

***Patient Group Direction for the supply of Nystatin Oral Suspension 100,000units/ml  
by Community Pharmacists in the management of Oral Candidiasis***

**PGD Development and Clinical Approval**

**PGD Working Group**

This PGD was developed by a working group involving pharmacists from NHS Kernow and GP Clinical leads from NHS Kernow

<b>Name and role</b>	<b>Job title and organisation</b>
<b>Fiona Lee</b> Pharmacist and Lead author	Pharmaceutical Advisor NHS Kernow
<b>Amanda Pell</b> Pharmacist and Lead author	Pharmaceutical Advisor NHS Kernow
<b>Dr Nick Gibson</b> GP	GP Prescribing Lead NHS Kernow Prescribing Lead
<b>Georgina Praed</b> Pharmacist	Head of Prescribing and Medicines Optimisation NHS Kernow
<b>Kathryn Wisner</b> Pharmacist	Pharmaceutical Advisor NHS Kernow
<b>Mr M Wilcock</b> Pharmacist	Head of Prescribing Support Unit, RCHT NHS Kernow Clinical Lead
<b>Dr Jonathan Katz</b> GP	NHS Kernow Clinical Lead
<b>Dr John Hamilton</b> GP	NHS Kernow Clinical Lead

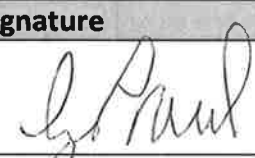

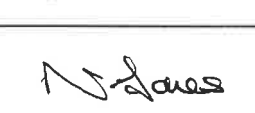
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<b>Clinical Condition</b>	
Situation/condition	<ul style="list-style-type: none"> <li>Oral candidiasis caused by Candida Albicans</li> </ul>
Inclusion criteria	<p>Adults and children over two years of age presenting with pseudomembranous oral candidiasis (presence of white spots and/or plaques, or erythematous areas on oral mucosal surfaces) including :</p> <ul style="list-style-type: none"> <li>those who have just completed a course of broad-spectrum antibiotics.</li> <li>those who use corticosteroid inhalers</li> </ul> <p>Parental consent must be obtained before offering to treat a patient less than 16 years of age who is not considered competent to consent to treatment.</p>
Exclusion criteria	<ul style="list-style-type: none"> <li>Patient refuses treatment/ no consent.</li> <li>Children under the age of 2 years</li> <li>Pregnancy and/or breastfeeding</li> <li>Allergy to any component of Nystatin Oral suspension.</li> <li>Patient presents with systemic symptoms and/or multiple site infection</li> <li>Immunocompromised patients.</li> <li>Patients with uncontrolled diabetes mellitus</li> <li>Patient has had a course of nystatin oral suspension in the last month</li> <li>Patients with oral thrush and retrosternal pain which may indicate oesophageal candidiasis</li> <li>Patients with denture stomatitis, acute erythematous oral candidiasis, chronic plaque-like oral candidiasis, leukoplakia, lichen planus and median rhomboid glossitis</li> <li>Patients with suspected systemic mycoses.</li> </ul>
Action if patient excluded	<ul style="list-style-type: none"> <li>Refer to GP, or minor injuries unit. If necessary provide patient with a referral form giving extra information on condition.</li> <li>For children under 2 years of age, but over 4 months, miconazole gel (P-Medicine) may be suitable.</li> <li>For denture stomatitis, the BNF recommends good dental hygiene, and applying miconazole gel to the inside of the denture if appropriate.</li> </ul>
<b>Medicinal Product Information</b>	
Medicinal Product	<ul style="list-style-type: none"> <li>Nystatin Oral Suspension 100,000 units/ml</li> </ul>
Legal status	<ul style="list-style-type: none"> <li>POM</li> </ul>
Dose and method of administration	<ul style="list-style-type: none"> <li>One millilitre (1ml) to be held in the mouth for as long as possible before swallowing four times a day.</li> </ul>
Pack size	<ul style="list-style-type: none"> <li>1 x 30ml bottle.</li> </ul>
Special precautions	<ul style="list-style-type: none"> <li>Nystan Oral Suspension contains sucrose- advise diabetic patients accordingly</li> </ul>
Follow up treatment	<ul style="list-style-type: none"> <li>If infection fails to respond after 7 days of treatment, or if condition worsens, see GP</li> </ul>
Advice to be given	<ul style="list-style-type: none"> <li>Use after food, four times a day for 7 days (Continue for 48 hours after</li> </ul>

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<b>Staff characteristics</b>	
Qualifications required	<ul style="list-style-type: none"> <li>Pharmacist currently registered with the General Pharmaceutical Council.</li> </ul>
Additional requirements	<ul style="list-style-type: none"> <li>Previous attendance at a specific NHS CIO/KCCG training event and satisfactory completion of any post-event training material* <b>OR</b></li> <li>Satisfactory completion of the Minor ailment CPPE learning pack 'Common Clinical Conditions and Minor Ailments' and successful completion of 'A Clinical Approach' e-assessment <b>AND</b></li> <li>Completion of the declaration of competence form on PharmOutcomes</li> <li>The Pharmacist must have returned the PGD signing-sheet with evidence of their accreditation* and been subsequently authorised to provide the service by the KCCG Prescribing Team in an accredited pharmacy</li> </ul>
Requirements for continuing training	<ul style="list-style-type: none"> <li>CPD in the management of oral candidal infections</li> <li>Annual self-assessment of competency</li> </ul>

<b>Management</b>	
Date of PGD	<ul style="list-style-type: none"> <li>1<sup>st</sup> April 2017</li> </ul>
Date this PGD becomes due for review	<ul style="list-style-type: none"> <li>31<sup>st</sup> March 2019</li> </ul>

<b>Approved by:</b>	<b>Name</b>	<b>Signature</b>
NHS Kernow CCG Head of Prescribing and Medicines Optimisation	Georgina Praed	
NHS Kernow CCG GP Prescribing Lead	Dr Nick Gibson	
NHS Kernow CCG Director of Clinical and Corporate Affairs	Natalie Jones	

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	<p>lesions have resolved)</p> <ul style="list-style-type: none"> <li>• Identify the patient information leaflet</li> <li>• Demonstrate the use of the dosing pipette</li> <li>• Shake bottle well before use</li> <li>• If used because of inhaled corticosteroids, check inhaler technique, and advise rinsing mouth with water (or brushing child's teeth) immediately after using inhaler. Refer to GP if inhaler problems persist</li> <li>• Oral irritation and sensitisation may occur, rarely nausea</li> </ul>
Record keeping	<ul style="list-style-type: none"> <li>• Completion of PMR</li> <li>• Completion of PGD checklist on PharmOutcomes</li> <li>• Completion of consent form and completion of the audit claim on PharmOutcomes</li> </ul>
Audit trail	<ul style="list-style-type: none"> <li>• PMR entry</li> <li>• The container must be labelled with the directions above and the words "<b>Supplied under Patient Group Direction</b>".</li> <li>• PharmOutcomes entry</li> </ul>
Reporting procedure for adverse reactions	<ul style="list-style-type: none"> <li>• All severe reactions (including minor reactions in children under 18 years) to Nystatin Oral Suspension 100,000 units/ml are to be reported to the MHRA through the Yellow Card System</li> </ul>
Specific Guidance	<ul style="list-style-type: none"> <li>• <a href="https://cks.nice.org.uk/candida-oral">https://cks.nice.org.uk/candida-oral</a></li> <li>• Summary of Product Characteristics available at <a href="https://www.medicines.org.uk/emc/medicine/20153">https://www.medicines.org.uk/emc/medicine/20153</a></li> </ul>
References-general	<ul style="list-style-type: none"> <li>• <b>Current British National Formulary</b>, London: BMA and Royal Pharmaceutical Society</li> <li>• <b>Current Cornwall Joint Formulary</b> available at <a href="https://www.eclipsesolutions.org/Cornwall/">https://www.eclipsesolutions.org/Cornwall/</a></li> </ul>

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**PRIVATE AND CONFIDENTIAL**

<b>Patient Details</b>
Name
Address

**Check List for Management of Oral Candidiasis**

<b>Inclusion criteria</b>	<b>Yes</b>	<b>No</b>
Patient is present at consultation and consents to treatment		
Parental consent obtained for a patient under 16 years who does not demonstrate competence		
Patient presents with pseudomembranous oral candidiasis. (Infection seen)		
Criteria for exclusion for treatment checked and none apply. (see table below)		
Consent form completed by Pharmacist & signed. Prescription charge collected if applicable and patient has signed form.		
PMR completed and Nystatin Oral Suspension 100,000 units/ml labelled as per PGD		
Treatment regimen explained and understood including: <ul style="list-style-type: none"> <li>• How to use the dosing pipette</li> <li>• Advice given should condition not improve.</li> </ul>		
Follow up advice given, including: <ul style="list-style-type: none"> <li>• Corticosteroid inhaler users, check inhaler technique and advise on appropriate usage</li> </ul>		

Pharmacist's Signature

Date.

<b>Exclusion criteria</b>	<b>Yes</b>	<b>No</b>
Allergy to Nystatin or any other component		
Presence of systemic symptoms and/or multiple infection sites		
Immunocompromised patient		
Previous Nystatin usage in the past month		
Patient has retrosternal pain		
Patient presents with an excluded oral condition		

**If the patient answers yes to any of the above questions then they must be referred to GP.**

