



Publications reference number: PRN01658

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

This PGD is for the initial supply of ciprofloxacin 500mg tablets, to adults and children aged 12 years and over exposed to a known or suspected deliberate release of anthrax, by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference: Ciprofloxacin 500mg tabs initial supply anthrax

Version number: 5.0a

Valid from: 1 April 2025 Review date: 1 April 2027 Expiry date: 31 March 2028

The UK Health Security Agency (UKHSA) has developed this PGD for local authorisation

Those using this PGD must ensure it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)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 (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided.

As operation of this PGD is the responsibility of commissioners and service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD. Sections 2, 3 and 7 must be completed and amended within the designated editable fields provided, but only for the purposes for which these sections are provided, that is the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in Section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.

The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA Chemical, Biological, Radiological and Nuclear (CBRN) PGD templates for authorisation can be found from:

NHS England » Hazardous Materials (HAZMAT) and Chemical, Biological, Radiological and Nuclear (CBRN)

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

¹ This includes any relevant amendments to legislation 20250401Ciprofloxacin500mgtabs_initialsupply_anthrax_PGD5.0a Valid from: 1 April 2025 Expiry: 31 March 2028

Change history

Version number	Change details	Date
PGD 2014/1	Original template developed and ratified	10 June 2014
PGD 2.0	 Put into the new PHE template format For use in anthrax only, tularemia and plague put in separate PGDs Clinical indications: "another biological agent" removed Abbreviated lists of warnings and contra-indications included these medicines must be offered in all cases where exposure to these biological agents may have occurred unless there are life-threatening contra-indications. Interactions: advice simplified. References updated. 	1 May 2016
PGD 3.0	Put into the new PHE template format References updated	7 December 2018
PGD 4.0	 Addition of 'following deliberate release' to page 1, clinical indication and criteria for inclusion for clarity Removal of concurrent administration of aminophylline and theophylline from exclusion criteria Cautions: amended wording for additional advice / actions to be taken; initiate supply for renal impairment to avoid delay; other medications added Additional information under drug interactions section, adverse reactions and patient advice section Minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates 	17 January 2022
PGD 5.0	 Minor rewording, layout and formatting changes in line with UKHSA PGD templates and references updated Title and clinical condition changed to specify inhalational exposure, use first line replaced with incident specific advice Not showing symptoms added to inclusion criteria Previous severe reactions, history of tendon disease with quinolones, stages of renal impairment, additional drug interactions and no consent added to exclusion criteria Wording under cautions changed, tendinitis risk, heart valve regurgitation and aortic aneurysm risk, diabetes, G6PD deficiency and medications requiring monitoring added with advice Symptoms of anthrax added to advice if declines Information for individuals unable to swallow added to dose and frequency of administration Drug interactions updated to include specific information on interactions and medicines to avoid Identification and management of adverse effects, advice to be given updated in line with MHRA alerts MHRA leaflet added to written information to be provided 	14 January 2025

PGD 5.0a	Title and clinical condition amended for greater clarity and consistency across PGDs	1 April 2025	
	2. Wording amendments for consistency across PGDs		
	Wording in cautions amended for greater clarity		
	4. Off-label use updated with information for breastfeeding and		
	pregnancy		
	5. Drug interactions section refined to exclude rarely used or		
	non-UK medicines		

1. PGD development

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

Developed by:	Name	Signature	Date
Doctor (Expert panel chair)	Ruth Milton, Head of Advice, All Hazards Public Health Response, UKHSA		1 April 2025
Pharmacist (Lead author)	Anna Wilkinson, Clinical Response Pharmacist, All Hazards Public Health Response, UKHSA	Al akinom	1 April 2025
Registered Nurse	Gemma Hudspeth, Senior Health Protection Practitioner, UKHSA	Sh	1 April 2025

This PGD has been peer reviewed by the CBRN PGD expert panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee

Expert panel

Name	Post	
Claire Gordon	Consultant in Infectious Diseases and Deputy head of the UKHSA Rare and Imported Pathogens Laboratory	
Diane Ashiru-Oredope	Lead Pharmacist, HCAI, Fungal, AMR, AMU and Sepsis Division, UKHSA	
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service	
Michelle Jones	Principal Medicines Optimisation Pharmacist NHS Bristol, North Somerset and South Gloucestershire ICB	
Kiran Attridge	Senior Medical Advisor, All Hazards Public Health Response, UKHSA	
Craig Prentice	Consultant Practitioner Paramedic, Surrey and Sussex Healthcare NHS Trust	
Rachel Berry	Chief Pharmaceutical Officer's Clinical Fellow, HCAI, Fungal, AMR, AMU and Sepsis Division, UKHSA	
Sherine Thomas	Consultant in Emerging Infections and Zoonoses, UKHSA	
Sarah Upton	Lead Pharmacist for Medication Safety, community services, Locala Health and Wellbeing	
Kelly Stoker	Nurse Consultant for Adult Social Care, Health Equity and Inclusion Health Division, UKHSA	

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

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

Insert authorising body name authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services				
Limitations to authorisation				
For instance any local limitations	s the authorising organis	ation feels they need t	o apply in-line with	
the way services are commission	ned locally. This organis	sation does not authoris	se the use of this	
PGD by				
Organisational approval (legal requirement)				
Role	Name	Sign	Date	

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to (insert contact details)

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement, or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	To be completed by the organisation authorising the PGD for example registered professionals with one of the following bodies:	
	 nurses currently registered with the Nursing and Midwifery Council (NMC) 	
	 pharmacists currently registered with the General Pharmaceutical Council (GPhC) 	
	 paramedics currently registered with the Health and Care Professions Council (HCPC) 	
	 additional registered practitioners, appropriate for the role, who can legally operate under a PGD 	
	The practitioners above must also fulfil the <u>Additional requirements</u> detailed below.	
	Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD	
Additional requirements	Additionally, practitioners:	
	must be authorised by name as an approved practitioner under the current terms of this PGD before working to it	
	 must have undertaken appropriate training for working under PGDs for supply/administration of medicines 	
	must have undertaken training appropriate to this PGD	
	must be competent in the use of PGDs (see <u>NICE Competency framework</u> for health professionals using PGDs)	
	must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC)	
	must be competent to assess the individual and discuss treatment options	
	must have access to the PGD and associated online resources	
	should fulfil any additional requirements defined by local policy	
	authorising organisation to insert any additional requirements	
	The individual practitioner must be authorised by name, under the current version of this PGD before working according to it	
Continued training requirements	Authorising organisation to insert any continued training requirements	

4. Clinical condition or situation to which this PGD applies

Initial chemoprophylaxis following exposure to a known or suspected deliberate release of anthrax Note: Doxycycline is also indicated for post-exposure prophylaxis to anthrax. See doxycycline initial supply PGD Incident specific advice should be followed to support choice of antimicrobial	
For additional information on anthrax, including post-exposure prophylaxis, see CBRN guidance	
Adults and children aged 12 years and over following exposure to a known or suspected deliberate release of anthrax	
And	
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 or carer declines prophylaxis section of this PGD and the CBRN guidance for symptoms	
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	
Individuals are excluded from this PGD if:	
 Individuals are excluded from this PGD if: They have a known history of severe allergic reaction to ciprofloxacin, other fluoroquinolones or quinolones, or to any of the listed excipients (see SPC) 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 < 30ml/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) See Action to be taken if individual is excluded section of this PGD 	

 $^{^2}$ Exclusion under this PGD does not necessarily mean the antibiotic is contraindicated, but it would be outside its remit and another form of authorisation will be required

20250401Ciprofloxacin500mgtabs_initialsupply_anthrax_PGD5.0a Valid from 1 April 2025 Expiry: 31 March 2028

Cautions including any relevant action to be taken

(continued overleaf)

Caution is advised for individuals with the following conditions or who are taking certain medicines.

Doxycycline is the preferred option for these individuals if it is not contraindicated and is available. See the Doxycycline initial supply PGD.

If doxycycline is contraindicated, or not available then ciprofloxacin can be supplied as the benefit of taking it to prevent anthrax infection outweighs the risks. 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. At increased risk of tendinitis or tendon rupture:

- 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

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

2. Conditions with risk factor for QT interval prolongation:

- 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)

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, such as:
 - o connective tissue disorders such as Marfan's syndrome or Ehlers-Danlos syndrome
 - Turner syndrome
 - o Behçet's disease
 - o hypertension
 - rheumatoid arthritis
- presence of other risk factors or conditions for aortic aneurysm and dissection, such as:

Cautions including any relevant action to be taken

(continued overleaf)

- vascular disorders including Takayasu arteritis or giant cell arteritis
- known atherosclerosis
- o 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 their GP if individuals experience a rapid onset of shortness of breath, especially when lying down flat in bed, swelling of the

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

ankles, feet or abdomen or new-onset heart palpitations

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

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.

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 their GP or anticoagulant clinic if they notice any signs of bleeding or

Note: INR also needs to be monitored with doxycycline

unexplained/excessive bruising.

9. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine:

Advise individual to self-monitor for any signs of toxicity, and to contact the service responsible for monitoring these medicines as soon as possible to inform them of the treatment and to arrange appropriate follow up and monitoring

Cautions including any relevant action to be taken (continued)	Refer to the <u>SPC</u> for ciprofloxacin for full details on special warnings and precautions for use
Action to be taken if the	Refer the individual to the supervising doctor
individual or carer declines prophylaxis	Advise the individual or their parent/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 anthrax infection or signs or symptoms of sepsis.
	Symptoms of anthrax will depend on the type of exposure:
	 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
	See CBRN guidance for further information on symptoms
	Document the advice given and the decision reached
Action to be taken if the	Explain why they have been excluded
individual is excluded	Consider supply of doxycycline: see <u>Doxycycline initial supply PGD</u> .
	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
Arrangements for referral for medical advice	Follow local procedures for referral to the supervising doctor and/or other services

5. Description of treatment

Name, strength and formulation of drug	Ciprofloxacin 500mg tablets
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	Yes
	Pregnancy
	The manufacturers advise as a precautionary measure to avoid the use of ciprofloxacin during pregnancy. However, the data available indicates no malformative or feto/neonatal toxicity but the SPC 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 anthrax 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)
	Breastfeeding
	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.
	Ciprofloxacin may cause some babies to have mild stomach upsets and oral candidiasis.
	Where a product is recommended off-label consider, as part of the consent process, informing the individual/carer the product is being offered in accordance with national guidance but this is outside the product licence
Route / method of	Oral
administration	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
Dose and frequency of	Adults and children aged 12 years or over:
administration	One tablet (500mg) to be taken twice a day
(continued overleaf)	Administration should begin as soon as possible after suspected or confirmed exposure

Dose and frequency of administration (continued)	For individuals who are unable to swallow the tablets, refer to the supervising doctor for assessment and consideration of alternative antibiotics or formulation.		
Duration of treatment	10 days		
Quantity to be supplied	20 (twenty) tablets		
	When supplying under a PGD, this must be a complete over-labelled manufacturer's original pack or over-labelled pre-packs. The individual's name, the date and additional instructions must be written on the label at the time of supply. As split manufacturers packs cannot be supplied, if an over-supply is required, individuals must be advised to take any remaining medicine to a community pharmacy for destruction.		
Storage	Store in original container below 25 °C		
Disposal	Any unused product or waste material should be disposed of in accordance with local requirements.		
Drug interactions (continued overleaf)	Concurrent medications should be checked for interactions. This list is not exhaustive. Full details of drug interactions are available in the SPC and the BNF .		
	Excluded from PGD 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 Caution 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		

Drug interactions

(continued)

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 <u>Cautions</u> 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

Identification and management of adverse reactions

Although there are some potential and serious side effects, the benefit of using ciprofloxacin to prevent disease associated with anthrax exposure outweighs these risks

Most commonly reported adverse reactions are nausea and diarrhoea. Nausea may be relieved by taking ciprofloxacin after food.

Other side effects are classified as uncommon to very rare.

There have been cases of prolonged, disabling and potentially irreversible serious drug reactions reported rarely.

Advise individuals to stop taking ciprofloxacin immediately and seek urgent medical advice by dialling 999 if the following severe adverse effects occur:

- anaphylaxis (delayed or immediate)
- sudden, severe pain in the stomach, chest or back
- seizures
- thoughts about harming themselves or ending their life

Advise individuals to stop taking ciprofloxacin and seek immediate medical advice by calling 111 or their GP if any of the following rare effects occur:

- · 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

A detailed list of adverse reactions is available in the SPC

Reporting procedure of All suspected adverse reactions in children and severe adverse adverse reactions 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. Any serious adverse reaction to the drug should be documented in the individual's record and the individual's GP informed. Written information to Supply the marketing authorisation holder's Patient Information Leaflet be aiven (PIL). The additional information leaflet covering the use of ciprofloxacin in response to known or suspected exposure to a biological agent should also be provided. Consider providing the MHRA information leaflet on side effects Explain the treatment. Advice/follow up treatment Advise the individual or their parent/carer to: 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 mineralfortified 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 Inform the individual or their parent/carer: 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 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 anthrax 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 When applicable, advise individual/carer when the subsequent supply is due and where they can obtain this further supply

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, 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 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

6. Key references

Key references

- <u>Ciprofloxacin Summary of Product Characteristics</u> accessed 21 November 2024
- MHRA Fluoroquinolone Drug Safety Updates accessed 21 November 2024
- British National Formulary last updated 30 October 2024
- Chemical, biological, radiological and nuclear incidents: clinical management and health protection May 2018
- NHS Medicines A-Z: Ciprofloxacin Accessed December 2024
- Bower WA, Yu Y, Person MK, et al. CDC Guidelines for the Prevention and Treatment of Anthrax, 2023. MMWR Recomm Rep 2023;72(No. RR-6):1–47.
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions updated 27 March 2017
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions updated 4 January 2018
- Health Technical Memorandum 07-01: Safe and sustainable
 Management of Healthcare Waste. 7 March 2023

7. Practitioner authorisation sheet

Name PGD vXX.XX Valid from: XX/XX/20XX Expiry: XX/XX/20XX

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date
Authorising manager			

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **insert name of organisation** for the above-named health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.