

Patient Group Direction (PGD)

This PGD authorises community pharmacists to supply aciclovir tablets / dispersible tablets to patients aged 18 years and over presenting with symptoms of shingles under NHS Pharmacy First Scotland.

Protocol Number 568 Version 2

Publication date: 20th February 2024



Most Recent Changes

Version	Date	Summary of changes
2.0	February 2024	Original PGD transferred into new NHS PFS template. 1.2 Inclusion criteria: amended to remove "torso" 1.3 Exclusion criteria: Removal of following to prevent duplication with inclusion criteria: Patients under 18 years of age
		 Rash involving more than one dermatome Rash appeared more than 72 hours ago Clarification on which areas of body are excluded from treatment under PGD
		 Addition of exclusion if patient already taking oral antiviral medication Removal of new vesicles forming after 7 days exclusion Addition of examples of impaired gastrointestinal
		 absorption Clarification on immunosuppression definition and removal of reference to HIV Removal of breastfeeding exclusion
		 Removal of fever and headache examples from systemically unwell exclusion Clarification on moderate to severe renal impairment
		 Clarification on definition of recurrent shingles Removal of severe pain not responding to over-the-counter analgesics exclusion Standardisation across all NHS PFS PGDs of wording on interactions
		1.4 "Cautions/need for further advice": Title – changed "doctor" to "prescriber" Updated to reflect range of professionals who are able to independently prescribe
		 Addition of further guidance on renal impairment Addition of guidance to patients taking aciclovir whilst breastfeeding.

Version	Date	Summary of changes
		 Removal of paragraph regarding patient's physical presence in pharmacy to obtain treatment. 2.3 Dosage section: amendment to guidance on timing of dosage 2.4 Frequency section: amendment to guidance on frequency of dosage 2.6 Maximum or minimum treatment period section: amendment to clarify duration of treatment. 3.1 "Warnings including possible adverse reactions and management of those" section: removal of specific drugs which may interact with aciclovir and addition of generic statement about checking for clinically significant interactions. 3.3. "Advice to patient and carer": Clarification on avoiding contact with others Clarification on symptoms not improving after 7 days 3.5 "Follow up": clarification on advice to be given.

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Authorisation

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

PGD aciclovir tablets / dispersible tablets

This specimen PGD template has been produced in collaboration with the Primary Care Community Pharmacy Group to assist NHS Boards in the uniform provision of services under '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 community pharmacist who may supply aciclovir tablets / dispersible tablets under this PGD can do so only as a named individual. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals and to ensure familiarity with the manufacturer's product information/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 must be by the same practitioner who has assessed the patient under the PGD.

This PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor Dr Ronald Cook Signature

Pharmacist Dr John McAnaw Signature

NHS Scotland
Representative

Mr Jim Miller

Signature

Approved on behalf of NHS Forth Valley by:

Medical Director Andrew Murray Signed by Andrew Murray

Director of Pharmacy Laura Byrne Signed by Laura Byrne

Director of Nursing Karen Goudie Signed by Karen Goudie

Date approved: 22 March 2024

Effective from: 20 February 2024

It is the responsibility of the person using the PGD to ensure they are using the most recent issue.

Expiry date: 19 February 2027

1. Clinical situation

1.1. Indication

Treatment of herpes zoster (shingles) infection.

1.2. Inclusion criteria

Patients aged 18 years and older with untreated acute shingles rash involving a single dermatome and present for less than 72 hours.

Immunocompetent patient.

Valid consent to receiving treatment under this PGD has been obtained.

1.3. Exclusion criteria

Rash affecting areas other than those relating to dermatomes T1 - L2 e.g., rash extending to eye and any eye symptoms (including change in vision, redness, irritation, discomfort, gritty etc).

Patients already taking oral antiviral treatment.

Hypersensitivity to aciclovir or to any of the excipients within the tablets.

Patients with impaired gastro-intestinal absorption e.g., Crohn's disease, ulcerative colitis.

Acute diarrhoea and vomiting where aciclovir absorption could be impaired.

Current immunosuppression e.g., chemotherapy, long-term corticosteroids or other immunosuppressant therapies.

Known pregnancy.

Patients who are systemically unwell.

Known moderate to severe renal impairment – patients with eGFR <25mL/minute/1.73m² should be referred to GP/OOH for consideration of reduced dose due to increased risk of neurological reactions.

Recurrent shingles – immunocompetent patient with a history of 2 or more episodes in 12 months.

Concomitant use of interacting medicines - See current BNF and SPC for full risk of possible interactions. If clinically significant interactions are identified, then patients should be referred to GP/OOH for consideration of an alternative treatment.

Individuals for whom no valid consent has been received.

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a prescriber

Caution should be used in:

- Elderly patients
- Patients with mild renal impairment:
 - Patients with no known renal impairment can be treated without the requirement to independently check levels of impairment.
 Determination of "no known renal impairment" can be made by asking patient if GP has advised that they have some degree of renal/kidney function impairment, or if they have ongoing reviews with a renal doctor.
 - o If there are any patient factors which could indicate an increased risk of renal impairment (e.g., current medication, relevant co-morbidities or age), treatment can be considered in community pharmacy if relevant patient records/blood results can be independently checked e.g., using Clinical Portal. If this is not possible, the patient should be referred to GP/OOH).
- Patients taking other drugs with an increased risk of renal impairment (See current BNF and SPC for full risk of possible interactions)
- Patients with liver impairment

 Patients who are breastfeeding – make patient aware that manufacturer advises caution, but not known to be harmful.

1.5. Action if excluded

Refer to GP Practice / Out-of-hours (OOH) service and document reason for exclusion and any action taken in Patient Medication Record (PMR).

1.6. Action if patient declines

If patient declines treatment: advise on self-care to relieve symptoms and advise to see their GP practice if symptoms fail to resolve within three days or if symptoms worsen.

Ensure patient is aware of risks and consequences of declining treatment.

Document the reason for declining treatment and advice given in PMR.

2. Description of treatment

2.1. Name of medicine/form/strength

Aciclovir 800mg (or 2 x 400mg) tablet

OR

Aciclovir 800mg (or 2 x 400mg) dispersible tablet

NB: The dispersible form of tablet is strictly limited to use in patients who are unable to swallow standard tablets.

2.2. Route of administration

Oral

2.3. Dosage

Adults aged 18 years and over:

 800mg to be taken FIVE times daily spread evenly throughout the day during waking hours, usually at 4 hourly intervals.

2.4. Frequency

FIVE times daily spread evenly throughout the day during waking hours, usually at 4 hourly intervals.

2.5. Duration of treatment

7 days

2.6. Maximum or minimum treatment period

One treatment cycle of 7 days

2.7. Quantity to supply

35 x 800mg tablets or 70 x 400mg tablets

2.8. ▼ black triangle medicines

No

2.9. Legal category

Prescription Only Medicine (POM).

In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.

2.10. Is the use out with the SPC?

No.

2.11. Storage requirements

As per manufacturer's instructions.

Store below 25°C in a cool, dry place

2.12. Additional information

None

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these.

Please refer to current BNF or SPC for full details.

If a patient experiences any side effects that are intolerable or hypersensitivity reactions occur, the medication should be discontinued.

Common side effects include gastrointestinal disorders (nausea, vomiting, diarrhoea and abdominal pain), taste disturbance, photosensitivity, pruritis, urticaria, fever, tiredness and occasionally headaches or dizziness.

For a full list of side effects, refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional supplying the medication under this PGD. This can be accessed on www.medicines.org.uk.

In the event of severe adverse reaction e.g., swelling of eyes, face, lips or throat, shortness of breath or wheezing, developing of rash, or feeling faint, individuals should be advised to seek medical advice immediately.

Aciclovir is eliminated primarily unchanged in the urine via active renal tubular secretion. Any drugs administered concurrently that compete with this mechanism may increase aciclovir plasma concentrations.

Pharmacists should check patient medication history for clinically significant interactions using appropriate reference sources e.g., BNF, Stockley.

3.2. Reporting procedure for adverse reactions

Pharmacists should document and report all adverse incidents through their own internal governance systems.

All adverse reactions (actual and suspected) should be reported to the appropriate medical practitioner and recorded in the patient's medical record. Pharmacists should record in their PMR and inform the patient's GP as appropriate.

Where appropriate, healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. Yellow cards and guidance on their use are available at the back of the BNF or online at www.mhra.gov.uk/yellowcard.

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

 Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) and information on shingles e.g. British Association of Dermatologists: Shingles-Update-May-2020-lay-reviewed-March-2020.pdf (bad.org.uk) (Accessed 19th December 2023)

Verbal advice to be given to individuals/parent/carer:

- Advise the individual on mode of action, benefits of the medicine, possible side effects and their management.
- This medicine should be taken with water and the patient should drink plenty
 of water whilst taking this course of treatment.
- This medicine should be taken regularly until the course is completed.
- Ensure the patient has access to appropriate analgesia for symptomatic relief.
- Advise on self-care avoid sharing of towels and clothes, maintain good hand hygiene, wear loose fitting clothes to minimise irritation.
- Avoid use of topical creams and adhesive dressings as these can cause irritation and delay rash healing.

- Shingles is infectious until all the vesicles have crusted over (usually 5-7 days after rash onset). Avoid contact with others wherever possible if the rash is weeping and can't be covered.
- A person who has not had chicken pox or the varicella vaccine can catch chicken pox from a person with shingles (if possible, avoid pregnant women, immunocompromised people, and babies younger than 1 month old.)
- Ensure the patient is aware that if symptoms worsen, the patient becomes systemically unwell, or develops a temperature then they should seek further medical advice that day from their GP practice or Out of hours (OOH).
- If symptoms have not improved after 7 days of treatment, or if there is formation of new vesicles despite 7 days of antiviral treatment, or the eyes/hearing are affected, or other evidence of infection/discharge is present the patient should seek further medical advice from their GP practice.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on:
 www.mhra.gov.uk/yellowcard.

3.4. Monitoring

Not applicable

3.5. Follow up

Advise patient to seek further medical advice if symptoms worsen, or there is ongoing concern following the completion of treatment course.

3.6. Additional facilities

The following should be available when the medication is supplied:

- An acceptable level of privacy to respect patient's rights to confidentiality and safety
- Access to a working telephone
- Access to medical support (this may be via telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel
- Access to current BNF (online version preferred)
 - o BNF British National Formulary NICE
 - o BNF for Children British National Formulary NICE
- Access to SmPC/PIL/Risk Minimisation Material:
 - o Home electronic medicines compendium (emc)
 - o MHRA Products | Home
 - o RMM Directory (emc)
- Access to copy of current version of this PGD

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

Pharmacist with current General Pharmaceutical Council (GPhC) registration.

Under PGD legislation there can be no delegation. Supply of the medication must be completed by the same practitioner who has assessed the patient under this PGD.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD must:

- Be familiar with aciclovir medicine and alert to changes in the manufacturer's product information/summary of product information.
- Have successfully complete the NES Pharmacy e-learning module:

Shingles for NHS Pharmacy First Scotland | Turas | Learn

https://learn.nes.nhs.scot/43887/pharmacy/cpd-resources/shingles-for-pharmacy-first-scotland

 Be able to assess the person's/ parent's/ carer's capacity to understand the nature of the purpose of the medication in order to give or refuse consent.

4.3. Continuing education and training

All practitioners operating under this PGD are responsible for:

- Maintaining their skills, knowledge, and their own professional level of competence in this area according to the General Pharmaceutical Council Standards for Pharmacy Professionals
- Ensuring they remain up to date with the use of medications included and be aware of local treatment recommendations.
- Attending approved training and training updates as appropriate.
- Undertake relevant continuing professional development when PGD or NES Pharmacy modules are updated.

5. Audit trail

5.1. Authorisation of supply

Pharmacists can be authorised to supply the medicine specified in this PGD when they have completed local Board requirements for service registration.

Pharmacists should complete the individual authorisation form contained in the PGD (Appendix 1) and submit to the relevant NHS Health Board prior to using the PGD.

5.2. Record of supply

All records must be clear, legible, contemporaneous and in an easily retrievable format to allow audit of practice.

A Universal Claim Framework (UCF) record of the screening and subsequent supply, or not, of the medicine specified in this PGD should be made in accordance with the NHS Pharmacy First Scotland service specification.

Pharmacists must record the following information, included in the assessment form, in the PMR (either paper or computer based):

- name of individual, address, date of birth / CHI number
- name of GP with whom the individual is registered (if known)
- confirmation that valid consent to be treated under this PGD was obtained (include details of parent/guardian/person with parental responsibility where applicable)
- details of presenting complaint and diagnosis
- details of medicine supplied name of medicine, batch number and expiry date, with date of supply.
- details of exclusion criteria why the medicine was not supplied (if applicable)

- advice given, including advice given if excluded or declines treatment under this PGD
- details of any adverse drug reactions and actions taken
- referral arrangements (including self-care)
- signature and printed name of the pharmacist who undertook assessment of clinical suitability and, where appropriate, subsequently supplied the medicine

The patient's GP (where known) should be provided with a copy of the GP notification form for the supply of aciclovir tablets or dispersible tablets, or appropriate referral on the same, or next available working day.

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 (Accessed 19th December 2023)

6. Additional references

Practitioners operating the PGD must be familiar with:

- National Institute for Clinical Excellence / Public Health England. Available at: Shingles | Health topics A to Z | CKS | NICE (Accessed 19th December 2023)
- Current edition of British National Formulary (BNF) <u>BNF British National</u> <u>Formulary - NICE</u>, and BNF for children <u>BNF for Children British National</u> <u>Formulary - NICE</u>
- Marketing authorisation holder's Summary of Product Characteristics.
 Electronic Medicines Compendium. Aciclovir 800mg tablets. SPC. Available
 Aciclovir 800mg Tablets Summary of Product Characteristics (SmPC) (emc) (medicines.org.uk) (Accessed 19th December 2023)

7. Individual authorisation (Appendix 1)

PGD FOR THE SUPPLY OF ACICLOVIR TABLETS OR DISPERSIBLE TABLETS BY COMMUNITY PHARMACISTS UNDER THE "NHS PHARMACY FIRST SCOTLAND" SERVICE

This PGD does not remove professional obligations and accountability.

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

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a copy of the document showing their authorisation.

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

I have read and understood the PGD authorised by each of the NHS Boards I wish to operate in and agree to provide aciclovir tablets or dispersible tablets only in accordance with the specific PGD.

Name of Pharmacist	GPhC Registration Number	
	-	

Normal Pharmacy Location

(Only one Pharmacy name and contractor code is required for each Health Board area where

Name of Pharmacy	Contractor Code	Health Board
Click or tap here to enter text.	Click or tap here to enter text.	Choose an item.
Click or tap here to enter text.	Click or tap here to enter text.	Choose an item.
Click or tap here to enter text.	Click or tap here to enter text.	Choose an item.

appropriate. If you work in more than 2 Health Board areas, please use additional forms.)

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Please indica	ate your	position within th	e pharm	acy by ticking	one of the	following:		
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Signature					Date	e		
	•	form, sign and ddresses are give			lth Board	d you work	c in.	
NHS Pharma	cv First S	Scotland			UNCONTR	OLLED WHEN	N PRINTED	

NHS Board	Address	
Ayrshire & Arran	lain Fulton, NHS Ayrshire & Arran, Eglington House, Ailsa Hospital, Dalmellington Road, Ayr, KA6 6AB margaret.scott3@aapct.scot.nhs.uk	Please email or post
Borders	Malcolm Clubb, Lead Pharmacist Pharmacy Department, Borders General Hospital, Melrose, TD6 9BS communitypharmacy.team@borders.scot.nhs.uk	Please email 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 email or post
Fife	PGD Administrator, Pharmacy Services, NHS Fife, Pentland House, Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UW Fife.pgd@nhs.scot	Please email or post
Forth Valley	Community Pharmacy Development Team, Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR fv.communitypharmacysupport@nhs.scot	Please email or post
Grampian	Pharmaceutical Care Services Team NHS Grampian, Pharmacy & Medicines Directorate, Westholme, Woodend, Queens Road, Aberdeen, AB15 6LS gram.pharmaceuticalcareservices@nhs.scot	Please email or post
Greater Glasgow & Clyde	Janine Glen, Contracts Manager, Community Pharmacy, NHS Greater Glasgow & Clyde, Clarkston Court, 56 Busby Road, Glasgow G76 7AT ggc.cpdevteam@nhs.scot	0141 201 6044 Or email
Highland	Community Pharmaceutical Services, NHS Highland, Assynt House, Beechwood Park, Inverness. IV2 3BW nhsh.cpsoffice@nhs.scot	Please email or post
Lanarkshire	Pharmacy/Prescribing Admin Team, NHS Lanarkshire Headquarters, Kirklands, Fallside Road, Bothwell, G71 8BB Pharmacy.AdminTeam@lanarkshire.scot.nhs.uk	Please email or post
Lothian	Primary Care Contractor Organisation, 2 ND Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG CommunityPharmacy.Contract@nhslothian.scot.nhs.uk	Please email or post
Orkney	Lyndsay Steel, Lead General Practice Pharmacist. The Balfour, Foreland Road, Kirkwall, KW15 1NZ	Please email or post
Shetland	Phone: 01856 888 911 ork.primarycarepharmacy@nhs.scot Mary McFarlane, Principle Pharmacist, NHS Shetland, Gilbert Bain Hospital, Lerwick, Shetland, ZE1 0TB	01595 743370
Tayside	Diane Robertson Pharmacy Department, East Day Home, Kings Cross Hospital, Clepington Road, Dundee, DD3 8AE Diane.Robertson9@nhs.scot	Please email or post
Western Isles	Michelle Taylor, Primary Care Dept, The Health Centre, Springfield Road, Stornoway, Isle of Lewis, HS1 2PS	Please post

8. Version history

Version	Date	Summary of changes	
1.0	March 2021	New National Specimen PGD produced.	
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