Public Health England

NHS England

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PATIENT GROUP DIRECTION (PGD)

Supply of ciprofloxacin 250mg tablets, 500mg tablets or ciprofloxacin 250mg/5ml suspension for the management of clusters of meningococcal disease when two or more cases are reported in a congregate setting

- For the supply of ciprofloxacin 250mg tablets, 500mg tablets or ciprofloxacin 250mg/5ml suspension for the management of clusters of meningococcal disease when two or more cases are reported in a congregate setting by Nurses currently registered with the Nursing and Midwifery Council (NMC) or Pharmacists currently registered with the General Pharmaceutical Council (GPhC).

Reference:	*20170130PHEPGDMenCipro*
Version no:	*01.00*
Valid from:	*10 February 2017*
Review date:	*10 February 2019*
Expiry date:	*10 February 2020*

Public Health England has developed this PGD Template for local authorisation

Those using this PGD must ensure that it is formally authorised and signed by a clinical governance or patient safety lead, who has designated responsibility for signing PGDs, so this document meets legal requirements for a PGD. **THE PGD IS NOT LEGAL OR VALID WITHOUT THIS LOCAL, FORMAL AUTHORISATION.**

Authorising organisations must not alter or amend the *clinical* content of this document (sections 4, 5 and 6); such action will invalidate the *clinical sign-off* with which it is provided.

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

THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

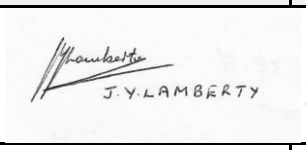
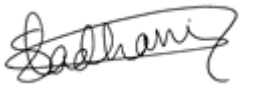
Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Change history

Version number	Change details	Date
01.00	Original version	10 February 2017

1. PGD template development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead author)	Jacqueline Lamberty Lead Pharmacist Medicines Management Services, Public Health England		10 February 2017
Doctor	Dr Shamez Ladhani Paediatric Infectious Disease Consultant, Public Health England		10 February 2017
Registered nurse	Nicky Brown Senior Nurse Chief Nurse Directorate Public Health England		10 February 2017

This PGD template has been peer reviewed by an expert panel in accordance with the PHE PGD Policy. It has been agreed by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Steering Group.

Expert panel

Name	Designation
Dr Philip Monk (Chair)	Consultant in Health Protection Public Health England East Midlands
Dr Ed Kaczmarski	Consultant Medical Microbiologist, Manchester Lead Public Health Microbiologist, Public Health England NW Head of the National Meningococcal Reference Unit
Dr Sally Millership	Consultant in communicable disease control (CCDC) Public Health England East of England
Dr Karthik Paranthaman	Consultant in Health Protection Public Health England South East
Kate Wedgwood	Senior Health Protection Specialist Public Health England East Midlands
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire and Lincolnshire

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 England South, (South West) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
This patient group direction (PGD) must only be used by registered nurses or pharmacists who have been named by their organisation to practice under it. The most recent in-date final version signed off by NHS England South, (South West) must be used.
Limitations to authorisation
This PGD is only authorised for post exposure prophylaxis of meningococcal disease under the direction of Public Health England.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director, NHS England South, (South West)	**Dr Caroline Gamlin**	Caroline Gamlin	**08/03/17**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Head of Pharmacy, NHS England South, (South West)	**Sue Mulvenna**	Sue Mulvenna	**06/03/17**

Organisations must add an individual practitioner authorisation sheet or list of authorised practitioners. This varies according to local policy but this should be a signature list or an individual agreement as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	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 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 be competent in the use of PGDs (see NICE Competency framework for health professionals using Patient Group Directions) • must be familiar with the product and alert to changes in the Summary of Product Characteristics • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Continued training requirements	As specified by Public Health England

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 two or more cases are reported in a congregate setting, when a decision has been made by a Consultant in Health Protection (CHP) or a Consultant in public health medicine (CPHM) to offer chemoprophylaxis to, 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.
Criteria for inclusion	Groups of individuals, including pregnant and breast-feeding mothers, as identified by the CHP or CPHM 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 (see exclusion criteria).
Criteria for exclusion[1]	Individuals are excluded from this PGD if: • they have a known allergy or previous hypersensitivity reaction to ciprofloxacin, other quinolones or any of the excipients in the preparation • they are taking tizanidine • they have impaired renal function (because a dose adjustment may be required) • they present more than 4 complete weeks after the index case has been diagnosed
Action to be taken if the patient 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 CHP/ CPHM and the General Practitioner without delay.
Action to be taken if the patient 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 CHP/ CPHM or the GP for advice without delay.

[1] 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 patient is excluded (continued)	Individuals who: • have a known allergy or previous hypersensitivity reaction to ciprofloxacin, other quinolones or any of the excipients in the preparation or • are taking tizanidine or • present more than 4 complete weeks after the index case has been diagnosed 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). Individuals who have renal impairment will need individual clinical assessment and once assessed, if they are to be given the medicine (regardless of the dose required) will need another form of authorisation, such as a Patient Specific Direction (PSD). Some patients 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 that 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 the details when appropriate and/or seek advice from the CHP/CPHM or GP.

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 Children and babies: Yes. PHE *Guidance for public health management of meningococcal disease in the UK* recommends the use of ciprofloxacin for all age ranges.
Route / method of administration	Oral
Dose and frequency of administration	Adults and children over 12 years: one 500 mg tablet as a single dose Children aged 5–12 years: one 250 mg tablet or one 5ml spoonful of the suspension (250mg/5ml) as a single dose Children under 5 years of age: 30mg/kg (up to a maximum of 125 mg) of the suspension as a single dose Ciprofloxacin should preferably be taken on an empty stomach, as the active substance is more rapidly absorbed. However it can be taken independently of mealtimes. Ciprofloxacin should not be taken with dairy products (eg milk, yoghurt) or mineral-fortified fruit juice (eg 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 (eg calcium, magnesium, aluminium, iron) • polymeric phosphate binders (eg sevelamer or lanthanum carbonate) • sucralfate or antacids • highly buffered drugs (eg 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.
Duration of treatment	A single dose
Quantity to be supplied	A single dose
Storage	Do not store above 25^{o}C

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 one dose is required, the benefits of taking the chemoprophylaxis outweigh any risks. Refer to the SPC, PIL or BNF. A detailed list of interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & 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 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, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of adverse reactions	All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow card system on http://yellowcard.mhra.gov.uk Any serious adverse reaction to the drug should be documented in the individual's record. Alert a doctor promptly in the event of a serious adverse reaction.
Written information to be given to patient or carer	Supply the marketing authorisation holder's patient information leaflet (PIL). When the suspension is supplied, provide an information leaflet explaining how to use the oral syringe.
Patient advice /follow up treatment (continued overleaf)	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. Inform the individual or their carer: • for the tablets: to swallow the medicine whole with water; do not chew or crush the tablets • for the suspension: the remaining suspension must be returned to a community pharmacy for destruction • 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 (eg milk, yoghurt) or mineral-fortified fruit juice (eg calcium-fortified orange juice) at the same time as taking ciprofloxacin • if relevant to the individual, ciprofloxacin should be taken either 1-2 hours before or at least 4 hours after the following preparations:

Patient advice /follow up treatment (continued)	• multivalent cation-containing drugs and mineral supplements (eg calcium, magnesium, aluminium, iron) • polymeric phosphate binders (eg sevelamer or lanthanum carbonate) • sucralfate • antacids • omeprazole • highly buffered drugs (eg didanosine tablets) containing magnesium, aluminium, or calcium The 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 before taking the medication and to seek medical advice if side effects, including painful or inflamed joints, or any other unexplained side effects on health are experienced.
Records	Record: • whether valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of the 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 chemoprophylaxis • the product was supplied via Patient Group Direction (PGD) 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 treatment under this Patient Group Direction 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 www.medicines.org.uk • British National Formulary (BNF) http://www.evidence.nhs.uk/formulary/bnf/current/5-infections/51-antibacterial-drugs/5112-quinolones/ciprofloxacin • Guidance for public health management of meningococcal disease in the UK https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/322008/Guidance_for_management_of_meningococcal_disease_pdf.pdf • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions https://www.nice.org.uk/guidance/mpg2/resources • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20th March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste

7. Individual practitioner authorisation sheet

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PATIENT GROUP DIRECTIONS DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTISE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE

Practitioner

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct

Signed……..……..Date…….…….....

Name (Print)……..……..……..…….…….....

Designation……..…….....

Authorising manager

Manager to give authorisation on behalf of INSERT **NAME OF ORGANISATION** for the named healthcare professional who has signed the PGD

Signed…….……. Date…….....

Name (Print)……..……..……..…….....

Designation……..…….…….....

Note to authorising manager

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so.

You must give this signed PGD to each authorised practitioner as it shows their authorisation to use the PGD.