incidents.</p> <p>The dose for 8-12 years is higher than in the SmPC but follows the recommendations in the guidance on CBRN incidents.</p> <p>Where a product is recommended off-label consider, as part of the consent process, informing the individual, parent or carer the product is being offered in accordance with national guidance, but this is outside the product licence.</p>
Route / method of administration	<p>Oral</p> <p>To be swallowed whole with a full glass of water, in either the sitting or standing position. It can be taken with food or milk to reduce the risk of gastric irritation.</p>
Dose and frequency of administration	<p>ONE capsule (100 mg) to be taken TWICE a day</p> <p>For individuals who are unable to swallow the capsules, refer to the supervising doctor for assessment and consideration of alternative antibiotics or formulation.</p>
Duration of treatment	10 days
Quantity to be supplied	<p>20 (twenty) capsules OR</p> <p>a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the 10-day course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise individual or their parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>
Storage	Store in original container below 25°C.

<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>
<p>Drug interactions</p>	<p>This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p> <p>Contraindications</p> <ul style="list-style-type: none"> ➤ individuals taking systemic retinoids and enzyme-inducing anti-epileptics are excluded from this PGD (see exclusion criteria). <p>Cautions</p> <ul style="list-style-type: none"> ➤ anticoagulants, vitamin K antagonists, ciclosporin, lithium, penicillin, alcohol: see cautions for advice to be given. ➤ individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be advised to contact the administering clinic or GP as soon as possible for advice as doxycycline may reduce the efficacy of these vaccines. ➤ antacids, aluminium, calcium, iron, magnesium, bismuth and zinc salts: greatly decrease the absorption of doxycycline. Administration should be separated by 2 to 3 hours. <p>Oral contraceptives.</p> <p>Doxycycline does not reduce their efficacy but if it makes them vomit or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).</p>
<p>Identification & management of adverse reactions</p> <p>(continued over page)</p>	<p>A detailed list of adverse reactions is available in the SmPC.</p> <p>Advise the individual that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999:</p> <ul style="list-style-type: none"> ➤ allergic reactions such as sudden difficulty with breathing, speaking and swallowing. ➤ extreme dizziness or fainting. ➤ severe itchy skin rash especially if blistering, soreness of the eyes, mouth or genital organs. <p>Commonly reported side effects include:</p> <ul style="list-style-type: none"> ➤ nausea, vomiting and headache. ➤ hypersensitivity reactions. ➤ photosensitivity and rash including maculopapular and erythematous rashes.

<p>Identification & management of adverse reactions (continued)</p>	<p>Advise individuals to take doxycycline after food or with a drink of milk instead of water to help with nausea.</p> <p>To help with photosensitivity, advise individuals to wear clothes that cover them up and a hat and sunglasses when going outside. Advise they use a high SPF sunscreen of at least 30 to prevent any sunburn.</p> <p>If individuals are concerned about other side effects, they should be advised to continue with treatment and contact a GP or pharmacist.</p>
<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Any serious adverse reaction to the medicine should be documented in the individual's record and the individual's GP informed.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p>
<p>Advice / follow up treatment (continued over page)</p>	<p>Provide the individual, parent or carer with the following advice:</p> <ul style="list-style-type: none"> ➤ the dose, frequency and method of administration. ➤ to swallow the capsules whole with plenty of fluid during meals in either the sitting or standing position. ➤ to not lie down within an hour of taking the medication, so not to take at bedtime. ➤ to not take on an empty stomach because of the risk of oesophagitis. ➤ to not take indigestion remedies or medicines containing aluminium, calcium, iron, magnesium zinc or bismuth, 2 to 3 hours before or after taking the medicine. ➤ if gastric irritation occurs, the capsules may be taken with milk. ➤ if a dose is missed, advise to refer to the PIL supplied with the product. ➤ to space the doses evenly throughout the day. ➤ to avoid exposure to direct sunlight or ultraviolet light including sunbeds and sun lamps. If unavoidable, advise to cover up and use high SPF sun cream. ➤ to avoid alcohol. ➤ to keep taking this medicine until the course is finished, unless they are told to stop. ➤ to return any unused medication at the end of the course to a community pharmacy for destruction.

<p>Advice / follow up treatment</p> <p>(continued)</p>	<p>For individuals with conditions listed in the cautions section, provide the additional recommended advice.</p> <p>Inform the individual, parent or carer:</p> <ul style="list-style-type: none"> ➤ to read the PIL provided with the medicine. ➤ of possible side effects and their management. ➤ to seek medical advice if side effects or any other unexplained effects on health are experienced. ➤ if side effects become serious, severe or prolonged, or if the individual notices any side effects not listed in the PIL, to contact their local doctor or pharmacist immediately. ➤ if symptoms of tularemia develop, to seek medical advice immediately. ➤ when the subsequent supply is due and where they can get the supply.
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> ➤ whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005. ➤ name of individual, address, date of birth, allergies, and GP with whom the individual is registered (or record where an individual is not registered with a GP). ➤ name of member of staff who supplied the product. ➤ name and brand of the product. ➤ date of supply. ➤ dose, form and route of administration of the product. ➤ quantity supplied. ➤ batch number and expiry date. ➤ advice given; including advice given if the individual is excluded or the individual or the parent or carer declines treatment. ➤ details of any adverse drug reactions and actions taken. ➤ that the product was supplied via PGD. <p>All records should be signed and dated (or password-controlled on records). 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 doxycycline or an alternative antibiotic, where appropriate.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

PGD for the further supply of doxycycline for post-exposure prophylaxis to tularemia in adults and children aged 12 years and over

1. Clinical Condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Where continuing chemoprophylaxis is required following a known exposure to a deliberate release of tularemia.</p> <p>Notes:</p> <p>Use doxycycline wherever possible, reserving continuity of prophylaxis with ciprofloxacin for children under 12 years of age.</p> <p>Incident specific advice should be followed to support choice of antimicrobial.</p> <p>For additional information on tularemia, including post-exposure prophylaxis, see CBRN guidance.</p>
<p>Inclusion criteria</p>	<p>Adults and children aged 12 years and over following exposure to a known deliberate release of tularemia.</p> <p>AND</p> <p>who have already received chemoprophylaxis for 10 days with doxycycline or ciprofloxacin</p> <p>AND</p> <p>are not showing symptoms compatible with tularemia infection. Individuals with symptoms should be referred urgently to the supervising doctor. See action to be taken if individual, parent or carer declines prophylaxis below and the chemical, biological, radiological and nuclear (CBRN) incident guidance for symptoms.</p>
<p>Exclusion criteria²¹</p> <p>(continued over page)</p>	<p>Individuals are excluded from this PGD if:</p> <ul style="list-style-type: none"> ➤ they are under 12 years of age. ➤ they are pregnant or suspected to be pregnant as doxycycline affects teeth and bone growth in the baby, notably in the second and third trimester. ➤ they are currently breastfeeding. ➤ they have known severe liver impairment. ➤ they have a known history of severe allergic reaction to doxycycline or other tetracyclines or to any of the listed excipients (see SmPC). ➤ they have experienced unacceptable side effects while taking the initial ten days' supply of doxycycline. ➤ they are receiving systemic retinoid treatment (for example acitretin, alitretinoin, isotretinoin, tretinoin) due to possible increased risk of benign intracranial hypertension when tetracyclines are given with retinoids.

²¹ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

<p>Exclusion criteria (continued)</p>	<ul style="list-style-type: none"> ➤ they are taking enzyme inducing anti-epileptic medications (carbamazepine, fosphenytoin, phenobarbital / phenobarbitone (barbiturates), primidone, phenytoin) as the effectiveness of doxycycline may be reduced. ➤ they have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained). <p>See action to be taken if the individual is excluded section.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued over page)</p>	<p>For individuals where the following cautions apply, supply doxycycline unless there are life-threatening contraindications as benefit outweighs risk in the case of a deliberate release of tularemia. 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>1. Myasthenia gravis:</p> <p>Advise to self-monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise individuals to seek urgent medical attention.</p> <p>Note: ciprofloxacin is also cautioned for individuals with myasthenia gravis.</p> <p>2. Systemic lupus erythematosus (SLE):</p> <p>Consider supply of ciprofloxacin (see ciprofloxacin further supply PGD) if no contra-indications or advise to self-monitor for any increase in severity of SLE. If increase in severity of SLE occurs, advise individual to seek medical advice.</p> <p>3. Liver impairment:</p> <p>Doxycycline has been associated with rare incidents of hepatic injury. Manufacturers advise caution in those with liver impairment or those receiving potentially hepatotoxic medicines. Those with known severe liver impairment are excluded from this PGD (see exclusion criteria).</p> <p>4. Chronic alcohol dependence:</p> <p>Alcohol may reduce the half-life of doxycycline, particularly for individuals with chronic alcohol dependence. Twice daily dosing may reduce the significance of this interaction. If ciprofloxacin is contraindicated, advise of risk and to seek immediate medical advice if symptoms compatible with tularemia infection develop.</p> <p>5. Severely immunocompromised individuals:</p> <p>Individuals who are severely immunocompromised (as defined in chapter 28a Green book) should be advised to arrange an appointment with a GP or specialist to determine whether they need to continue treatment beyond the course outlined in this PGD.</p> <p>6. Taking vitamin K antagonists (for example, warfarin, phenindione and acenocoumarol):</p> <p>Advise individual to arrange for INR to be monitored 3-5 days after starting</p>

<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>treatment and to speak to a GP or anticoagulant clinic if they notice any signs of bleeding or unexplained / excessive bruising.</p> <p>Note: INR also needs to be monitored with ciprofloxacin.</p> <p>7. Taking penicillin:</p> <p>Doxycycline may reduce the effect of penicillin. For individuals taking penicillin for a serious infection, seek advice from the supervising doctor.</p> <p>8. Taking ciclosporin or lithium:</p> <p>Consider supply of ciprofloxacin (see ciprofloxacin further supply PGD) if appropriate or advise individual to contact the service who prescribe / monitor the affected medicines to arrange monitoring and any dose adjustments. Advise to be aware of any signs of toxicity.</p> <p>9. Already taking doxycycline or other tetracycline for another condition:</p> <p>Advise individual to stop their existing course. They should now take doxycycline at the dose and frequency outlined in this PGD. If doxycycline or another tetracycline has previously been prescribed for ongoing treatment, the individual can be advised to continue at the previous dose once the course for tularemia post-exposure prophylaxis is complete.</p> <p>Refer to the SmPC for doxycycline for full details on special warnings and precautions for use.</p>
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> ➤ Explain why they have been excluded. ➤ Consider supply of ciprofloxacin (see ciprofloxacin further supply PGD). ➤ If ciprofloxacin is contraindicated refer the individual to the supervising doctor for assessment and consideration of alternative antibiotics. ➤ Document reasons for exclusion and any referrals that have been made. ➤ Note: tularemia is not sensitive to penicillins such as amoxicillin or co-amoxiclav.
<p>Action to be taken if the individual, parent or carer declines prophylaxis</p>	<ul style="list-style-type: none"> ➤ Refer the individual to the supervising doctor. ➤ Advise the individual, parent 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 to seek urgent medical attention if they develop symptoms compatible with tularemia infection or signs or symptoms of sepsis. Symptoms of pneumonic tularemia include: <ul style="list-style-type: none"> ○ fever, chills, headache, myalgia, sore throat, dry cough, pleuritic chest pain, dyspnoea. ➤ See CRBN guidance for further information on symptoms to be aware of depending on the type of exposure. ➤ Document the advice given and the decision reached.

**Arrangements for
referral for medical
advice**

Follow local procedures for referral to the supervising doctor and / or other services.

2. Description of treatment

Name, strength & formulation of drug	Doxycycline 100 mg capsules
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Tularemia post exposure prophylaxis is not included under the therapeutic indications in the SmPC but is recommended in the guidance on CBRN incidents.</p> <p>Where a product is recommended off-label consider, as part of the consent process, informing the individual, parent or carer the product is being offered in accordance with national guidance, but this is outside the product licence.</p>
Route / method of administration	<p>Oral</p> <p>To be swallowed whole with a full glass of water, in either the sitting or standing position. It can be taken with food or milk to reduce the risk of gastric irritation.</p>
Dose and frequency of administration	<p>ONE capsule (100 mg) to be taken TWICE a day</p> <p>For individuals who are unable to swallow the capsules, refer to the supervising doctor for assessment and consideration of alternative antibiotics or formulation.</p>
Duration of treatment	4 days following an initial 10-day supply of antibiotics.
Quantity to be supplied	<p>8 (eight) capsules OR</p> <p>a sufficient quantity of whole packs (either over labelled manufacturer's original packs or over labelled prepacks) for the 10-day course.</p> <ul style="list-style-type: none"> ➤ Pack sizes may vary subject to availability. Original packs should not be split. ➤ Medications should not be taken out from their original packs and should not be combined to provide the quantity for treatment. ➤ Always highlight to patient the date for the last day of treatment. ➤ If the quantity supplied exceeds the duration – advise patient to stop taking the medication after the last day of treatment. ➤ The individual's name, the date and additional instructions must be written on the label at the time of supply. <p>Advise individual or their parent or carer to safely discard any excess capsules/tablets/liquid antibiotics by taking these to the local community pharmacy. Disposal via household waste or pouring them down the sink/toilet may lead to antibiotic resistance.</p>
Storage	Store in original container below 25°C.

<p>Disposal</p>	<p>Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.</p>
<p>Drug interactions</p>	<p>This list is not exhaustive. A detailed list of drug interactions can be found in the SmPC or the BNF.</p> <p>Contraindications</p> <ul style="list-style-type: none"> ➤ individuals taking systemic retinoids and enzyme-inducing anti-epileptics are excluded from this PGD (see exclusion criteria). <p>Cautions</p> <ul style="list-style-type: none"> ➤ anticoagulants, vitamin K antagonists, ciclosporin, lithium penicillin, alcohol: see cautions for advice to be given. ➤ individuals who have received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days should be advised to contact the administering clinic or GP as soon as possible for advice as doxycycline may reduce the efficacy of these vaccines. ➤ antacids, aluminium, calcium, iron, magnesium, bismuth and zinc salts: greatly decrease the absorption of doxycycline. Administration should be separated by 2 to 3 hours. <p>Oral contraceptives</p> <p>Doxycycline does not reduce their efficacy but if it makes them vomit or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).</p>
<p>Identification & management of adverse reactions</p> <p>(continued over page)</p>	<p>A detailed list of adverse reactions is available in the SmPC.</p> <p>Advise the individual that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999:</p> <ul style="list-style-type: none"> ➤ allergic reactions such as sudden difficulty with breathing, speaking and swallowing. ➤ extreme dizziness or fainting. ➤ severe itchy skin rash especially if blistering, soreness of the eyes, mouth or genital organs. <p>Commonly reported side effects include:</p> <ul style="list-style-type: none"> ➤ nausea, vomiting and headache. ➤ hypersensitivity reactions. ➤ photosensitivity and rash including maculopapular and erythematous rashes. <p>Advise individuals to take doxycycline after food or with a drink of milk instead of water to help with nausea.</p>

<p>Identification & management of adverse reactions</p> <p>(continued)</p>	<p>To help with photosensitivity, advise individuals to wear clothes that cover them up and a hat and sunglasses when going outside. Advise they use a high SPF sunscreen of at least 30 to prevent any sunburn.</p> <p>If individuals are concerned about other side effects, they should be advised to continue with treatment and contact a GP or pharmacist.</p>
<p>Reporting procedure for suspected adverse reactions</p>	<p>All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.</p> <p>Any serious adverse reaction to the medicine should be documented in the individual's record and the individual's GP informed.</p>
<p>Written information to be given</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.</p>
<p>Advice / follow up treatment</p> <p>(continued over page)</p>	<p>Provide the individual, parent or carer with the following advice:</p> <ul style="list-style-type: none"> ➤ the dose, frequency and method of administration. ➤ to swallow the capsules whole with plenty of fluid during meals in either the sitting or standing position. ➤ to not lie down within an hour of taking the medication, so not to take at bedtime. ➤ to not take on an empty stomach because of the risk of oesophagitis. ➤ to not take indigestion remedies or medicines containing aluminium, calcium, iron, magnesium, bismuth or zinc 2 to 3 hours before or after taking the medicine. ➤ if gastric irritation occurs, the capsules may be taken with milk. ➤ if a dose is missed, advise to refer to the PIL supplied with the product. ➤ to space the doses evenly throughout the day. ➤ to avoid exposure to direct sunlight or ultraviolet light including sunbeds and sun lamps. If unavoidable, advise to cover up and use high SPF sun cream. ➤ to avoid alcohol. ➤ to keep taking this medicine until the course is finished, unless they are told to stop. ➤ to return any unused medication at the end of the course to a community pharmacy for destruction. <p>For individuals with conditions listed in the cautions section, provide the additional recommended advice.</p>

<p>Advice / follow up treatment (continued)</p>	<p>Inform the individual, parent or carer:</p> <ul style="list-style-type: none"> ➤ to read the PIL provided with the medicine. ➤ of possible side effects and their management. ➤ to seek medical advice if side effects or any other unexplained effects on health are experienced. ➤ if side effects become serious, severe or prolonged, or if the individual notices any side effects not listed in the PIL to contact a GP or pharmacist immediately. ➤ if symptoms compatible with tularemia infection develop to seek medical advice immediately.
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> ➤ whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005. ➤ name of individual, address, date of birth, allergies, and GP with whom the individual is registered (or record where an individual is not registered with a GP). ➤ name of member of staff who supplied the product. ➤ name and brand of the product. ➤ date of supply. ➤ dose, form and route of administration of the product. ➤ quantity supplied. ➤ batch number and expiry date. ➤ advice given; including advice given if the individual is excluded or the individual, parent or carer declines treatment. ➤ details of any adverse drug reactions and actions taken. ➤ that the product was supplied via PGD. <p>All records should be signed and dated (or password-controlled on records). 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 or an alternative antibiotic, where appropriate.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>



Appendices

Appendix A: Key references

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Appendix B: Practitioner authorisation sheet

Patient Group Directions for the supply of antibiotics by healthcare practitioners responding to an incident following activation of the NHS Wales CBRN emergency planning procedures v1.0

Valid from: 01 May 2025 Expiry: 31 March 2028

Check the PGDs that the practitioner and authorising manager signatures overleaf apply to:

<input type="checkbox"/> Anthrax	<input type="checkbox"/> Plague	<input type="checkbox"/> Tularemia
Initial supply of ciprofloxacin to adults and children aged 12 years and over	Supply of ciprofloxacin to adults and children aged 12 years and over	Initial supply of ciprofloxacin to adults and children aged 12 years and over
Initial supply of ciprofloxacin to children aged under 12 years	Supply of ciprofloxacin to children aged under 12 years	Initial supply of ciprofloxacin to children aged under 12 years
Further supply of ciprofloxacin to adults and children aged 12 years and over	Supply of doxycycline to adults and children aged 8 years and over	Further supply of ciprofloxacin to adults and children aged 12 years and over
Further supply of ciprofloxacin to children aged under 12 years		Further supply of ciprofloxacin to children aged under 12 years
Initial supply of doxycycline to adults and children aged 8 years and over		Initial supply of doxycycline to adults and children aged 8 years and over
Further supply of doxycycline to adults and children aged 12 years and over		Further supply of doxycycline to adults and children aged 12 years and over

Before signing these PGDs, check that the document has had the necessary authorisations in [section 3](#). Without these, these PGDs are not lawfully valid. Signed copies of these sheets should be kept in accordance with the retention statement in [section 3](#).

Practitioner

By signing these PGDs 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.



Appendix C: PTHB Additional local appendix for CBRN PGD booklet

Section of PGD	Additional requirements
Characteristics of staff	<p>Practitioner must have completed Patient Group Directions training (available via eLH PGD eLearning programme. PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion.</p> <p>The practitioner must update at least every 2 years on the administration/use, contra-indications and adverse effects of the medication.</p> <p>Practitioners must make a self-declaration of competency on PADR (if relevant). The personal development plan (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning.</p> <p>Individuals operating under this PGD must be assessed as competent -refer to Appendix B: Practitioner authorisation sheet and the PTHB competency checklist.</p> <p>Compliance with all mandatory NHS training (if relevant), including safeguarding at the level relevant to the role.</p> <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.</p>
Clinical Condition: Situation	It is the responsibility of the supplying healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding. If there is any reason for concern, seek medical advice.
Clinical Condition: Inclusion criteria	<p>Medical and drug history taken, no reason for exclusion.</p> <p>Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to supply (or a best-interests decision in accordance with the Mental Capacity Act 2005 must be obtained). Refer to PTHB Consent to Treatment and Examination Policy</p>
Clinical Condition: Cautions	<p>Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list).</p> <p>Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub:</p> <ul style="list-style-type: none"> to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and Central Safeguarding number: 01686 252806 Out of hours: 0345 0544847 <p>Advice can also be sought from local Safeguarding leads</p>
Clinical Condition: Action to be taken if the individual, parent or carer declines	The patient information leaflet should be available to inform consent.
Description of treatment: Records	<p>Record consultation details as required by local procedures, to include:</p> <ul style="list-style-type: none"> Name of representative who gave consent if appropriate. Medical and drug history taken, including allergies and previous adverse events PGD title and version number



Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

	Name: Role:	Sign / Initial	Further training identified (Y/N) Specify in " comments	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to the individual's line manager and to the staff member, in conjunction with the practitioner authorisation sheet. A copy of this form should also be kept by the service lead in the training file.