PATIENT GROUP DIRECTIONS*

The Supply of Nystatin Oral Suspension 100,000 units in 1ml for the treatment of Oral Candidiasis (Thrush) in Infants by Community Pharmacists participating in the NHS Cheshire Clinical Commissioning Group Pharmacy First Minor Ailments Service

Version 9

Date of introduction June 2021

(It is intended that this document will be updated in 2 years subject to no amendments in the interim period)

Review Date May 2023

***HSC 2000/026 Patient Group Directions (England Only)**

Version Control:
Nystatin Oral Suspension100, 000units in 1ml for the treatment of oral candidiasis (Thrush) in infants

Version	Date of introduction	Author	Status	Comment
V1	August 2004	PGD Development and review group	final	Review date July 2006
V2	August 2006	PGD Development and review group	final	Review date July 2008
V3	August 2008	PGD Development and review group	final	Review Date July 2010 V3 extended to September 2013 PGD group informed.
V4	October 2013	PGD Development and review group	Draft	Document review awaiting ratification
V5	April 2014	PGD Development and review group	Draft	Document updated with information about treatment for breastfeeding women.
V5	April 2014	PGD Development and review group	Approved	Approved with minor amendments recommended by the PGD subgroup
V6	April 2016	PGD Development and review group	Draft	Awaiting development group comment
V6	April 2016	PGD Development and review group	Approved	Approved with minor amendments recommended by the PGD subgroup
V7	April 2017	PGD Development and review group	Approved	Approved by PGD subgroup on 8 Mar 2017
V8	April 2019	PGD Development and review group	Approved	Addition of NHS West Cheshire CCG. Change to the age of range eligible for treatment to between 1 and 4 months. Approved by PGD subgroup on 12 December 2018.
V9	April 2021	PGD Development and review group	Approved	Poor feeding/nappy rash added to symptoms
V9	June 2021	PGD subgroup	Approved	Approved by PGD subgroup 17 Jun 2021

Patient Group Direction:	Nystatin oral suspension for the treatment of oral candidiasis (thrush) in infants.
Clinical Department/Service:	Community Pharmacists participating in the Pharmacy First Minor Ailments Service commissioned by NHS Cheshire Clinical Commissioning Group

1. Clinical Condition

1.1	Define situation/condition	The treatment of oral candidiasis (thrush) in infants.
1.2	Criteria for inclusion	Babies aged between 1 and 4 months of age presented by parent / carer in the pharmacy with signs of oral thrush e.g. white plaques or white spots which do not move or rub off easily (not to be confused with milk curds in the mouth). Other symptoms in babies can be reluctance to feed or nappy rash. • Enquire if the mother is breastfeeding to ascertain if they have sore nipples. *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.* Parent / carer agrees to treatment under this PGD
1.3	Criteria for exclusion	• Infants with known hypersensitivity/allergy to nystatin or any other excipient in the product. • If child unwell or on immunosuppressant therapy. • If this is a recurrence within the last 8 weeks.
1.4	Cautions/additional information	• Refer to Summary of Product characteristics. (http://emc.medicines.org.uk/

1.5	Action if patient excluded	• Advise the parent / carer that over-the-counter items are available to purchase for self care for infants aged more than 4 months. • Refer to GP practice or out of hours via NHS 111 as appropriate for clinical concerns or if the baby is <1 month old. • Supply the patient with a referral note to hand to the GP practice indicating the reasons for the referral. • Record the decision on the patient's consultation proforma, advice given and any action taken.
1.6	Action if patient declines	Record the decision on the patient's consultation proforma, including any advice given and action taken, refer to GP practice or out of hours via NHS 111 as appropriate.

2. Characteristics of staff

2.1	Class of Health Professional for whom PGD is applicable	Qualified Pharmacist registered with the General Pharmaceutical Council (GPhC)
2.2	Additional requirements	• 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.
2.3	Continued training requirements	• 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 or changes to the recommendations for the medicine listed, as part of their Continual Professional Development.

3. Description of Treatment

3.1	Generic Name of Medicine and Form	Nystatin oral suspension 100,000 units in 1 ml.
3.2	Legal status	POM
3.3	Storage	Room temperature not above 25^{o}C.
3.4	Licensed or unlicensed	Licensed
3.5	Dose(s)	1ml should be dropped into the mouth Four Times a Day, to be given after feeds. Continue treatment for 48 hours after condition has resolved.

3.6	Route/Method of Administration	Oral
3.7	Frequency of Administration	As detailed above
3.8	Total dose and number of times treatment can be administered over what time	Usual treatment period 7 days. Supply 1x30 ml per treatment episode. Maximum of two treatment courses in any six month period.
3.9	Side effects of drugs (including potential Adverse Drug Reaction)	• Oral irritation and sensitisation, sometimes nausea. • Large doses can cause diarrhoea. • Rash including urticarial. • Very rare: cases of Stevens – Johnson Syndrome. • Refer to SPC or current BNF for full details.
3.10	Advice/management of adverse reactions/events	Seek advice from GP practice or out of hours via NHS 111 as appropriate.
3.11	Procedure for reporting Adverse Drug Reactions (ADR's)	• Report serious suspected adverse drug reactions (or all suspected ADRs if the medicine is black triangle) to the Medicines Health and Regulatory Agency using either the yellow cards or via www.yellowcard.gov.uk • Record any adverse drug reaction in the patient's consultation record and PMR. • Notify patients GP.
3.12	Information on follow up treatment	Contact GP practice / Health Visitor if symptoms persist or recur.
3.13	Written/verbal advice for patient/carer before/after treatment.	• Discuss side effects and administration with the parent/carer and provide a manufacturers patient information leaflet. • Advise the patient's 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. • Advise the patient's parent/carer to discard any unused suspension after completing the treatment. • The suspension should be given after feeds.
3.14	Specify method of recording supply/administration, names of health	The following will be recorded in the patient's consultation proforma: • Quantity supplied.

	professional, patient identifiers, sufficient to enable audit trail.	• Advice given to patient/ carer. • Date of supply. • The signature of the person supplying the medicine.

4. Development of the PGD

Multidisciplinary Group:
The group who have been involved in the development of this PGD included the following people:

Name	Designation	Signature	Date
Janet Kenyon	Assistant Director of Medicines Strategy and Optimisation NHS Cheshire Clinical Commissioning Group		8.6.2021
Dr Graham Duce	GP Prescribing Lead NHS Cheshire Clinical Commissioning Group.		17.6.2021
Dr Andrew Dunbavand	GP Prescribing Lead NHS Cheshire Clinical Commissioning Group.		8.7.2021
Suzanne Austin	Pharmacy Local Professional Network Chair.		17.6.2021
Susan Nixon	Minor Ailments Co-ordinator NHS Cheshire Clinical Commissioning Group.		17.6.2021
Dr Ildiko Kustos	Consultant Medical Microbiologist Countess of Chester Hospital NHS Foundation Trust		15.7.2021

5. References

- SPC for contraindications and cautions (http://emc.medicines.org.uk/)
- BNF for Children July 2020
- NICE CKS Breastfeeding problems **(**Last revised in May 2017) https://cks.nice.org.uk/topics/breastfeeding-problems/

Responsible Organisation:
NHS Cheshire Clinical Commissioning Group

Responsibilities of each Organisation:

Each organisation is required to:

1. Approve the contents of this documentation (in the knowledge that it has been prepared by a multidisciplinary group as above).

2. Ensure that every PGD is approved and signed by a nominated Senior Pharmacist and Senior Doctor.

3. Ensure that the PGD is approved and signed by a senior member of staff, representative of the staff to whom the PGD relates eg. nurses, chiropodists etc.

4. Ensure that the PGD is approved and signed by the Clinical Governance Lead for the Organisation.

5. Ensure that individual health professionals working under the direction sign appropriate documentation.

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Organisation (s)	NHS Cheshire Clinical Commissioning Group
Approved by **Patient Group Direction Subgroup Chair** Name Position Signature Date	 Andrea Lunt Assistant Director of Medicines Strategy and Optimisation & Lead Pharmacist for PGD subgroup NHS Cheshire Clinical Commissioning Group.  20.09.2021
Clinical Governance Lead Name Position Signature Date	 Dr Andrew McAlavey Joint Medical Director NHS Cheshire Clinical Commissioning Group  17.09.21