



# Patient Group Direction (PGD) 367

**This PGD authorises community pharmacists to supply nystatin oral suspension to patients aged 4 weeks and over for the treatment of symptoms of oral thrush under NHS Pharmacy First Scotland.**

Publication date: 11<sup>th</sup> March 2026

# Most Recent Changes

Version	Date	Summary of changes
1.0	March 2026	<ul style="list-style-type: none"><li data-bbox="655 365 831 394">• New PGD</li></ul>

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# Authorisation

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


## **PGD Nystatin oral suspension**

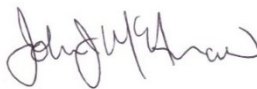
This specimen PGD template has been produced in collaboration with the Community Pharmacy Advisory Group (CPAG) and the Scottish Antimicrobial Prescribing Group (SAPG) to assist NHS boards in the uniform provision of services under the 'NHS Pharmacy First Scotland' banner across NHS Scotland. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The community pharmacist who may supply nystatin oral suspension under this PGD can do so only a named individual. 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 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.

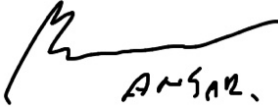
This PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor (Name / Signature): Dr Ron Cook 

Pharmacist (Name /Signature): Dr John McAnaw 

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

Approved on behalf of **NHS FIFE** by:

Medical Director (Name / Signature): Dr. Moontarin Ansar 

Deputy Director of Pharmacy (Name / Signature): Cara Mackenzie 

Clinical Governance Lead (Name / Signature): Dr. Iain Macleod 

Date approved: 17/03/2026

Effective from: 17/03/2026

If this PGD is past the review date, it shall remain valid until such time that the review is complete, and a new version has been published. This does not apply where a decision has been made by the Health Board to withdraw the PGD.

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

Expiry date: 10<sup>th</sup> March 2029

# 1. Clinical situation

## 1.1. Indication

Treatment of oral candidiasis (thrush).

(This usually presents as a curd-like, white or yellowish plaques that can occur anywhere in the mouth, especially cheeks, gums, palate and tongue. These are easily removed, revealing an underlying red base that is not usually painful.)

NICE Guidance recommends miconazole as first line treatment of oral candidiasis in **children 4 months and over** and **adults over 16 years**.

## 1.2. Inclusion criteria

Individual aged 4 weeks and over, presenting with symptoms of oral candidiasis **AND** has an identified risk factor for oral candidiasis (see list below).

Individual is presenting with first episode of oral candidiasis or with second episode of oral candidiasis within 6 months (and more than 7 days apart from the first episode).

Risk factors for developing oral candidiasis (see Cautions section for further advice):

- Extremes of age – either due to immature or weakened immunity
- Immunocompromise or systemic immunosuppression e.g. from disease state or medication related
- Recent or concurrent use of drugs which promote candidal growth e.g. treatment with broad spectrum antibiotic or corticosteroid (inhaled or oral)
- Diabetes
- Other endocrine disorders or deficiencies
- Dentures
- Poor dental hygiene
- Local trauma to mouth

- Smoking
- Poor diet
- Nutritional deficiency e.g. known iron, folate or vitamin B12 deficiency
- Impaired salivary function

### ***Additional supply inclusion criteria***

*Individuals who are unsuitable to use miconazole oral gel (see SPMC) via NHS Pharmacy First Scotland).*

*This PGD may also cover individuals presenting with a prescription for miconazole oral gel or presenting with symptoms eligible for treatment with miconazole, but stock is unavailable to make a supply (assuming no nystatin PGD exclusion criteria apply – full PGD assessment required prior to supply)*

## **1.3. Exclusion criteria**

Individual is under 4 weeks of age (neonate).

Signs of widespread or severe infection e.g. difficulty or pain on swallowing, or retrosternal pain.

Individual has a single red, or red and white plaque that cannot be rubbed off (erythroplakia, erythroleukoplakia).

Individuals with known immunosuppression or being treated with a drug that can cause immunosuppression e.g. DMARD, AND the infection is extensive or severe.

Individual continues to have symptoms despite appropriate treatment with nystatin oral suspension for seven days.

Individual has been treated for two or more episodes (> 7 days apart) of oral thrush in the last 6 months (due to risk of treatment failure).

Individuals currently receiving oncology or haematology treatment including chemotherapy, radiotherapy, immunotherapy, or other systemic anti-cancer therapies.

Hypersensitivity to nystatin or any of the excipient ingredients.

Hypersensitivity to other polyene antifungals (e.g., amphotericin B) due to potential cross-sensitivity.

Individuals with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose, isomaltase insufficiency (nystatin oral suspension contains sucrose).

Individuals who are unable to administer the product effectively themselves or do not have a parent/guardian/carer to administer or apply the product for them.

Valid consent has not been received (either from the individual or, if applicable, from the parent/guardian/carer).

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

Hypersensitivity reactions: treatment should be discontinued and advise to consult a doctor immediately if the reaction is severe e.g. anaphylaxis or angioedema.

Skin reactions: discontinue treatment at first appearance of a skin rash and advise to consult a prescriber immediately.

### **Risk factors:**

Immunocompromised: For either disease state or medication related. When treatment is supplied, the individual should be advised to seek further medical advice if the symptoms get worse or do not resolve after 7 days treatment.

Diabetes: When treatment is supplied, a diabetic review is recommended.

Use in pregnancy: absorption of nystatin is negligible. When treatment is supplied, the individual should use for a maximum of 7 days and seek further advice from GP practice / midwife if symptoms persist.

Use while breastfeeding: the manufacturer advises caution when using nystatin during breastfeeding as it is not known whether nystatin is excreted in human milk. However, there is extensive experience of safe use in breastfeeding. Please note: it is no longer routine practice to treat an individual for nipple thrush if a breast fed baby has oral thrush.

Infants: if unable to feed refer to GP practice or the GP Out Of Hours (OOH) service using the Direct Referral/Prof to Prof number. Only advise a call to NHS 24 on 111 when neither option is available to you.

Person living with HIV (PLWHIV): individuals are classed as immunocompromised if their CD4 count is < 200. If a PLWHIV presents with symptoms of thrush, treatment can be considered and advised to seek further medical advice if the symptoms get worse or do not resolve after 7 days.

Refer to GP practice if symptoms get worse or do not resolve after 7 days.

## **1.5. Action if excluded**

If appropriate, offer suitable alternative to nystatin oral suspension available to purchase over the counter, or supply via NHS PFS Approved List.

If appropriate, refer to GP practice or the GP Out of Hours (OOH) service using the Direct Referral/Prof to Prof number. (if evidence of systemic illness or widespread infection e.g. oesophageal candidiasis characterised by difficulty or pain on swallowing or retrosternal pain). Only advise a call to NHS 24 on 111 when neither option is available to you. Document the reason for exclusion and any action taken in Patient Medication Record (PMR).

If the single red or red/white plaque cannot be rubbed off, where possible refer to a dentist, otherwise refer to GP practice.

## **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**

Nystatin oral suspension 100,000 units/mL

### **2.2. Route of administration**

Oral (via dropper)

### **2.3. Dosage**

1mL (100,000 units) suspension dropped into the mouth.

### **2.4. Frequency**

Four times daily

### **2.5. Duration of treatment**

Continue for 48 hours after lesions have resolved up to 7 days treatment.

### **2.6. Maximum or minimum treatment period**

Use for a maximum of 7 days before seeking further medical advice if symptoms persist.

## 2.7. Quantity to supply

1 x 30 mL bottle

## 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 25°C in a cool, dry place, avoid freezing.

## 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**

Nystatin is generally well tolerated by all age groups, even during prolonged use.

The following side effects have been reported:

Nausea (occasionally during therapy).

Diarrhoea, gastrointestinal distress, nausea and vomiting (occasionally with large doses).

Rash, including urticaria (rarely).

Stevens-Johnson syndrome (very rarely).

Hypersensitivity and angioedema, including facial oedema.

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](http://www.medicines.org.uk)

If irritation or sensitisation occurs, treatment should be discontinued.

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 as appropriate.

Where appropriate, healthcare professionals and individuals/guardians/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](http://www.mhra.gov.uk/yellowcard)

### 3.3. Advice to patient or carer including written information

Written information to be given to individuals or their parent/guardian/carer:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL)
- Direct parent/guardian/carer to [Nystatin for Candida infections – Medicines For Children](#) leaflet if using for a child.
- [Oral thrush in adults | NHS inform](#)
- [Oral thrush \(mouth thrush\) - NHS](#)

Individual/guardian/carer verbal advice:

- Explain the treatment, course of action and potential side effects.
- Shake the bottle well before use.
- Advise to space the doses evenly throughout the day, administer after food or drink, and not eat or drink for at least 30 minutes after using the suspension.
- Use the dropper to place the liquid inside the mouth, near the affected area, taking care not to touch the mouth with the dropper.
- Circulate the suspension around the mouth, keeping in contact with the affected areas for as long as possible before swallowing.
- Continue to use for 48 hours after the lesions have resolved for a maximum of 7 days.
- If condition worsens or symptoms persist for longer than 7 days, stop using and seek further medical advice.
- The individual or their parent/guardian/carer should be advised to seek medical advice in the event of a severe adverse reaction.

- Inform the individual or their parent/guardian/carer that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)
- Advise to contact the GP practice after treatment for follow up if the individual is immunocompromised, pregnant or has diabetes.

#### General dental advice

- Good dental hygiene is essential: brush at least twice daily with fluoride toothpaste, floss daily, visit a dentist regularly for check-ups.
- If the individual is a smoker, give advice on smoking cessation.
- If the individual uses a steroid inhaler:
  - Use good inhaler technique, rinsing the mouth with water (or cleaning the teeth) after inhalation to remove drug particles.
  - Use a spacer to reduce the impact of drug particles in the oral cavity.
  - Step down the dose of corticosteroid if appropriate, and in accordance with instructions given by their managing healthcare professional.
- If the individual wears dentures:
  - Clean dentures by brushing then soaking them in a disinfectant solution (e.g. chlorhexidine or hexetidine); the dentures can be soaked in any solution marketed to sterilize baby's bottles (provided the dentures do not contain any metal).
  - Allow dentures to air dry after disinfection: this also kills adherent Candida. Brush the mucosal surface regularly with a soft brush.
  - Remove dentures at bedtime.
  - Leave dentures out for at least 6 hours in each 24-hour period to promote healing of gums: if the gums are inflamed, they may benefit

from leaving dentures out for longer. See a dentist to correct ill-fitting dentures.

### 3.4. Monitoring

Not applicable

### 3.5. Follow up

Refer to GP practice if symptoms worsen or do not resolve within 7 days.

### 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 medical support (this may be via telephone or email)
- 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)

## 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 nystatin medicine and alert to changes in the manufacturer's product information/summary of product information.
- must have successfully complete the NES Pharmacy e-learning module:

### **Oral thrush for NHS Pharmacy First Scotland**

- must be able to assess capacity of the individual or parent/guardian/carer 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 the PGD are responsible for 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 should complete the individual authorisation form contained in the PGD (Appendix 1) and, where required, 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.

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/carer 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 nystatin oral suspension, or appropriate referral on the same, or next available working day.**

These records should be retained in accordance with national guidance<sup>1</sup> (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 11<sup>th</sup> March 2026)

## 6. Additional references

Practitioners operating the PGD must be familiar with:

1. Current edition of British National Formulary (BNF) and BNF for children. Available at [BNF \(British National Formulary\) | NICE and BNFC \(British National Formulary for Children\) | NICE](#) (Accessed 6<sup>th</sup> March 2026)
2. Marketing authorisation holder's Summary of Product Characteristics. Electronic Medicines Compendium. *Nystatin Oral Suspension BP SPC*. Available at [Nystatin 100,000 unit/ml Oral suspension \(Ready Mixed\) - Summary of Product Characteristics \(SmPC\) - \(emc\) | 100765](#) (Accessed 6<sup>th</sup> March 2026)
3. National Institute for Health and Care Excellence. *Clinical knowledge summary. Candida – oral*. Available at: [Candida - oral | Health topics A to Z | CKS | NICE](#) (accessed 6<sup>th</sup> March 2026)
4. Medicines for Children (NPPG, RCPCH, Wellchild). *Nystatin for Candida infections*. Available at [Nystatin for Candida infections – Medicines For Children](#) (accessed 6<sup>th</sup> March 2026)
5. Specialist Pharmacy Service. *Information resources for advice on medicines and breastfeeding*. Available at: [Information resources for advice on medicines and breastfeeding – NHS SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#) (accessed 6<sup>th</sup> March 2026)
6. La Leche League GB. *Thrush and Breastfeeding*. Available at [Thrush and Breastfeeding - La Leche League GB](#) (accessed 6<sup>th</sup> March 2026)
7. Briggs, G.G., Freeman, R.K., Towers, C.V. & Forinash, A.B., 2021. *Drugs in pregnancy and lactation: A reference guide to fetal and neonatal risk*. 12th ed. Wolters Kluwer.
8. Schaefer, C., Peters, P.W.J. & Miller, R.K., 2007. *Drugs during pregnancy and lactation: Treatment options and risk assessment*. 2nd ed. Academic Press
9. National Institute for Health and Care Excellence. *Clinical knowledge summary. Breastfeeding problems: management and basis for recommendation*. Available at [Breastfeeding problems - management | Management | Breastfeeding problems | CKS | NICE](#) (Accessed 14<sup>th</sup> January 2026)

# 7. Individual authorisation (Appendix 1)

## PGD FOR THE SUPPLY OF NYSTATIN ORAL SUSPENSION 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 nystatin oral suspension only in accordance with this PGD.

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.)

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

Signature \_\_\_\_\_ Date \_\_\_\_\_

Please tick and send to each Health Board you work in. Email and postal addresses are given overleaf.

- |                     |                          |                    |                          |               |                          |
|---------------------|--------------------------|--------------------|--------------------------|---------------|--------------------------|
| Ayrshire & Arran    | <input type="checkbox"/> | Grampian           | <input type="checkbox"/> | Orkney        | <input type="checkbox"/> |
| Borders             | <input type="checkbox"/> | Gr Glasgow & Clyde | <input type="checkbox"/> | Shetland      | <input type="checkbox"/> |
| Dumfries & Galloway | <input type="checkbox"/> | Highland           | <input type="checkbox"/> | Tayside       | <input type="checkbox"/> |
| Fife                | <input type="checkbox"/> | Lanarkshire        | <input type="checkbox"/> | Western Isles | <input type="checkbox"/> |
| Forth Valley        | <input type="checkbox"/> | Lothian            | <input type="checkbox"/> |               |                          |

NHS Board	Address	
Ayrshire & Arran	Complete MS Form available at <a href="#">Patient Group Directions – NHS Ayrshire &amp; Arran</a>	Microsoft Form
Borders	Complete MS Form available at <a href="https://nhsborders.scot.nhs.uk/patients-and-visitors/our-services/pharmacies/community-pharmacy/patient-group-directions-(pgds)-and-unscheduled-care-(cpus)/">nhsborders.scot.nhs.uk/patients-and-visitors/our-services/pharmacies/community-pharmacy/patient-group-directions-(pgds)-and-unscheduled-care-(cpus)/</a>	Microsoft Form
Dumfries & Galloway	NHS Dumfries & Galloway, Primary Care Services, Ground Floor North, Mountainhall Treatment Centre, Bankend Rd, Dumfries, DG1 4TG <a href="mailto:Dg.pcd@nhs.scot">Dg.pcd@nhs.scot</a>	Please email or post
Fife	Complete MS Form available at: <a href="#">PGDs - NHS Fife - Confirmation of Signature</a>	Microsoft Form
Forth Valley	Complete MS Form – see local Health Board information for relevant link.	Microsoft Form
Grampian	Pharmaceutical Care Services Team Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE <a href="mailto:gram.pharmaceuticalcareservices@nhs.scot">gram.pharmaceuticalcareservices@nhs.scot</a>	Please email or post
Greater Glasgow & Clyde	Complete MS Form available at <a href="#">PGDs - Greater Glasgow and Clyde</a>	Microsoft Form
Highland	Complete MS Form available at <a href="#">NHS Highland PGDs</a>	Microsoft Form
Lanarkshire	Complete MS Form available at <a href="#">NHS Lanarkshire - Patient Group Directions V2</a>	Microsoft Form
Lothian	No longer require pharmacists to return signed copies of PGDs. For any queries, please contact <a href="mailto:loth.communitypharmacycontract.nhs.scot">loth.communitypharmacycontract.nhs.scot</a>	
Orkney	Pharmacy Department, The Balfour Hospital, Foreland Road, Kirkwall, KW15 1NZ Phone: 01856 888 911 <a href="mailto:ork.pharmacyadmin@nhs.scot">ork.pharmacyadmin@nhs.scot</a>	Please email or post
Shetland	Pharmacy Primary Care Services, NHS Shetland, Gilbert Bain Hospital, Lerwick, Shetland, ZE1 0TB <a href="mailto:shet.pharmacyprimarycare@nhs.scot">shet.pharmacyprimarycare@nhs.scot</a>	Please email or post
Tayside	Diane Robertson Pharmacy Department, East Day Home, Kings Cross Hospital, Clepington Road, Dundee, DD3 8AE <a href="mailto:TAY.pharmacydepartment@nhs.scot">TAY.pharmacydepartment@nhs.scot</a>	Please email or post
Western Isles	Michelle Taylor, Primary Care, 37 South Beach, Stornoway HS1 2BB <a href="mailto:Michelle.taylor44@nhs.scot">Michelle.taylor44@nhs.scot</a>	Please email or post

# 8. Version history

Version	Date	Summary of changes
1.0	March 2026	New National Specimen PGD produced.