



Patient Group Direction (PGD 350)

This PGD authorises community pharmacists to supply olopatadine 1mg/ml eye drops to patients aged 3 years and over presenting with symptoms of seasonal allergic conjunctivitis under NHS Pharmacy First Scotland.

Publication date: 17 May 2023

Most Recent Changes

| Version | Date | Summary of changes |
|---------|------------|--|
| 1.0 | 17/05/2023 | <ul style="list-style-type: none">New national PGD produced. |

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Authorisation

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


PGD olopatadine 1mg/ml eye drops

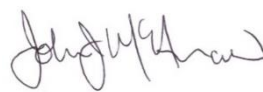
This specimen PGD template has been produced in collaboration with the Primary Care Community Pharmacy Group to assist NHS Boards in the uniform provision of services under 'NHS Pharmacy First Scotland' banner across NHS Scotland. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The community pharmacist who may supply olopatadine eye drops 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 Fife by:

Deputy Medical Director (Name / Signature) Dr Helen Hellewell 

Deputy Director of Pharmacy & Medicines (Name / Signature)
Fiona Forrest 

Director of Nursing (Name / Signature) Nicola Robertson 

Date approved: July 2023

Effective from: June 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 signs and symptoms of seasonal allergic conjunctivitis

1.2. Inclusion criteria

Patients aged 3 years and older with ocular symptoms of seasonal allergic rhinitis **who have been diagnosed with allergic conjunctivitis.**

AND

Who have had treatment failure or remain symptomatic despite use of at least one other allergy treatment for ocular symptoms available over the counter.

NB: A combination of oral, nasal spray and eye treatment products may be required to obtain acceptable symptom control. However, olopatadine should not be used together with other topical eye treatments for allergic conjunctivitis.

1.3. Exclusion criteria

Patients under 3 years of age.

Patient without a diagnosis of allergic conjunctivitis.

Previous hypersensitivity to olopatadine or to any of the excipients.

Pregnancy.

Patient of child-bearing ability not using effective contraception.

Breast Feeding.

Current treatment with olopatadine which exceeds 4 months in duration.

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/optometrist

Caution in previous frequent or prolonged use of olopatadine in patients with dry eyes.

Compromised cornea.

Red eye caused by another reason e.g., accompanied by purulent discharge, altered visual acuity, wearing of contact lenses, chemical exposure, anticoagulation.

1.5. Action if excluded

Seek advice from local optometrist. Document the reason for exclusion and any action taken in Patient Medication Record (PMR).

1.6. Action if patient declines

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

2. Description of treatment

2.1. Name of medicine/form/strength

Olopatadine 1mg/ml eye drops

2.2. Route of administration

Topical ocular administration

2.3. Dosage

One drop into affected eye(s)

2.4. Frequency

Twice daily (Eight hourly)

2.5. Duration of treatment

Until resolution of symptoms (e.g., red, itchy, gritty, watery discharge, swollen eyelids).

2.6. Maximum or minimum treatment period

MAXIMUM treatment period in total – FOUR months (28 days per individual bottle).

2.7. Quantity to supply

One 5ml bottle per supply

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.

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

Common side effects include headache, distortion in the sense of taste (dysgeusia), eye pain, eye irritation, dry eye, abnormal sensation in eyes, nasal dryness and fatigue.

Other less common side effects include: rhinitis, dizziness, hypoaesthesia, corneal erosion, corneal epithelium defect, corneal epithelium disorder, punctate keratitis, keratitis, corneal staining, eye discharge, photophobia, blurred vision, visual acuity reduced, blepharospasm, ocular discomfort, eye pruritis, conjunctival follicles, conjunctival disorder, foreign body sensation in eyes, lacrimation increased, eyelids pruritis, erythema of eyelid, eyelid oedema, eyelid disorder, ocular hyperaemia

In the event of severe adverse reaction individuals should be advised to seek medical advice.

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/optometrist 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 individual on mode of action, benefits of the medicine, possible side effects and their management.
- 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.
- Wearers of contact lenses should remove lenses prior to application of olopatadine eye drops and wait at least 15 minutes after instillation before re-inserting lenses.
- In case of concomitant therapy with other topical ocular medicines, an interval of 10 minutes should be allowed between successive applications. Eye ointments should be administered last.

- Demonstrate the best way to self-administer eye drops.
- Vision may be blurred for a few minutes after instillation – if affected, the patient should not drive or operate hazardous machinery.
- Advise that there might be mild stinging on instillation of drops.
- Treatment with olopatadine should be for a maximum of four months at a time.
- In patients of childbearing potential, effective contraception is required whilst using olopatadine.
- Olopatadine contains benzalkonium chloride which may cause eye irritation.
- Advise to seek medical advice in the event of a severe adverse reaction.
- If the condition worsens or symptoms persist, seek further advice from an optometrist.
- 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

None

If patient is requiring to use for longer than 4 months, then refer to optometrist/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 olopatadine 1mg/ml eye drop 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/ 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.
- Attend 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

An electronic or paper record must be completed to allow audit of practice. All records must be clear, legible, contemporaneous and in an easily retrievable format.

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 olopatadine 1mg/ml eye drops, 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 on 31st March 2023)

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 31st March 2023)
2. Current edition of British National Formulary (BNF) and BNF for children
3. Marketing authorisation holder's Summary of Product Characteristics. Electronic Medicines Compendium. *Olopatadine 1mg/ml eye drops, Solution SPC*. Available at [Olopatadine 1 mg/ml Eye drops, Solution - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#) (Accessed 31st March 2023)

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

| 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 3 Health Board areas, please use additional forms.)

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. E mail 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, 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 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 | 17/05/2023 | New National PGD produced. |