Patient Group Direction (PGD)

This PGD authorises community pharmacists to supply fexofenadine 120mg tablets to patients aged 12 years and over presenting with symptoms of seasonal allergic rhinitis under NHS Pharmacy First Scotland.

Publication date: 17 May 2023

Version 1.0

NHS SCOTLAND

Most Recent Changes

Version	Date	Summary of changes
1.0	17/05/2023	• New National PGD produced

Contents

Authorisation

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

PGD fexofenadine 120mg 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 fexofenadine 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 has to 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 (Name / Signature): Dr Laura Ryan

Pharmacist (Name /Signature): Dr John McAnaw

NHS Scotland representative (Name / Signature): Mr Jim Miller

Approved on behalf of NHS Lanarkshire by:

Medical Director (Name / Signature): Dr Chris Deighan

Senior Pharmacist (Name / Signature: Lauren Gibson

Clinical Governance Lead (Name / Signature): Dr Mark Russell

Date approved: 15/08/2023

Effective from: 15/08/2023

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

Expiry date: 17 May 2026

1. Clinical situation

1.1. Indication

Relief of symptoms of seasonal allergic rhinitis

1.2. Inclusion criteria

Patients aged 12 years and over with symptoms of seasonal allergic rhinitis:

- **Who have had treatment failure or remain symptomatic despite use of at least two other allergy treatments available over the counter within the last six months.**

  OR

- **Who have required fexofenadine to treat symptoms in previous presentations**.

NB: A combination of other allergy treatment products may be required to obtain acceptable symptom control. However, fexofenadine should not be taken together with other oral antihistamine treatments.

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

1.3. Exclusion criteria

Patients under 12 years of age.

Previous hypersensitivity to fexofenadine or any excipients (including colouring Allura Red AC Lake which may cause allergic reactions).

Pregnancy.

Breast Feeding.

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 doctor

Caution in patients with a history of, or ongoing cardiovascular disease – patients should be warned that, antihistamines as a medicine class, have been associated with the adverse reactions, tachycardia and palpitations.

Caution in elderly (although no significant CNS effects noted).

Caution in renal or hepatic impairment (no dosage adjustment necessary).

Concomitant administration with erythromycin or ketoconazole can increase plasma level of fexofenadine but this was not accompanied by any effect on QT interval or increase of adverse reactions.

1.5. Action if excluded

Consider alternative NHS Pharmacy First Scotland treatments (either under PGD or otherwise).

If appropriate, refer to GP practice and document the reason for exclusion and any action taken in Patient Medication Record (PMR).

1.6. Action if patient declines

If appropriate, refer to GP practice and document the reason for declining treatment and advice given in PMR.

2. Description of treatment

2.1. Name of medicine/form/strength

Fexofenadine 120mg film coated tablets

2.2. Route of administration

Oral

2.3. Dosage

One tablet

2.4. Frequency

Once daily (before a meal)

2.5. Duration of treatment

Supply can be repeated for up to 6 months if required i.e., duration of hay fever season.

2.6. Maximum or minimum treatment period

Ongoing need to be assessed before further supply.

Can be stopped after hay fever season is complete.

2.7. Quantity to supply

30 tablets – usual initial supply to assess response.

60 tablets may be given at subsequent supplies if acceptable response is achieved or has been previously achieved.

2.8. ▼ black triangle medicines

No

2.9. Legal category

Prescription Only Medicine (POM)

2.10. Is the use out with the SPC?

No.

2.11. Storage requirements

As per manufacturer's instructions.

Store below 25ºC 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.

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 at **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.

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).

Verbal advice to be given to individuals:

- Advise the individual on mode of action, benefits of the medicine, possible side effects and their management.
- Advise that medication should be taken before a meal.
- Advise if taking aluminium or magnesium containing antacids – leave at least 2 hours between administration of fexofenadine and these medicines.
- Give general advice for managing high pollen count: stay indoors as much as possible, keeping windows and doors shut; avoid cutting grass, large grassy places and camping; shower and wash your hair after being outdoors, especially in the countryside; wear wrap-around sunglasses when outside; keep car windows closed and consider buying pollen filters for car air vents.
- Advise to seek medical advice in the event of a severe adverse reaction.
- If the condition worsens or symptoms persist, seek further medical advice initially from the pharmacy.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme at: **www.mhra.gov.uk/yellowcard.**

3.4. Monitoring

Not applicable

3.5. Follow up

Advise patient if symptoms do not improve after 1 month of regular use or worsening symptoms, return to pharmacy for re-assessment.

If patient has exhausted all treatment options available in community pharmacy or is requiring to use for more than 6 months then refer to GP for review.

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)
    - BNF British National Formulary - NICE
    - BNF for Children British National Formulary - NICE
- Access to SmPC/PIL/Risk Minimisation Material:
    - Home - electronic medicines compendium (emc)
    - MHRA Products | Home
    - 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 has to 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 the fexofenadine medicine and alert to changes in the manufacturer's product information/summary of product information.
- Have successfully complete the NES Pharmacy e-learning module:

  Seasonal Allergic Rhinitis (Hay Fever) for NHS Pharmacy First Scotland | Turas | Learn

  https://learn.nes.nhs.scot/67704/pharmacy/cpd-resources/seasonal-allergic-rhinitis-hay-fever-for-nhs-pharmacy-first-scotland
- Be able to assess the person'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.
- Undertaking 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 fexofenadine 120mg tablets, or appropriate referral on the same, or next available working day.

These records should be retained in accordance with national guidance[1] (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 on 31st March 2023)

6. Additional references

Practitioners operating the PGD must be familiar with:

1. National Institute for Clinical Excellence / Public Health England. Available at: **Allergic rhinitis | Health topics A to Z | CKS | NICE**. (Accessed 23rd November 2022)

2. Current edition of British National Formulary (BNF) and BNF for children

3. Marketing authorisation holder's Summary of Product Characteristics. Electronic Medicines Compendium. *Fexofenadine hydrochloride 120mg film-coated tablets SPC.* Available at **Fexofenadine hydrochloride 120mg film-coated Tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)** (Accessed 23rd November 2022)

7. Individual authorisation (Appendix 1)

PGDs FOR THE SUPPLY OF TREATMENTS FOR SEASONAL ALLERGIC RHINITIS 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 PGDs authorised by each of the NHS Boards I wish to operate in and agree to provide the following only in accordance with the specific PGD.

Beclometasone 50 micrograms nasal spray ☐ Mometasone 50 micrograms nasal spray ☐

Olopatadine 1mg/ml eye drops ☐ Fexofenadine 120 mg tablets ☐

Name of Pharmacist _____ GPhC Registration Number _____

Normal Pharmacy Location

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

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.

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

Locum ☐ Employee ☐ Manager ☐ Owner ☐

Signature _____ Date _____

Please complete form, sign and send to each Health Board you work in.
Email and postal addresses are given overleaf.

NHS Board	Address	
Ayrshire & Arran	Iain 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, 2ND 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 Phone: 01856 888 911 **ork.primarycarepharmacy@nhs.scot**	Please email or post
Shetland	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	17/03/2023	New National PGD produced.