

This Patient Group Direction (PGD) must only be used by registered pharmacists 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

for the supply of

Nystatin Oral Suspension 100,000 units in 1ml

by registered pharmacists for the

Treatment of Oral Candidiasis Thrush in Infants (from 1 to 4 months of age)

under the Wirral Clinical Commissioning Group Minor Ailments Service

Version number: 4.0

Change history

Version number	Change details	Date
1.0	Original Document developed with the PGD Development and review group	May 2015
2.0	Review and Amendments by the PGD Development and review group	March 2016
3.0	Review and Amendments by the PGD Development and review group. Document updated from previous version written by Nicola Bradley.	March 2017
3.1	Review and Amendments by the PGD development and review group	January 2020
4.0	Final document ratified and issued	April 2020

Valid from: April 2016

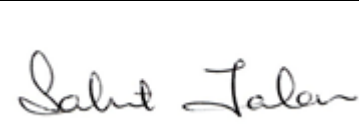


Updated: March 2017, March 2020

Review date: March 2023

PGD development

Name	Job title and organisation
Lead author Victoria Vincent	Medicines Optimisation Pharmacist Midlands and Lancashire Commissioning Support Unit (MLCSU)
Lead doctor Dr Diane Atherton	Prescribing Lead GP, Wirral Health & Care Commissioning (WHCC)
Lead pharmacist Rob Hebdon	Senior Medicines Optimisation Lead, MLCSU
Representative of other professional group using PGD – Nick Thayer	Community Pharmacy Cheshire and Wirral (CPCW)
Other members of the PGD working group: Richard Crockford – Deputy Director, Quality and Safety, Wirral Health & Care Commissioning (WHCC)	

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr Saket Jalan	GP Clinical Lead for Urgent Care and medicines Management (WHCC)		21.02.2020
Senior pharmacist Rob Hebdon	Senior Medicines Optimisation Lead, MLCSU		13.03.2020
Person signing on behalf of WHCC Lorna Quigley	Director of Quality and Patient Safety Outcomes (WHCC)		24.02.2020

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Training and competency of registered pharmacist

	Requirements of registered pharmacists working under the PGD
Qualifications and professional registration	Qualified pharmacist registered with the General Pharmaceutical Council (GPhC)
Initial training	Competent to work under Patient Group Directions, including satisfactory completion of training to administer/supply in accordance with this Patient Group Direction. Working as a community pharmacist and accredited to provide the Minor Ailments Service.
Competency assessment	CPPE Declaration of Competence Documents (DoCs)
Ongoing training and competency	Commitment to continuing updating and re-validation according to the accreditation requirements of the commissioning organisation. 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 Continual Professional Development.

Clinical condition

Clinical condition or situation to which this PGD applies	Treatment of oral candidiasis (thrush) in infants.
Inclusion criteria	<p>Babies over 1 month and under 4 months of age presented by parent/carer in the pharmacy with signs of oral thrush e.g. white plaques which do not move (not to be confused with milk curds in the mouth) under the minor ailments service.</p> <p>Enquire if the mother is breastfeeding to ascertain if they have sore nipples. Treatment for sore, cracked nipples can be purchased over the counter. <i>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.</i></p> <p>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.</p> <p><i>Patient/carer agrees to treatment under this PGD.</i></p>
Exclusion criteria	<ul style="list-style-type: none"> Children over 4 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. Please note - the mother can be supplied miconazole 2% cream as per the PGD (if appropriate). Infants with known hypersensitivity/allergy to nystatin or any other excipient in the product. If child is unwell or on immunosuppressant therapy. Children with diabetes, haematinic deficiencies or poor dental hygiene. 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)	<ul style="list-style-type: none"> Refer to generic product (Nystatin) Summary of Product Characteristics http://www.medicines.org.uk/emc/
Arrangements for referral for medical advice	<ul style="list-style-type: none"> Supply the patient with a referral note to hand to the GP indicating the reasons for the referral.
Action to be taken if patient excluded	<ul style="list-style-type: none"> Refer to GP practice. Clearly record the decision on the patient's consultation proforma including any advice given and action taken.
Action to be taken if patient declines treatment	Record the decision on the patient's consultation proforma including any advice given and action taken. Refer to GP as appropriate.

Details of the medicine

Name, form and strength of medicine <i>Include ▼ for black triangle medicines</i>	Nystatin oral suspension 100,000 units in 1ml
Legal category	POM
Indicate any off-label use (if relevant)	N/A
Route/method of administration	Oral
Dose and frequency	Give 100,000 units (1ml) 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. (Dose taken from BNF and BNFc).
Quantity to be administered and/or supplied	Supply 1 x 30ml per treatment episode. The generic formulation should be supplied. Maximum of two treatment courses in any 6 month period.
Maximum or minimum treatment period	Maximum treatment period 7 days.
Adverse effects	<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>Refer to SPC or current BNF/BNFc for full details.</p>
Records to be kept	<p>The following will be recorded in the patient's consultation proforma:</p> <ul style="list-style-type: none"> • Advice given to parent or carer • Baby's name, address, date of birth and GP (if registered) • Date and time of supply • The batch number and expiry date • Name of person supplying the medicine

Patient information

<p>Verbal/written advice to be given to patient</p>	<p>Discuss side effects and administration with the parent/carer and provide a manufacturer's patient information leaflet.</p> <p>Advise the parent/care 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>Follow-up advice to be given to patient or carer</p>	<p>Contact GP/health visitor if symptoms persist or recurs.</p>

Appendices

Appendix A Key references

1. Clinical Knowledge Summaries Guideline. [Candida oral](#). (Accessed January 2020)
2. Nystan SPC [Summary of Product Characteristics](#) (Accessed January 2020)
3. Nystatin SPC [Supply of Product Characteristics](#) (Accessed January 2020)
4. [BNFc](#) (Accessed January 2020)

Appendix B Health professionals' agreement to practise

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD.

Name of pharmacist	Signature	Senior representative authorising pharmacist	Date