



**Patient Group Direction PGD226**  
**FOR THE ADMINISTRATION OR SUPPLY OF NYSTATIN**

<b>Staff Grade:</b>	Qualified and Year Two Trainee: Advanced Paramedic Practitioners Advanced Nurse Practitioners (Urgent and Primary Care)
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<b>Document Author(s) / Owner</b>	
<b>Version</b>	1.0
<b>Issue Date</b>	28/03/2025
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<b>Division / Organisation Wide</b>	Advanced Practice (Urgent & Primary Care) only

Health Care Professionals must be HCPC or NMC registered and authorised by name under this PGD before attempting to treat any patient according to it and have signed the relevant declaration.

Before using this PGD, healthcare professionals must ensure they are working within their scope of practice and be competent in the treatment of patients identified as suitable for inclusion under this PGD.

“Your scope of practice is the limit of your knowledge, skills and experience and is made up of the activities you carry out within your professional role. As a health and care professional, you must keep within your scope of practice at all times to ensure you are practising safely, lawfully and effectively. This is likely to change over time as your knowledge, skills and experience develop.” (HCPC 2024)

Staff should not deviate from their training, guidelines and scope of practice without taking professional clinical advice. All staff are expected to maintain their fitness to practice and undertake appropriate professional development to allow them to be fit for the role in which they are practising.

## 1. Document Control Sheet

### 1.1 Key Information

<b>Title:</b>	Patient Group Direction PGD226 Nystatin
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### 1.2 Revision History

Version	Date	Summary of Changes	Name	Changes Marked
0.1	13/11/2024	Initial draft		N/A
1.0	26/03/2025	Updated to approved version no., guidance comments removed		Yes
1.0	01/05/2025	First issue – supersedes entry in PGD001a		Yes

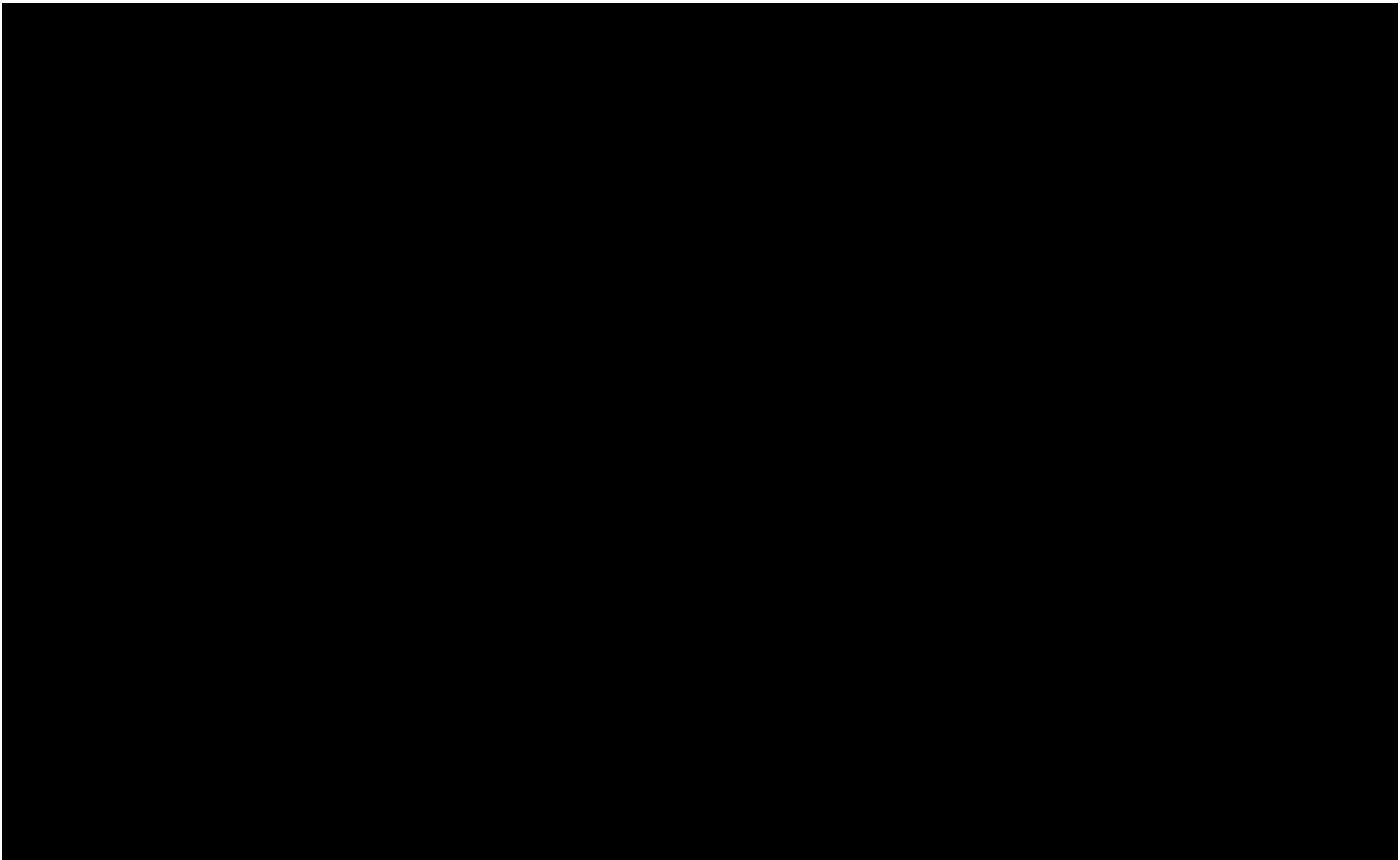
### 1.3 Approvals: This document requires the following approvals:

Name	Date	Version
National Advanced Practice Clinical Lead	30/01/2025	1.0
Medicines Management Group	30/01/2025	1.0
Pharmaceutical Advisor	03/03/2025	1.0
Medical Director	27/02/2025	1.0

### 1.4 Distribution: This document has been distributed to:

Name	Date	Version
Medicines Management Group	28/03/2025	1.0
Advanced Practice Leadership Team	28/03/2025	1.0
All Advanced Practitioners (UPC) & trainees	28/03/2025	1.0

1.5 Names and signatures of professionals drawing up the protocol



1.6 Professional / Advisory groups which have approved the protocol

Scottish Ambulance Service Medicines Management Group	Date	30/01/2025
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## 2. Using this PGD for Administration and/or Supply of Medicines

### 3. Characteristics of Staff

<b>Qualifications required</b>	HCPC or NMC registered, qualified and year two trainee: Advanced Paramedic Practitioners Advanced Nurse Practitioners (in Urgent and Primary Care)
<b>Specific or additional experience / training required</b>	Undertaken an SCQF Level 11 module in Advanced Clinical Assessment (or equivalent) which included a period of supervised practice and signed off as competent. Passed all relevant written and practical assessments and ratified by a university exam board.  Familiarisation with the signs and symptoms of conditions listed in “Criteria for Inclusion” in this PGD and possible differential diagnoses.  Familiarisation with the use of Nystatin, its indications, contra-indications and other details.
<b>Continuing training requirements</b>	The clinician should be aware of any changes to the evidence base for treatment conditions listed in “Criteria for Inclusion” below.  The individual clinician is responsible for their own CPD and for keeping up to date with the use of medicine(s) in this PGD.
<b>Other</b>	You must be authorised by name under the current version of this PGD before you attempt to work to it

#### 4. Clinical Situations / Conditions to Which the Patient Group Direction Applies

<b>Definition of condition / situation to be treated</b>	<p>Treatment of susceptible fungal infections:</p> <ul style="list-style-type: none"> <li>• Oral candidiasis</li> <li>• Oral and perioral fungal infections</li> </ul>
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>• Adults 16 years and over</li> <li>• Appropriate safety-netting can be made</li> <li>• Antifungal therapy indicated for any of the above conditions</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• Children under 16 years of age</li> <li>• Informed non-consent</li> <li>• Known allergy or hypersensitivity to Nystatin or excipients of the drug, in particular: sucrose and saccharin</li> <li>• Pregnancy and breastfeeding</li> <li>• Significantly unwell patients requiring further assessment (blood tests, x-ray, etc.) or admission</li> </ul>
<b>Action if patient is excluded or declines treatment</b>	<p>Document in ePR / patient record. Discuss alternatives with patient / carer as appropriate and advise on risks of declining treatment. Consider referral to primary or urgent care or a community pharmacy. If necessary, consider referral or transfer to a suitable receiving unit.</p>

## 5. Description of Treatment (including dosage and administration)

Name, form(s) and strength(s) of medicine	Nystatin 100,000 IU per ml in 30ml oral suspension
Legal status	POM
Is the use outwith the SmPC?	No
Storage requirements	Room temperature
Route(s) / method(s) of administration	Using the supplied syringe or dropper (depending on supplier) to the oral mucosa. The suspension should be in contact with the infection site until absorbed rather than swallowed for optimal effect
Dose and frequency of administration	<b>All indications listed in this PGD:</b> 100,000 IU (1ml) 4 times per day until 48 hours after all lesions are resolved. A normal course will be 7 days but may be up to 14 days
Maximum dose and number of treatments	Per notes above.  Normal supply is one 30ml bottle, patients requiring more should refer to their GP.

## 6. Cautions and Identification & Management of Adverse Reactions

<b>Cautions</b>	No specific cautions within the scope of this PGD
<b>Drug interactions</b>	No known interactions within the dosing regimen of this PGD
<b>Identification and management of adverse reactions</b>	<p>Anaphylactic reactions to Nystatin are extremely unlikely but should be managed as per standard protocol / JRCALC guidance.</p> <p>Side-effects are so rare that their frequency is unknown, but can include: Nausea, GI distress</p> <p>A detailed list of adverse reactions can be found in the product's SmPC and PIL, see references below.</p> <p>Any adverse reactions, and action taken, are to be recorded in the patient's notes and other appropriate documentation e.g.: clinical incident form, Yellow Card scheme, etc.</p>

## 7. Patient Advice and Documentation

<b>Patient advice (verbal and written)</b>	<ul style="list-style-type: none"> <li>• Explain treatment plan and gain consent</li> <li>• Clinician should inform the patient / carer of the realistic timeframe for improvement of symptoms being treated</li> <li>• Patients using an oral contraceptive should be informed that while Nystatin does not affect it directly, if they have the side effect of vomiting or diarrhoea this may reduce their protection from pregnancy</li> <li>• Must complete the course as described, even if feeling better (note that this is to continue use for 48 hours after symptoms clear)</li> <li>• Any remaining suspension at the end of the course <u>must</u> be discarded and not kept for future use</li> <li>• Advise to contact GP / nurse / pharmacist / out-of-hours service if unexpected side effects or adverse reactions occur</li> <li>• Advise to call 999 if any life-threatening side-effects occur</li> <li>• Patients should be given a copy of the manufacturer's Patient Information Leaflet where available or signposted to an electronic copy if not</li> <li>• Patients should be advised to maintain adequate hydration</li> </ul>
<b>Arrangements for referral to medical advice</b>	Local arrangements apply
<b>Additional facilities / supplies required</b>	<p>None.</p> <p>There is no suitable alternative to Nystatin for indications listed in this PGD. If the patient is excluded from this PGD refer them to their GP.</p>
<b>Monitoring</b>	No specific monitoring required
<b>Follow up</b>	Patients should be advised to follow-up with their GP if symptoms have not fully resolved by the end of the course



## Details of treatment records required

The ePR, or other patient record, must contain the following:

- Name of the HCP using this PGD
- Patient's name, address and date of birth. CHI number is also preferred
- Name of medication and expiry date
- Date and time of administration / supply
- Dose, form and route of administration
- For supplied medicine:
  - Dose and frequency to take
  - Number of items supplied
- That it is administered and/or supplied under this PGD and not prescribed or via an exemption

The ePR, or other patient record, must also contain:

- The patient's medical and medication history
- Medication and safety-netting / worsening advice given to the patient / carer

All records should be clear, legible and contemporaneous.

## 8. References and Further Reading

### **NICE Medicines Practice Guideline MPG2: Patient group directions**

[Overview](#) | [Patient group directions](#) | [Guidance](#) | [NICE](#)

### **General guidance on antimicrobial stewardship**

[Antimicrobial stewardship](#) | [Medicines guidance](#) | [BNF](#) | [NICE](#)

### **Antimicrobial prescribing guidance**

[Antimicrobial Prescribing](#) | [Right Decisions \(scot.nhs.uk\)](#)

### **Nystatin in BNF**

[Nystatin](#) | [Drugs](#) | [BNF](#) | [NICE](#)

### **Nystatin on EMC**

[Nystatin Oral Suspension SmPC \(medicines.org.uk\)](#)

[Nystan Oral Suspension Patient Information Leaflet \(medicines.org.uk\)](#)

### **BNF Treatment Summaries**

[Antifungals, systemic use](#) | [Treatment summaries](#) | [BNF](#) | [NICE](#)

[Oropharyngeal fungal infections](#) | [Treatment summaries](#) | [BNF](#) | [NICE](#)

[Drugs for the mouth](#) | [Nurse Prescribers' Formulary](#) | [BNF](#) | [NICE](#)

### **NICE Clinical Knowledge Summaries (CKS)**

[Candida – oral](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Palliative care – oral care](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

### **NICE Clinical Guidelines**

[CSG4 Improving supportive and palliative care for adults with cancer](#) | [Guidance](#) | [NICE](#)

### **Other Useful Links**

[Oral thrush in adults](#) | [NHS inform](#)

[Mouth problems in palliative care](#) | [NHS inform](#)

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