


Nystatin Oral Suspension 100,000 units/mL


GG&C PGD ref no: 2024/2730

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

| Clinical Condition | |
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| Indication: | The treatment of oral thrush. |
| Inclusion criteria: | <ul style="list-style-type: none"> • Patients aged 4 weeks and over, presenting with symptoms of oral candidiasis including white spots or plaques in the mouth which can be wiped off leaving red patches • Patients who are unsuitable to use Miconazole oral gel – see SPMC (via Pharmacy First or prescribed) • Patients presenting with a miconazole oral gel prescription but stock is unavailable to make a supply • Informed consent has been given (patient, parent/guardian, carer) |
| Exclusion criteria: | <ul style="list-style-type: none"> • Infants less than 4 weeks of age • signs of widespread or severe infection e.g. difficulty or pain on swallowing, or retrosternal pain • If the individual is systemically unwell • If the individual has no obvious risk factor outlined in the inclusion criteria and is otherwise healthy • If the individual has a single red or red and white plaque that cannot be rubbed off. (erythroplakia, erythroleukoplakia) • No contraindications to nystatin – see SmPC • Individuals with known hypersensitivity to nystatin or any of the excipients – see SmPC • Individuals with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrose, isomaltase insufficiency; nystatin contains sucrose • Individuals receiving chemotherapy • Individuals with known immunosuppression AND the infection is extensive or severe or there is suspicion that their immunosuppressive treatment e.g. DMARDs are causing marked immunosuppression • Individuals who are HIV positive • Individuals with suspected immunosuppression and not currently receiving treatment • If the individual continues to have symptoms despite appropriate treatment for seven days |

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| | <ul style="list-style-type: none"> Individuals who are unable to administer the product effectively themselves or who do not have a parent/guardian/carer to administer or apply the medication for them If an individual does not agree to share relevant clinical information |
| Cautions/Need for further advice/Circumstances when further advice should be sought from the prescriber: | <p>Please refer to the SmPC for nystatin oral suspension for full details of special warnings and precautions for use:</p> <ul style="list-style-type: none"> Hypersensitivity Reactions: advise to consult a doctor immediately Skin reactions: discontinue treatment at the first appearance of a skin rash and to consult a doctor immediately. Diabetes: Where treatment is supplied, a diabetic review is recommended. Pregnancy: Absorption of nystatin is negligible. When treatment supplied a GP/midwife review is recommended. Breast feeding: There is extensive experience of safe use in breastfeeding. Excipients: see SmPC for full details and avoid as appropriate |
| Action if patient declines or is excluded: | <p>Explain the reasons for exclusion to the individual and document in the consultation record.</p> <p>If the individual declines, record the reason and advise of the consequences of not receiving treatment.</p> <p>Document the advice given alongside details of any referral made and their (patient, parent, guardian) intended actions. If appropriate, patients may be offered a suitable alternative to nystatin oral suspension if available from Pharmacy First Approved List.</p> <p>Alternatively, refer the individual to their GP if appropriate and/or provide them with information about further options.</p> <p>Where there are safeguarding concerns, seek advice from local safeguarding services.</p> <p>If the red or red and white plaque cannot be rubbed off, advise the individual to see a dentist.</p> |
| Referral arrangements for further advice / cautions: | <p>Further information can be found in the SmPC, BNF and the Pharmacy Approved List</p> <p>NHS Pharmacy First Scotland Approved List of Products Community Pharmacy Scotland (cps.scot)</p> |

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| Drug Details | |
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| Name, form & strength of medicine: | Nystatin oral suspension 100,000 units/mL |
| Route/Method of administration: | Oral (via dropper) in the mouth |
| Dosage (include maximum dose if appropriate): | 1 mL (100,000 units) suspension dropped into the mouth Treatment should be continued for 48 hours after lesions have resolved |
| Frequency: | FOUR TIMES DAILY |
| Duration of treatment: | Continuing for 48 hours after lesions have resolved up to 7 days of treatment. |
| Maximum or minimum treatment period: | 7 days |
| Quantity to supply/administer: | 1 x 30ml |
| Supply, Administer or Both: | Supply only |
| ▼ Additional Monitoring:* | No |
| Legal Category: | POM |
| Is the use outwith the SPC:** | No |
| Storage requirements: | Store in a cool place - avoid freezing |

* The black triangle symbol has now been replaced by European “additional monitoring” (▼)


** Summary of Product Characteristics

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| <p>Warnings including possible adverse reactions and management of these:</p> | <p>Please refer to current BNF or SPC for full details</p> <p>If the patient experiences any of the following they must discontinue treatment and seek medical help:</p> <ul style="list-style-type: none"> • difficulty breathing or swallowing • swelling of the mouth, face, lips, tongue or throat (severe allergic reaction symptoms) • severe itching of the skin, with a rash or raised lumps, hives or blisters <p>The following side effects have been reported:</p> <ul style="list-style-type: none"> • nausea, vomiting, diarrhoea, gastrointestinal stress (with large doses) • rash including urticaria (rarely) • Stevens-Johnson syndrome (very rarely) • hypersensitivity and angioedema, including facial oedema • N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. <p>Use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/</p> |
| <p>Advice to patient/carer including written information provided:</p> | <p>Explain treatment and course of action:</p> <ul style="list-style-type: none"> • Administer the medicine after food or drink; advise individual not to eat or drink for 30 minutes after using the suspension. • Shake the bottle well before use. • Use the dropper to drop the liquid inside the mouth near to the affected area(s) but to not touch the mouth with the dropper. • Swish the suspension around the mouth; the suspension should be kept in contact with the affected area(s) • Space the doses evenly throughout the day. • The treatment should be continued for 48 hours after lesions have resolved. <p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>Inform the individual or their carer:</p> <ul style="list-style-type: none"> • To seek medical advice if their condition deteriorates and/or they become systemically unwell. • If they get any side effects, to talk to their doctor, pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme; this includes any possible side effects not listed in the PIL. |

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| | <ul style="list-style-type: none"> • If the individual is immunocompromised or diabetic or pregnant and treatment is supplied, advise that they contact their GP for follow up. To read the PIL before taking the medication. • To read the Medicines for Children leaflet on nystatin for Candida infections if using for a child. • To visit the NHS website on nystatin for more information. • If they use dentures: <ul style="list-style-type: none"> ○ Clean dentures by brushing and then soaking them in a disinfectant solution (for example chlorhexidine or hexetidine) overnight; the dentures can be soaked in any solution marketed to sterilize baby's bottles (providing the dentures contain no metal). ○ Allow the dentures to air-dry after disinfection; this also kills adherent Candida. To brush the mucosal surface regularly with a soft brush. To see a dentist to correct ill-fitting dentures long as possible before swallowing. ○ Remove dentures at bedtime. ○ Leave the dentures out for at least 6 hours in each 24 hour period to promote healing of the gums; if the gums are inflamed, they may benefit from the dentures being left out for longer. • The importance of good dental hygiene. • If they are a smoker, offer advice on smoking cessation. • If they use a steroid inhaler advise the following: <ul style="list-style-type: none"> ○ Use good inhaler technique, rinsing the mouth with water (or cleaning the teeth) after inhalation to remove drug particles. ○ To use a spacer device to reduce the impaction of particles in the oral cavity. ○ Stepping down the dose of corticosteroid when appropriate and in accordance with the instructions given by their managing healthcare professional. |
| Monitoring (if applicable): | |
| Follow up: | If not resolving after seven days seek further medical advice. |

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| Staff Characteristics | |
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| Professional qualifications: | Registered pharmacist with a current GPhC registration |
| Specialist competencies or qualifications: | Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD Has undertaken appropriate training for working under PGDs for the supply and administration of medicines |
| Continuing education & training: | The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development |

| Referral Arrangements and Audit Trail | |
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| Referral arrangements | <i>As per local arrangements/national guidelines</i> |
| Records/audit trail: | <ul style="list-style-type: none"> • Note should be made that administration or supply is under PGD • Patient's name, address, date of birth and consent given • Contact details of GP (if registered) • Diagnosis • Dose, form administered and batch details • Advice given to patient (including side effects) • Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record • Referral arrangements (including self-care) |

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| References/Resources and comments: | <p>Notes:</p> <p>SPC – Summary of Product Characteristics</p> <p>BNF – British National Formulary</p> <p>National Institute for Health and Care Excellence: Clinical Knowledge Summaries. Candida – oral.</p> <p>Specialist Pharmacy Service. Lactation Safety Information: Nystatin.</p> <p>Nystatin: medicine for fungal or yeast infections - NHS (www.nhs.uk)</p> <p>Nystatin for Candida infections – Medicines For Children Yellow Card Reporting</p> <p>Brigg's Drugs in Pregnancy and Lactation: A Reference Guide to Fetal and Neonatal Risk (2021) 12th Edition - Briggs, Gerald G.; Freeman, Roger K.; Tower, Craig V.; et al.¹</p> |
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This Patient Group Direction must be agreed to and signed by all healthcare professionals involved in its use. The original signed copy will be held at Pharmacy Services, Clarkston Court, 56 Busby Road, Glasgow. The PGD must be easily accessible in the clinical setting.

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| Organisation: | NHS Greater Glasgow & Clyde |
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| Professionals drawing up PGD/Authors | Designation and Contact Details |
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| *Name: Lorna Brown  Signature: _____ Date: 01/10/2024 | Designation: Primary Care Pharmacist E-mail address: lorna.brown8@nhs.scot |
| Name: Pamela Macintyre  Signature: _____ Date: 01/10/2024 | Designation: Pharmacist Community Pharmacy Development Team E-mail address: pamela.macintyre@nhs.scot |
| Name: Stuart Sutton  Signature: _____ Date: 01/10/2024 | Designation: Clinical Director & GP E-mail address: stuart.sutton@nhs.scot |
| Name: David Henry  Signature: _____ Date: 01/10/2024 | Designation: Community Pharmacist Independent Prescriber E-mail address: David.Henry1@nhs.scot |
| **Name: Scott Gillen  Signature: _____ Date: 01/10/2024 | Designation: Antimicrobials Pharmacist E-mail address: scott.gillen@nhs.scot |


* **Lead Author** **AMT representative (see below)

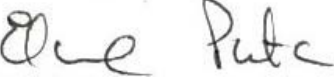
** **Antimicrobial Pharmacist** if appropriate

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AUTHORISATION:

| NHSGG&C PGD Sub-Committee of ADTC | | |
|-----------------------------------|---|------------|
| Chairman in BLOCK CAPITALS | Signature: | Date: |
| Dr Craig Harrow |  | 21/08/2024 |


| NHSGG&C PGD Sub-Committee of ADTC | | |
|--|--|------------|
| Lead Nurse, North Sector, NHS GG&C in BLOCK CAPITALS | Signature: | Date: |
| Kevin McAuley |  | 21/08/2024 |

| Pharmacist representative of PGD Sub-Committee of ADTC | | |
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| Name: in BLOCK CAPITALS | Signature: | Date: |
| Elaine Paton |  | 21/08/2024 |

| Antimicrobial use | | |
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| If the PGD relates to an antimicrobial agent, the use must be supported by the NHS GG&C Antimicrobial Management Team (AMT). A member of this team must sign the PGD on behalf of the AMT. | | |
| Microbiology approval | Name: Scott Gillen | Designation: Antimicrobials Pharmacist |
| |  | |
| | Signature: | Date: 02/10/2024 |
| (on behalf of NHS GG&C AMT) | | |

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Local Authorisation:

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| Service Area for which PGD is applicable: | Community Pharmacy | | |
| Record/Audit Trail | There must be appropriate records kept and maintained by the pharmacist to enable verification of service provision and training requirements, and provide information for internal and external audit and evaluation purposes. | | |
| Nominated individual who agrees to keep list of practitioners operating under the PGD current and up to date (Lead Professional): | | | |
| Name: | Signature: | Designation: | Date: |
| Alan Harrison Email contact address: alan.harrison@ggc.scot.nhs.uk |  | Lead Pharmacist Community Care | 07/10/2024 |

PGDs do not remove inherent professional obligations or accountability

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


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| Name of Pharmacist | | GPhC No | |
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I have read and understood the Patient Group Direction. I acknowledge that it is a legal document and agree to provide these medicines only in accordance with this PGD.

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| Sign: | | Date: |
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ONCE YOU HAVE SIGNED THE PGD, YOU MUST COMPLETE THE ELECTRONIC FORM (LINK BELOW)

[PGDs - Greater Glasgow and Clyde \(office.com\)](https://www.ggc.scot.nhs.uk/office/pgds)

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Patient Group Direction Audit Form
Form for the audit of compliance with PGD or PGDs

To ensure best practice all PGDs should be audited on a 6 monthly basis.

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| Name and post of Designated Lead person within each practice/clinic base: | | | |
| Location/Clinic Base: | | Date of audit: | |
| | | | |
| Tick as appropriate. If 'no', state action required | Y | N | Action |
| Is the PGD or PGDs utilised within the clinical area? | | | |
| Has the PGD or PGDs been reviewed within the 2 year limit? | | | |
| Do the managers listed on the PGD or PGDs hold a current list of authorised staff? | | | |
| Are all staff authorised to work under the PGD or PGDs members of one of the health professions listed in the PGD? | | | |
| Do all staff meet the training requirements identified within the PGD? | | | |
| Are you confident that all medicines supplied or administered under the PGD or PGDs are stored according to the PGD where this is specified? | | | |
| Do the staff working under the PGD or PGDs have a copy of the PGD which has governance sign off and is in date and, available for reference at the time of consultation? | | | |
| Where the medicine requires refrigeration. (Delete if not required). | | | |
| Is there a designated person responsible for ensuring that the cold chain is maintained? | | | |
| Is there a record that the fridge temperature has been monitored to required levels? | | | |
| If there is regular and sustained reliance on PGDs for service provision has a Non Medical Prescribing approach been considered as an alternative? (Please note reasons for either a Y/N response). | | | |
| Name: | | Date of audit: | |
| | | | |

**Keep copies of completed audits alongside your PGD for local reference.
Please retain at local level and ensure audit forms are readily available as they may be required for clinical governance audit purposes.**