



This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply of

Nystatin Oral Suspension 100,000 units in 1ml

for the Treatment of

Oral Candidiasis (Thrush) in Infants (from 1 to 6 months of age)

by Registered Pharmacists, as part of the

Doncaster Minor Ailments Service

Version Number 2.0

Change History	
Version and Date	Change details
1.0 April 2021	New PGD
2.0 Mar 2023	PGD Review Section 3. Clinical Condition or Situation to which this PGD Applies <ul style="list-style-type: none">• Babies over 1 month and under 6 months of age presented by parent/carer in the pharmacy with signs of oral thrush e.g. white plaques which do not rub off easily (not to be confused with milk curds in the mouth) – updated• If the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the child to use it - added• if the child continues to have symptoms despite appropriate treatment for seven days – added Section 3. Description of treatment <ul style="list-style-type: none">• Advise the parent/carer that if they notice any adverse reactions, they should discontinue medication and contact a pharmacist or their GP – updated• Patient advice / follow up treatment – updated• If the patient has increased risk of oral candidiasis due to medical treatments, including inhaled corticosteroids, give advice to reduce the risk. For example, drinking some water after using a steroid inhaler and reinforcing correct administration techniques where possible - removed

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PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	01/4/2024
Review date	01/01/2026
Expiry date:	31/03/2026

This PGD has been developed by the individuals named below. This PGD has been approved by the authorised signatories detailed in the Organisational Authorisations section of this document, on behalf of Doncaster Place.

Name	Designation
Chioma Nnamdi	Locality Lead Pharmacist, Medicines Optimisation Team
Faiza Ali	Locality Lead Pharmacist, Medicines Optimisation Team
Ning Wong	Locality Lead Pharmacist, Medicines Optimisation Team

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor Dr V V S Rao Kolusu	Locality lead GP and Prescribing lead Doncaster Place		28/03/2024
Senior pharmacist Charlotte McMurray	Chief Pharmacist Doncaster Place		28/03/2024
Senior representative of professional group using the PGD			
Person signing on behalf of authorising body Dr V V S Rao Kolusu	Locality lead GP and Prescribing lead Doncaster Place		28/03/2024

GLOSSARY

PGD	Patient Group Direction
GPhC	General Pharmaceutical Council
OOH	Out of Hours Clinic

1. Characteristics of Staff

Qualifications and professional registration	Qualified pharmacist registered with the General Pharmaceutical Council (GPhC)
Initial training	<p>Competent to work under Patient Group Directions, including satisfactory completion of training to assess patients and supply in accordance with this Patient Group Direction.</p> <p>Working as a community pharmacist and accredited to provide the Minor Ailments Service.</p>
Competency assessment	<p>CPPE Declaration of Competence Documents (DoCs). See Minor ailments (cppe.ac.uk)</p> <p>Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions</p> <p>Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training, provided as required.</p>
Ongoing training and competency	<p>Commitment to undertake training updates and revalidation according to the accreditation requirements of the commissioning organisation.</p> <p>Commitment to keep up to date with clinical developments in this area or changes to the recommendations for the medicine listed, as part of their Continuing Professional Development (CPD).</p> <p>Commitment to keep up to date Safeguarding training at a minimum of Level 2.</p> <p>The pharmacist must keep up to date with current legislation, including the Equality Act and Mental Capacity Act.</p>
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</p>	

2. Clinical Condition or Situation to which this PGD Applies

Clinical condition or situation to which this PGD applies	Treatment of oral candidiasis (thrush) in infants.
Criteria for inclusion	<ul style="list-style-type: none"> • Babies over 1 month and under 6 months of age presented by parent/carer in the pharmacy with signs of oral thrush e.g. white plaques which do not rub off easily (not to be confused with milk curds in the mouth) • Enquire if the mother is breastfeeding to ascertain if they have sore nipples. Treatment for sore, cracked nipples can be purchased over the counter. Where the baby is bottle fed, or where a breastfeeding mother is not experiencing any pain or other symptoms of thrush, the pharmacist may supply Nystatin as per the PGD • Where a breastfeeding mother meets the criteria for supply of miconazole 2% cream for nipple thrush and the baby meets the criteria for Nystatin as per the PGD both mother and baby should be treated simultaneously. (Miconazole has no published evidence of safety but extensive experience of safe use in breastfeeding. https://www.sps.nhs.uk/medicines/miconazole/) • Patient/carer agrees to treatment under this PGD
Criteria for exclusion	<ul style="list-style-type: none"> • Children over 6 months of age – advise patient/carer that over-the-counter products, e.g., miconazole 2% oral gel (if appropriate) are available to purchase as part of self-care. • Infants with known hypersensitivity/allergy to nystatin or any other excipient in the product • If child is systematically unwell or on immunosuppressant therapy • Children with diabetes, haematinic deficiencies or poor dental hygiene • If the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the child to use it • If the child continues to have symptoms despite appropriate treatment for seven days • If this episode is a recurrence within the last 8 weeks • Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine
Cautions including any relevant action to be taken	Refer to generic product (Nystatin) Summary of Product Characteristics http://www.medicines.org.uk/emc/ for full details of special warnings and precautions for use.
Action to be taken if the patient is excluded	<ul style="list-style-type: none"> • Record reasons for exclusion in patient notes • Advise parent/carer on alternative treatment if suitable. • Refer to a prescriber such as the patient's usual GP or NHS 111 if appropriate

Action to be taken if the patient or carer declines treatment	Refer to the patient's usual GP, or NHS 111 if the patient is not able to see their GP or is not registered with an NHS GP practice. Offer the parent/carer details of relevant local services such as walk-in centres and OOH services if applicable. You must: <ul style="list-style-type: none"> • Document advice given. • Advise parent/carer on alternative treatment. • Refer to a prescriber if appropriate
Arrangements for referral for medical advice	Supply the parent/carer with a referral note to hand to the prescriber indicating the reasons for the referral.

3. Description of Treatment

Name, strength & formulation of drug	Nystatin oral suspension 100,000 units in 1ml
Legal category	POM
Route / method of administration	Oral
Indicate any off-label use (if relevant)	The product must be supplied for use within its licenced posology and method of administration for the purpose of this PGD.
Dose and frequency of administration	Drop 1ml (100,000 units) of suspension into the mouth four times a day usually for 7 days and continued for 48 hours after lesions have resolved. Dose to be given after feeds.
Duration of treatment	Maximum treatment period 7 days.
Quantity to be supplied	1 x 30ml The branded (Nystan) or generic formulation can be supplied, choosing the most cost-effective available product. Maximum of two treatment courses in any 6-month period.
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	The following side effects may be seen with nystatin: <ul style="list-style-type: none"> • Local irritation and sensitization • Nausea has occasionally been reported. • Large doses can cause diarrhoea, gastrointestinal distress, nausea and vomiting. • Rash including urticarial rash. • Steven-Johnson Syndrome has been reported very rarely. • Hypersensitivity and angioedema, including facial oedema have been reported. <p>Advise the parent/carer that if they notice any adverse reactions, they should discontinue medication and contact a pharmacist or their GP.</p> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>

Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • Healthcare professionals and parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via the pharmacy's policy for reporting adverse reactions
Written information to be given to parent or carer	<p>Supply the marketing authorisation holder's patient information leaflet (PIL) with the product supplied every time.</p>
Patient advice / follow up treatment	<p>Inform the parent/carer of possible side effects and to seek medical advice if they occur.</p> <ul style="list-style-type: none"> ➤ to seek medical advice if the child's condition deteriorates and/or they become systemically unwell. ➤ to read the PIL before giving the medication. ➤ to read the medicines for children leaflet on nystatin for <i>Candida</i> infections. ➤ to visit the NHS website on nystatin for more information. ➤ to administer the medicine after food or drink; do not offer food or drink for 30 minutes after giving the suspension. ➤ to shake the bottle well before use. ➤ to space the doses evenly throughout the day. ➤ to 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.

	<p>Discuss side effects and administration methods with the parent/carer.</p> <p>Advise the parent/carer how to use the product. The longer the suspension is kept in contact with the affected area in the mouth before swallowing the greater the effect.</p> <p>Advise parent/carer to discard any unused suspension after completing the treatment.</p> <p>The suspension should be given after feeds.</p> <p>Refer to the Medicines for Children Leaflet: https://www.medicinesforchildren.org.uk/nystatin-candida-infection</p>
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • That valid informed consent was given. • Name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • Name of registered health professional • Name of medication supplied/administered. • Date of supply/administration • Dose, form and route of supply/administration • Quantity supplied/administered. • Batch number and expiry date (if applicable) • Advice given, including advice given if excluded or declines treatment. • Details of any adverse drug reactions and actions taken • That the medicine is supplied via a PGD <p>Records should be signed and dated (or a password-controlled e-records).</p> <p>All records should be clear, legible, and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

4. Key References

Key references	<ul style="list-style-type: none">• Electronic Medicines Compendium http://www.medicines.org.uk/• Electronic BNF https://bnf.nice.org.uk/• NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2• Common Conditions and Minor Ailments https://www.cppe.ac.uk/learningdocuments/pdfs/common_clinical_conditions_and_minor_ailments.pdf• CPPE Minor Ailments and Declaration of Competence https://www.cppe.ac.uk/gateway/minor• https://www.wmic.wales.nhs.uk/wp-content/uploads/2023/08/2023-PGD-RE-FINAL-Nystatin-100000-units-per-ml-oral-suspension-v1.0.docx• Yellow Card Reporting. Available from: http://yellowcard.mhra.gov.uk [accessed 27 February 2024]• Specialist Pharmacy Service. Lactation Safety Information: Miconazole. For oropharyngeal use. Reviewed 4th August 2020. Available from: https://www.sps.nhs.uk/medicines/miconazole/•
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