

**National Patient Group Direction (PGD)**

**Supply of flucloxacillin capsules/oral solution**

**Version – 1.0**

The purpose of this PGD is to allow management of skin infection in patients over 18 years of age by registered pharmacists within Community Pharmacies.

This PGD authorises pharmacists delivering the NHS Pharmacy First Scotland Service Level Agreement to supply flucloxacillin to patients aged 18 years and over presenting with symptoms of skin infection who meet the criteria for inclusion under the terms of the document.

**Change History - None**

**PGD Flucloxacillin Capsules / Oral solution**

**Authorisation**

This specimen PGD has been produced in collaboration with the Scottish Antimicrobial Prescribing Group, the Area Drug and Therapeutics collaborative and the Primary Care Community Pharmacy Group to assist NHS Boards provide uniform services under the ‘NHS Pharmacy First Scotland’ banner across NHS Scotland. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply flucloxacillin capsules or oral solution under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure familiarity with the marketing authorisation holder’s summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

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| **This specimen PGD has been approved on behalf of NHS Scotland by NHS 24 by:** |
| Doctor |  | Signature |  |
| Pharmacist |  | Signature |  |
| NHS Scotland Representative |  | Signature |  |

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| --- |
| **Approved on behalf of NHS [insert details] by**  |
| Medical Director |  | Signature |  |
| Director of Pharmacy/Senior Pharmacist |  | Signature |  |
| Clinical Governance Lead |  | Signature |  |

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| --- | --- | --- | --- |
| Date Approved |  |  |  |
| Effective from |  | Review Date |  |

**Clinical Situation**

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| Indication | Treatment of bacterial skin infection in patients over 18 years of age. |
| Inclusion Criteria | * Infected insect bite
* Cellulitis (patient afebrile and healthy other than cellulitis)
* Acute paronychia with signs of cellulitis
 |
| Exclusion Criteria | * Patient under 18 years old
* Known hypersensitivity to beta-lactam antibiotic (penicillins or cephalosporins) or any excipients
* Cellulitis where patient febrile and/or unwell (i.e. features suggestive of systemic infection)
* Cellulitis related to a human or animal bite
* Cellulitis related to surgical wound or chronic wound/ leg ulcer or burns
* Peri-orbital (preseptal)/facial cellulitis present
* Cellulitis on arms or torso **not** linked to an insect bite
* Recurrent cellulitis i.e. more than once within a year
* Acute paronychia with signs of cellulitis AND a collection of pus requiring drainage AND/OR in severe pain
* Diabetic foot infection
* Known hepatic impairment or flucloxacillin associated jaundice
* Known severe renal impairment
* History of MRSA infection or colonisation
* History of injecting drug use (e.g. illicit drugs, anabolic steroids)
* Concomitant use of interacting medication e.g. probenecid, methotrexate, oral typhoid capsule, warfarin
* History of porphyria
* Known immunosuppression or taking immunosuppressants
* Pregnant or breastfeeding
* Informed consent not obtained
 |
| Cautions /Need for further advice/Circumstances when further advice should be sought from a doctor | Healthcare professionals are reminded that: * Careful enquiry should be made about hypersensitivity reactions to beta-lactam antibacterials
* Cholestatic jaundice and hepatitis may occur very rarely, up to two months after treatment with flucloxacillin has been stopped.

Cautions - see BNF and Summary of Product Characteristics |
| Action if Excluded | Refer to GP Practice/Out-of-hours (OOH) service and document in Patient Medication Record (PMR) or Pharmacy Care Record (PCR). |
| Action if Patient Declines | * If patient declines treatment, advise on self-care to relieve symptoms and advise to see their GP if symptoms fail to resolve within 3 days or if symptoms worsen.
* The reason for declining treatment and advice given must be documented.
* Ensure patient is aware of risks and consequences of declining treatment.
* Record outcome in PMR or PCR if appropriate
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**Description of Treatment**

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| Name of Medicine | Flucloxacillin |
| Form/Strength | 500 mg (or 2 x 250 mg) capsules |
| Route of administration | Oral |
| Dosage | **Health Board Specific**  |
| Ayrshire & Arran | 500mg | Highland | 500mg |
| Borders | 500mg | Lanarkshire | 500mg |
| Dumfries & Galloway | 500mg | Lothian | 500mg |
| Fife | 1g | Orkney | 500mg |
| Forth Valley | 500mg | Shetland | 500mg |
| Grampian | 500mg | Tayside | 1g |
| GG&C | 500mg | Western Isles | 500mg |
| Frequency | Four times a day (during waking hours) |
| Duration of treatment | 5 days |
| Maximum or minimum treatment period | 500 mg dose - 2 g daily (10g in total)1g dose – 4 g daily (20g in total) |
| Quantity to supply/administer | 500 mg dose - 20 x 500 mg capsules or 40 x 250 mg capsules1g dose – 40 x 500 mg capsules or 80 x 250 mg capsules |
| ▼ additional monitoring | No |
| Legal Category | POM (Prescription Only Medicine) |
| Is the use outwith the SPC | No |
| Storage requirements | As per manufacturer’s instructionsEnsure capsules are within expiry date |
| Additional information | None |

**Description of treatment continued**

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| Name of Medicine | Flucloxacillin |
| Form/Strength | 250 mg/5ml oral solutionNB This form is strictly limited to use in patients who are intolerant of gelatine or have severe dysphagia in relation to capsules |
| Route of administration | Oral |
| Dosage | **Health Board specific**  |
| Ayrshire & Arran | 500mg | Highland | 500mg |
| Borders | 500mg | Lanarkshire | 500mg |
| Dumfries & Galloway | 500mg | Lothian | 500mg |
| Fife | 1g | Orkney | 500mg |
| Forth Valley | 500mg | Shetland | 500mg |
| Grampian | 500mg | Tayside | 1g |
| GG&C | 500mg | Western Isles | 500mg |
| Frequency | Four times a day (during waking hours) |
| Duration of treatment | 5 days |
| Maximum or minimum treatment period | 500 mg dose - 2 g daily (10g in total)1g dose – 4 g daily (20g in total) |
| Quantity to supply/administer | 500 mg dose - 2 x 100ml1g dose – 4 x 100ml |
| ▼ additional monitoring | No |
| Legal Category | POM  |
| Is the use out with the SPC | No |
| Storage requirements | As per manufacturer’s instructionsUnopened bottle – store at or below 25°C in a dry placeReconstituted solution – store between 2°C and 8°CAfter reconstitution or when container is opened for the first time – discard after 7 daysEnsure solution is within expiry date  |

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| Warnings including possible adverse reactions and management of these | Minor gastro-intestinal disturbances e.g. nausea, vomiting, diarrhoeaHypersensitivity For a full list of side effects – refer to the marketing authorisation holder’s SPC. A copy of the SPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on [www.medicines.org.uk](http://www.medicines.org.uk)  |
| Reporting procedure for adverse reactions | Pharmacists should document and report all adverse incidents through their own internal governance systems.Pharmacists should record all adverse reactions (actual and suspected) in their PMR and send an SBAR (situation, background, assessment, recommendation) communication to the appropriate medical practitioner for documenting in the patient’s medical record as appropriate. Where appropriate, use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at <http://yellowcard.mhra.gov.uk/> |
| Advice to Patient/carer including written information | * Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food
* Advise patient of the importance of taking flucloxacillin regularly and completing the course
* Inform patient of possible side effects and their management and who to contact should they be troublesome
* If rash or other signs of hypersensitivity occur, stop taking the medicine and contact your doctor for advice
* Ensure patient is aware that if symptoms worsen, the patient becomes systemically unwell e.g. develops a temperature, racing heartbeat, rapid shallow breathing or confusion then they should seek medical advice that day
* If symptoms have not improved after 2-3 days treatment, then patients should be advised to seek further medical advice
* Latest recommendations are that no additional contraceptive precautions are required when combined oral contraceptives are used with antibacterials that do not induce liver enzymes, unless diarrhoea and vomiting occur
* The Drug Manufacturer Patient Information Leaflet should be given. Patients should be informed who to contact should they experience an adverse drug reaction
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| Monitoring  | Not applicable |
| Follow-up | Advise patient to seek medical advice should symptoms worsen or not improve. |
| Additional Facilities | The following should be available where the medication is supplied:* An acceptable level of privacy to respect patient’s right to confidentiality and safety
* Access to medical support (this may be via the telephone)
* Approved equipment for the disposal of used materials
* Clean and tidy work areas, including access to hand washing facilities
* Access to current BNF (online version preferred)
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**Characteristics of staff authorised under the PGD**

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| Professional qualifications | Registered pharmacist with current General Pharmaceutical Council (GPhC) registration.***Under PGD legislation there can be no delegation. Supply of the medication has to be by the same practitioner who has assessed the patient under this PGD.*** |
| Specialist competencies or qualifications | Has undertaken appropriate training to carry out clinical assessment of patient which may lead to diagnosis that requires treatment according to the indications listed in this PGD, by successfully completing NES Pharmacy e-learning module on “Skin infections for NHS Pharmacy First Scotland”<https://learn.nes.nhs.scot/43886/pharmacy/cpd-resources/skin-infections-for-nhs-pharmacy-first-scotland>Able to assess the person’s capacity to understand the nature and purpose of the medication in order to give or refuse consent.Must be familiar with the flucloxacillin SPC.Authorised to use PGD on completion and submission of an approved practitioner form. |
| Continuing education and training | It is the responsibility of the individual to keep up-to-date with continued professional developmentHas read the most up to date guidance on the management of cellulitis e.g. PHE, NICE, SIGN, SAPG.Attends approved training and training updates as appropriate.Undertakes CPD when PGD or NES Pharmacy module are updated. |

**Audit Trail**

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| Record/Audit Trail | All records must be clear, legible and in an easily retrieval format.Pharmacists must record in PMR or PCR.The following records should be kept (paper or computer based) and are included in the patient assessment form:* Patient’s name/parent/guardian/person with parental responsibility, address, date of birth and consent given
* Patient’s CHI number
* Contact details of GP (if registered)
* Presenting complaint and diagnosis
* Details of medicine supplied
* The signature and printed name of the healthcare professional who supplied the medicine.
* Advice given to patient (including side effects)
* The PGD title and/or number
* Whether the patient met the inclusion criteria and whether the exclusion criteria were assessed
* Details of any adverse drug reaction and actions taken including documentation in the patient’s medical record
* Referral arrangements (including self-care)

***The patient’s GP, where known, should be provided with a copy of the client assessment form for the supply of flucloxacillin on the same, or next available working day.*** ***If the patient suffers an adverse drug reaction to flucloxacillin, the GP should also be informed.***These records should be retained in accordance with national guidance1 (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead.All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each service. A designated person within each service will be responsible for auditing completion of drug forms and collation of data.1. Scottish Government. *Scottish Government Records Management.* Edinburgh 2020. Available at [SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf](https://www.informationgovernance.scot.nhs.uk/wp-content/uploads/2020/06/SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf) (Accessed on 21/05/2021) |
| Additional references | British National Formulary (BNF) current editionflucloxacillin SPC.   |

**PATIENT GROUP DIRECTION FOR THE SUPPLY OF FLUCLOXACILLIN CAPSULES OR ORAL SOLUTION BY COMMUNITY PHARMACISTS UNDER THE ‘NHS PHARMACY FIRST SCOTLAND’ SERVICE**

**Individual Authorisation**

***PGD does not remove inherent professional obligations or accountability***

**It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals.**

**Note to Authorising Authority:** authorised staff should be provided with access to the clinical content of the PGD and a copy of the document showing their authorisation.

I have read and understood the Patient Group Direction authorised by each of the individual NHS Boards that I wish to operate in and agree to provide flucloxacillin capsules/oral solution.

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| Name of Pharmacist |  |
| GPhC Registration Number |  |

Normal Pharmacy Location

**(Only one Pharmacy name and contractor code is required for each Health Board (HB) area where appropriate. If you work in more than 3 HB areas please use additional forms.)**

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| --- | --- |
| Name & Contractor code HB (1) |  |
| Name & Contractor code HB (2) |  |
| Name & Contractor code HB (3) |  |

Please indicate your position within the pharmacy by ticking one of the following:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Locum |  |  | Employee |  |  | Manager |  |  | Owner |  |

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| Signature |  | Date |  |

Please tick and send to each Health Board you work in. Fax numbers, email and postal addresses are given overleaf.

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| Ayrshire & Arran |  |  | Grampian |  |  | Orkney |  |  |

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| Borders |  |  | Gr Glasgow & Clyde |  |  | Shetland |  |  |

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| Dumfries & Galloway |  |  | Highland |  |  | Tayside |  |  |

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| Fife |  |  | Lanarkshire |  |  | Western Isles |  |  |

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| Forth Valley |  |  | Lothian |  |
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| NHS Board | Address | Fax Number |
| Ayrshire & Arran | Allan Thomas, NHS Ayrshire & Arran, Eglington House, Ailsa Hospital,Dalmellington Road, Ayr, KA6 6ABAngela.oumoussa@aapct.scot.nhs.uk | Please e-mail or post  |
| Borders | Adrian Mackenzie, Lead PharmacistPharmacy Department, Borders General Hospital, Melrose, TD6 9BScommunitypharmacy.team@borders.scot.nhs.uk  | Please e-mail or post |
| Dumfries & Galloway | NHS Dumfries & Galloway, Primary Care Development, Ground Floor North, Mountainhall Treatment Centre, Bankend Rd, Dumfries, DG1 4TG Dg.pcd@nhs.scot | Please e-mail or post  |
| Fife | PGD Administrator, Pharmacy Services, NHS Fife,Pentland House, Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UWFife.pgd@nhs.scot  | Please e-mail or post |
| Forth Valley | Community Pharmacy Development Team, Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WRfv.communitypharmacysupport@nhs.scot | Please e-mail or post |
| Grampian | Pharmaceutical Care Services TeamNHS Grampian, Pharmacy & Medicines Directorate, Westholme, Woodend, Queens Road, Aberdeen, AB15 6LS gram.pharmaceuticalcareservices@nhs.scot | Please e-mail or post  |
| Greater Glasgow & Clyde | Janine Glen, Contracts Manager, Community Pharmacy, NHS Greater Glasgow & Clyde, Clarkston Court, 56 Busby Road, Glasgow G76 7ATggc.cpdevteam@nhs.scot | 0141 201 6044Or e-mail |
| Highland | Community Pharmaceutical Services, NHS Highland,Assynt House, Beechwood Park, Inverness. IV2 3BW nhsh.cpsoffice@nhs.scot | Please e-mail or post |
| Lanarkshire | Pharmacy/Prescribing Admin Team, NHS Lanarkshire Headquarters, Kirklands, Fallside Road, Bothwell, G71 8BBPharmacyAdminTeam@lanarkshire.scot.nhs.uk | Please e-mail or post |
| Lothian | Primary Care Contractor Organisation, 2ND Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EGCommunityPharmacy.Contract@nhslothian.scot.nhs.uk | Please e-mail or post |
| Orkney | Lyndsay Steel, Lead General Practice Pharmacist. The Balfour, Foreland Road, Kirkwall, KW15 1NZ Phone: 01856 888 911 ork.primarycarepharmacy@nhs.scot | Please e-mail or post |
| Shetland | Mary McFarlane, , Principle Pharmacist, NHS Shetland, Gilbert Bain Hospital, Lerwick, Shetland, ZE1 0TB | 01595 743356 |
| Tayside | Diane Robertson, Pharmacy Department, East Day Home, Kings Cross Hospital, Clepington Road, Dundee, DD3 8AEDiane.Robertson9@nhs.scot | Please e-mail or post |
| Western Isles | Stephan Smit, Primary Care Department,The Health Centre, Springfield Road, Stornoway, Isle of Lewis, HS1 2PS | No fax, please post |