UK Health Security Agency

NHS England

Publications gateway number: GOV-13505

Patient Group Direction (PGD) for ciprofloxacin for the management of clusters of meningococcal disease

For the supply or administration of ciprofloxacin 250mg tablets, 500mg tablets or 250mg/5ml suspension for the management of clusters of meningococcal disease when 2 or more cases are reported in a congregate setting, by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference:	CiprofloxacinMen_PGD
Version no:	04.00
Valid from:	20 October 2022
Review date:	20 April 2025
Expiry date:	19 October 2025

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 administered or 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 or amend the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided.

As operation of this PGD is the responsibility of commissioners and service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD. Therefore sections 2, 3 and 7 must be completed and can be amended in the editable field provided.

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 that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of the UKHSA PGD for authorisation can be found from: https://www.gov.uk/government/publications/meningococcal-disease-pgd-template-for-supply-of-ciprofloxacin

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

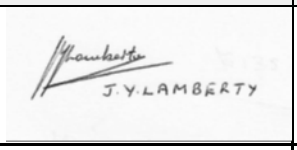
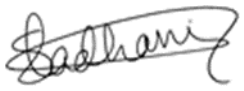
[1]This includes any relevant amendments to legislation

Change history

Version number	Change details	Date
01.00	Original version	February 2017
02.00	Wording changes on front page to be consistent with current wording on PHE PGDs Addition of administration as well as supply Amendments to criteria for inclusion Deletion of 4-week criterion Information on supply and administration Updated references and hyperlinks	May 2018
03.00	Additional information section added to clarify the EU-wide restrictions on the use of systemic fluoroquinolone antibiotics (including ciprofloxacin) due to very rare reports of serious side-effects, do not apply to the single dose of ciprofloxacin recommended for chemoprophylaxis of meningococcal disease. Addition in dose section for children and infants	August 2019
04.00	Amendment to wording in clinical setting Exclusion criteria and action to be taken if the patient is excluded: amendment of wording for allergy and removal of renal function Off-label use: addition of adolescents Details under dose and frequency of administration moved to route and method of administration Additional information under storage Amended standard work in line with UKHSA PGDs Updated references	20 October 2022

1. PGD development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead author)	Jacqueline Lamberty Lead Pharmacist Medicines Governance, UKHSA		20 October 2022
Doctor (Chair Expert Panel)	Dr Shamez Ladhani Consultant Epidemiologist, UKHSA Paediatric Infectious Disease Consultant, St. George's Hospital London Professor of Paediatric Infectious Diseases and Vaccinology, St. George's University of London		20 October 2022
Registered nurse	Kate Wedgwood Senior Health Protection Practitioner, East Midlands Health Protection Team UKHSA		20 October 2022

This PGD has been peer reviewed by an expert panel in accordance with the UKHSA PGD Policy. It has been agreed by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality Oversight Board.

Expert panel

Name	Designation
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Dr Eliza Alexander	Consultant in Public Health Infection, UKHSA
Prof Diane Ashiru-Oredope	Lead Pharmacist, HCAI, Fungal, AMR, AMU & Sepsis Division, UKHSA
Professor Ray Borrow	Head of UKHSA Meningococcal Reference Unit, UKHSA Manchester
Rosie Furner	Community Services Pharmacist, East Sussex Healthcare NHS Hospital Trust
Gemma Hudspeth	Health Protection Practitioner (North East) North East & Yorkshire Region
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), Medicines Use and Safety Division, NHS England (NHSE)
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire Integrated Care Board
Dr Sophia Makki	Public Health Consultant, Programmed Delivery Unit, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Dr Karthik Paranthaman	Consultant Epidemiologist, Field Epidemiology South East & London Field Service, UKHSA
Kevin Shaw	Deputy Director of Nursing and Quality, NHS Lincolnshire Integrated Care Board
Kelly Stoker	Head of Infection Prevention Control, Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

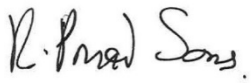
2. Organisational authorisations

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

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

NHS Cheshire and Merseyside authorises this PGD for use by the services or providers listed below:

Any service providing management of clusters of meningococcal disease when 2 or more cases are reported in a congregate setting, when a decision has been made by an experienced member of the UKHSA Health Protection Team or by the Incident Control Team, within the NHS Cheshire and Merseyside footprint
Limitations to authorisation
Only for services commissioned by NHS Cheshire and Merseyside or agreed by exception with the UKHSA

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Executive Medical Director, Cheshire and Merseyside ICB NHS	Prof Rowan Pritchard Jones		29.04.25

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

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 instance Registered professional with one of the following bodies: • Nurses currently registered with the Nursing and Midwifery Council (NMC). • Pharmacists currently registered with the General Pharmaceutical Council (GPhC). Additional registered healthcare professionals to be added by the organisation authorising the 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 or administration of medicines for example Patient Group Directions - elearning for healthcare • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC) • must have undertaken training appropriate to this PGD as required by local policy • 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 practitioner must be authorised by name, under the current version of the 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.

Clinical condition or situation to which this PGD applies	**Post exposure prophylaxis of meningococcal disease:** Ciprofloxacin is licensed for post exposure prophylaxis of invasive infections due to *Neisseria meningitidis.* This PGD is for the management of clusters of meningococcal disease when 2 or more cases are reported in a congregate setting, when a decision has been made by an experienced member of the UKHSA Health Protection Team or by the Incident Control Team to offer chemoprophylaxis[2].
Criteria for inclusion	Individuals as identified by the UKHSA local Health Protection Team, including young infants, pregnant women and breast-feeding mothers, eligible to be offered chemoprophylaxis. Ideally, chemoprophylaxis should be given as soon as possible and preferably within 24 hours after a decision has been made to offer chemoprophylaxis. However, during outbreaks and clusters, use is still indicated, including more than 4 weeks after the index case has been diagnosed, in accordance with Guidance for public health management of meningococcal disease in the UK and/or under advice from the UKHSA.
Criteria for exclusion[3]	Individuals are excluded from this PGD if: • they have a known severe allergic reaction to ciprofloxacin, other quinolones or any of the excipients in the preparation • they are taking tizanidine
Action to be taken if the individual or carer declines chemoprophylaxis	Advise the individual or their carer of the possible consequences of declining chemoprophylaxis and of alternative options. Advise about the protective effects of chemoprophylaxis, risks of infection, risk of spreading the disease to others and disease complications. Advise on the need for vigilance for symptoms of meningococcal disease, recognising symptoms and the need to seek urgent medical attention should symptoms occur. Document the individual has declined chemoprophylaxis and the advice given in their record. Inform the UKHSA Health Protection Team or the Incident Control Team and the GP without delay.
Action to be taken if the individual is excluded Continued overleaf	Explain the reasons for exclusion to the individual or their carer. Individuals excluded under this PGD should be referred urgently to the UKHSA Health Protection Team, the Incident Control Team or the GP for advice without delay.

[2] For example children and staff of the same preschool group, children of the same school year, children or students who share a common social activity or a group of friends

[3] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside it's remit, and another form of authorisation will be required

Action to be taken if the individual is excluded (continued)	Individuals who: • have a known reaction to ciprofloxacin, other quinolones or any of the excipients in the preparation or • are taking tizanidine will need individual clinical assessment and, if alternative antibiotics are required, they will need another form of authorisation, such as a Patient Specific Direction (PSD). Some individuals excluded under this PGD may still be suitable for post exposure chemoprophylaxis with ciprofloxacin, or alternatively may be considered as suitable for chemoprophylaxis with rifampicin; these medicines will need to be prescribed.
Cautions including any relevant action to be taken	Although the SPC states ciprofloxacin should be used with caution for individuals with certain conditions, on the balance of risk to benefit, these individuals should receive chemoprophylaxis with ciprofloxacin because only a single dose is required and the benefits of taking chemoprophylaxis outweigh any risk. Refer to the Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL) or British National Formulary (BNF) for details when appropriate and/or seek advice from the UKHSA Health Protection Team, the Incident Control Team or the GP.
Additional information	Ciprofloxacin is the recommended choice for meningococcal chemoprophylaxis because it has a number of advantages over rifampicin. Restrictions and precautions on the use of systemic fluoroquinolone antibiotics (including ciprofloxacin) recommended by the EMA do not apply to the single dose of ciprofloxacin recommended for chemoprophylaxis of meningococcal disease.

5. Description of Treatment

Name, strength & formulation of drug	Ciprofloxacin 250mg tables Ciprofloxacin 500mg tablets Ciprofloxacin 250mg/5ml suspension
Legal category	POM - Prescription only medicine
Black triangle▼	No
Off-label use	Adults: No Adolescents, children and babies: Yes Guidance for public health management of meningococcal disease in the UK recommends the use of ciprofloxacin for all age ranges. Where a product is recommended off-label consider, as part of the consent process, informing the individual or carer that the product is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration	Oral Tablets to be swallowed whole with water, as this will help to prevent the formation of tiny crystals in the urine (crystalluria). The suspension will need to be reconstituted according to the instructions in the SPC or the PIL. Ciprofloxacin can be taken independently of mealtimes but should preferably be taken on an empty stomach, as the active substance is more rapidly absorbed. Ciprofloxacin should not be taken with dairy products (for instance milk, yoghurt) or mineral-fortified fruit juice (for instance calcium-fortified orange juice). The simultaneous administration of ciprofloxacin and the following drugs reduces the absorption of ciprofloxacin: • multivalent cation-containing drugs and mineral supplements (for instance calcium, magnesium, aluminium, iron) • polymeric phosphate binders (for instance sevelamer or lanthanum carbonate) • sucralfate or antacids • highly buffered drugs (for instance didanosine tablets) containing magnesium, aluminium, or calcium Consequently, ciprofloxacin should be administered either 1-2 hours before or at least 4 hours after these preparations. The restriction does not apply to antacids belonging to the class of H2 receptor blockers.
Dose and frequency of administration Continued overleaf	Adults and children aged 12 years and over: one 500 mg tablet as a single dose Children aged 5 to 11 years: one 250 mg tablet or one 5ml spoonful of the suspension (250mg/5ml) as a single dose

Dose and frequency of administration (continued)	Children aged 1 to 4 years of age: 2.5ml (125mg) of the suspension as a single dose Infants less than 1 year of age: 30mg/kg (up to a maximum of 125mg) of the suspension as a single dose
Duration of treatment	A single dose
Quantity to be supplied/ administered	A single dose Ideally the product will be administered immediately. If it will be supplied to the individual to take away, this must either be from the manufacturer's original pack or over-labelled pre-packs, and the individual's name, the date and additional instructions must be written on the label at the time of supply. As split packs cannot be supplied, an over-supply might be required. Individuals must be advised to take any remaining product to a community pharmacy for destruction. If the suspension is to be supplied to take away, provide a 5ml spoon or an oral syringe.
Storage	Do not store above 25^{o}C. Following reconstitution the suspension is stable for 14 days only. The reconstituted suspension can be kept at ambient temperatures up to 30°C or in a refrigerator (2°C to 8°C). After this time, the reconstituted suspension should not be taken. Protect the reconstituted suspension from freezing.
Disposal	Any unused product or waste material should be disposed of in accordance with local requirements
Drug interactions	Individuals taking tizanidine are excluded from this PGD For other interactions, because only 1 dose is required, the benefits of taking the chemoprophylaxis outweigh any risks. A detailed list of interactions is available in the SPC
Identification and management of adverse reactions	Most commonly reported side effects are nausea and diarrhoea. Other side effects are classified as uncommon to very rare. Tendon inflammation and rupture have been observed, particularly in older patients and those treated concurrently with corticosteroids. However, this is very rare (< 1/10,000) and likely to be lower following a single dose only. If individuals experience pain or inflammation they must see their doctor at the earliest opportunity. A detailed list of adverse reactions is available in the SPC
Reporting procedure of adverse reactions	All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow card scheme 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. Alert the supervising doctor promptly in the event of a serious adverse reaction, document in the individual's record and inform the individual's GP.

Written information to be given	If the product is administered, offer the marketing authorisation holder's patient information leaflet (PIL) If the product is supplied to be taken away, the marketing authorisation holder's PIL **must** be given to comply with HMR2012. If the suspension is supplied rather than administered immediately and an oral syringe is required, provide an information leaflet explaining how to use the oral syringe.

Advice /follow up treatment	Explain why the treatment is necessary and that chemoprophylaxis is not fully protective. Close contacts must be alert to symptoms and signs of meningococcal disease.
	
	For the tablets advise to swallow the medicine whole with water; do not chew or crush the tablets
	
	Where relevant, inform the individual or their carer:
	• to preferably take ciprofloxacin on an empty stomach, as the active substance is more rapidly absorbed. However, it can be taken independently of mealtimes
	• to not consume dairy products (for instance milk, yoghurt) or mineral-fortified fruit juice (for instance calcium-fortified orange juice) at the same time as taking ciprofloxacin
	• ciprofloxacin should be taken either 1-2 hours before or at least 4 hours after the following preparations:
	  • multivalent cation-containing drugs and mineral supplements (for instance calcium, magnesium, aluminium, iron)
	  • polymeric phosphate binders (for instance sevelamer or lanthanum carbonate)
	  • sucralfate
	  • antacids
	  • omeprazole
	  • highly buffered drugs (for instance didanosine tablets) containing magnesium, aluminium, or calcium
	This restriction does not apply to antacids belonging to the class of H2 receptor blockers
	
	Inform the individual or their carer of possible side effects and their management
	
	Advise the individual or their carer to read the PIL leaflet and to seek medical advice if side effects, including painful or inflamed joints, or any other unexplained side effects on health are experienced
	
	If an over-supply has been required, individuals must be advised to take any remaining product to a community pharmacy for destruction

Records Continued overleaf	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 and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of the member of staff who administered / supplied the product • name and brand of the product

Records (continued)	• date of administration / supply • dose, form and route of administration of the product • quantity administered / supplied • batch number and expiry date • advice given; including advice given if the individual is excluded or declines chemoprophylaxis • details of any adverse drug reactions and actions taken • the product was supplied via PGD • whether the product was administered immediately or supplied to be taken later • if supplied and an over-supply has been required, record this and that advice to return the remaining product to a community pharmacy for destruction has been given Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous A record of all individuals receiving chemoprophylaxis under this PGD should also be kept for audit purposes in accordance with local policy

6. Key references

Key references	• Summary of Product Characteristics and Patient Information Leaflet • British National Formulary (BNF) • Guidance for public health management of meningococcal disease in the UK Updated August 2019 • NICE Guideline Patient Group Directions March 2017 • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20th March 2013

7. Practitioner authorisation sheet

CiprofloxacinMen_PGDv04.00 Valid from: 20 October 2022 Expiry: 19 October 2025

Before signing this PGD, check that the document has had the necessary authorisations in section 2. 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.