

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

Miconazole 2% cream

by registered pharmacists for

Candida of the nipple in breastfeeding mothers

under Wirral Clinical Commissioning Group Minor Ailments Service

Version number: 3.0




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
2.1	Updated in line with Wirral CCG Self Care Policy	February 2017
2.2	Amendments subsequent to the PGD Development group review	December 2019
3.0	Final document ratified and issued	April 2020

PGD development

Name	Job title and organisation
Lead author Nicola Bradley Updated by Lynne Sahlman Updated by Caroline Wake	Medicines Management Pharmacists Midlands and Lancashire Commissioning Support Unit (MLCSU) Midlands and Lancashire Commissioning Support Unit (MLCSU) December 2019
Lead doctor Dr Diane Atherton	Prescribing Lead GP, Wirral Health & Care Commissioning (WHCC)
Lead pharmacist Rob Hebdon	Senior Medicines Optimisation Pharmacist, 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, 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

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 Ailment Service
Competency assessment	CPPE Declaration of Competence Documents
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

<p>Clinical condition or situation to which this PGD applies</p>	<p>Treatment of candida (thrush) of the nipple in breastfeeding women.</p> <p>Treatment of cracked nipples, e.g., Lanolin nipple cream, can be purchased over the counter.</p>
<p>Inclusion criteria</p>	<p><i>Breastfeeding women whose baby is receiving simultaneous treatment for oral thrush under the minor ailments service or purchase over the counter (depending on babies age)</i></p> <p><i>Mother is not feverish and feels generally well but has one or more of the following:</i></p> <ul style="list-style-type: none"> • <i>Red/flaky/shiny skin on the nipple-areolae</i> • <i>Cracked nipples which don't heal</i> • <i>Nipple tenderness – sensitive to touch even by loose clothing</i> • <i>Burning sensation in the nipples</i> • <i>Nipples that becomes sore after a period of pain free breastfeeding. Pain becomes more intense as baby feeds and can last for up to an hour after the feed.</i> • <i>Patient agrees to treatment under this PGD.</i>
<p>Exclusion criteria</p>	<ul style="list-style-type: none"> • Patients taking oral anticoagulants e.g. warfarin - see MHRA alert • Patients taking any interacting medication - see current BNF or SPC • Lumps in the breast • Pyrexia • Breasts are red and inflamed and tender to the touch • Deep aching pain in the breast • Pregnancy • Systemically unwell • Known hypersensitivity/allergy to miconazole or any other excipient in the product • Previous treatment not effective • This episode is a recurrence within the last 8 weeks
<p>Cautions (including any relevant action to be taken)</p>	<ul style="list-style-type: none"> • Refer to Summary of Product Characteristics http://www.medicines.org.uk/emc/
<p>Arrangements for referral for medical advice</p>	<ul style="list-style-type: none"> • Supply the patient with a referral note to hand to the GP/midwife/health visitor as appropriate

Valid from: April 2017

Review date: March 2019 and March 2020

Expiry date: March 2023

	indicating the reasons for the referral
Action to be taken if patient excluded	<ul style="list-style-type: none"> • Refer to GP practice, health visitor or midwife as appropriate • 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/midwife as appropriate

Details of the medicine

Name, form and strength of medicine <i>Include ▼ for black triangle medicines</i>	Miconazole 2% cream
Legal category	P
Indicate any off-label use (if relevant)	N/A
Route/method of administration	Topical
Dose and frequency	Apply a small amount of cream to the nipple area after every feed for 2 weeks even if symptoms have resolved. Remove residual cream before next feed
Quantity to be administered and/or supplied	Supply 2x 30g tube per treatment episode Maximum of one treatment course under this PGD
Maximum or minimum treatment period	Maximum treatment period 14 days
Adverse effects	Local irritation and hypersensitivity including: <ul style="list-style-type: none"> • Mild burning sensation • Erythema • Itching Treatment should be discontinued if these are severe Refer to SPC or current BNF for full details
Records to be kept	The following will be recorded in the patient's consultation proforma: <ul style="list-style-type: none"> • Advice given to patient • Patients 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 and provide a manufacturers patient information leaflet</p> <p>Advise the mother to:</p> <ul style="list-style-type: none"> • Remove residual cream before next feed • Wash hands well before feeding • Use only plain water to wash nipples and dry thoroughly because thrush flourishes in damp conditions • Change nipple pads frequently (if used) • Clean breast pumps thoroughly (if used) • Take painkillers to ease breast pain if required • Cut down on sugary foods and foods containing yeast e.g. bread • Advise patient to discard any unused cream after completing the treatment. • If no improvement after 3 days or deep breast pain develops to contact GP/Midwife • Wash and sterilize dummies, teats, nipple shields, and toys that are put in the mouth.
<p>Follow-up advice to be given to patient or carer</p>	<p>Contact GP/midwife/health visitor if symptoms persist or recur, or deep breast pain develops</p>

Appendices

Appendix A Key references

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| <ol style="list-style-type: none"> 1. Clinical Knowledge Summaries Guideline
https://cks.nice.org.uk/breastfeeding-problems. (Accessed March 2020). 2. Daktarin 2% cream SPC https://www.medicines.org.uk/emc/medicine/22613
3. (Accessed March 2020). 4. BNF https://bnf.nice.org.uk/drug/miconazole.html (Accessed March 2020) |
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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