Lothian NHS Board

NHS Lothian Headquarters
Waverley Court
4 East Market Street
Edinburgh
EH8 8BG
www.nhslothian.scot

Date 08 October 2026
Your Ref
Our Ref 11922

Enquiries to Richard Mutch
Extension 35687
Direct Line 0131 465 5687
loth.freedomofinformation@nhs.scot
richard.mutch@nhs.scot

Dear

FREEDOM OF INFORMATION – AUGMENTATION OF LACTATION

I write in response to your request for information in relation to augmentation of lactation.

Question:

1. Copies of any evidence appraisal, literature review, application form or supporting documentation considered by the East Region Formulary Committee in relation to the treatment pathway "ADULT — augmentation of lactation" approved at its meeting of 30 March 2022.

Answer:

a. The content transferred into the March 2022 East Region Formulary came from the Lothian Joint Formulary appraisal after review by chapter experts looking at the content of the three board formularies. The original appraisal was completed in February 2012.
b. February 2012 - Prior to the East Region Formulary, NHS Lothian delegated formulary governance to the Lothian Joint Formulary. The formulary committee received a formulary application for domperidone to treat augmentation of lactation. A copy of the summary of evidence on comparative efficacy and safety is attached within the redacted formulary application form from 2012.
c. A copy of the draft chapter submitted to the East Region Formulary Committee for consideration in March 2022 is attached.

Question:

2. Copies of any evidence appraisal, literature review, formulary amendment form or supporting documentation considered in relation to the amendment for domperidone for augmentation of lactation agreed at the East Region Formulary Committee in May 2025.

Answer:

a. A copy of the redacted formulary amendment form is attached.
b. A copy of the draft chapter is attached.

Question:

3. Any recorded information indicating whether the Committee considered, at either the 2022 or 2025 review, the application of this pathway to the induction of lactation in non-gestational parents.

Answer:

a. The East Region Formulary Committee have not received any requests to review this indication.

Question:

4. Any recorded consideration by the Committee of the Medicines and Healthcare products Regulatory Agency's 2014 restrictions on domperidone in relation to this pathway.

Answer:

a. There is no record of the 2014 MHRA Drug Safety Update being considered at the committee in relation to this pathway.

Question:

5. Any recorded information held regarding the transfer of domperidone into milk, or infant exposure to domperidone, where lactation has been pharmacologically induced rather than augmented following pregnancy.

Answer:

a. There are medicines information enquiries from between 2012 and 2017 that include cases where lactation might be considered pharmacologically induced rather than augmented following pregnancy with some advice regarding the transfer of domperidone into milk or infant exposure to domperidone
    1. **Enquiry answer 2017** - *There is a UKMI Q&A on galactagogues which indicates that one week's treatment with domperidone is first choice if appropriate for the mum and baby, bearing in mind its side effect profile. https://www.sps.nhs.uk/articles/drug-treatment-of-inadequate-lactation/ . I am also providing a link to the Lothian guideline on the NHS Lothian intranet which also discusses the use of domperidone for this indication. I have checked with one of the reproductive medicine specialists and they advise that this guideline is the most current*
    2. **Enquiry answer 2013** - *Is it still appropriate to give a lady domperidone 20mg TDS for augmentation of lactation? The team involved with developing the "Domperidone for augmentation of lactation Maternity Services Pan Lothian – secondary and primary care" document advises that there are no plans to reduce the maximum dose of domperidone at present. The current guideline for review in 2014 takes into account cautions and contraindications in patients with e.g. renal or hepatic failure or those with underlying cardiac problems. The formulary also recommends that if non-pharmacological support alone does not help lactation then domperidone tablet 10mg domperidone tablet 10mg can be added. Starting dose 10mg 3 times a day and if no response after 1 week increase to 20mg three times a day for a maximum of 8 weeks. The MHRA published advice back in May 2012 identifying a small risk of QT prolongation*

and sudden cardiac death in susceptible patients taking domperidone and offered the following advice to healthcare professionals:

a. *domperidone should be used at the lowest effective dose*
b. *Non-prescription domperidone products are not recommended for use in patients with underlying cardiac disease, without medical supervision*
c. *Prescribers should exercise caution for patients who have: existing prolongation of cardiac conduction intervals (particularly QTc); significant electrolyte disturbances; or underlying cardiac diseases such as congestive heart failure, and patients who are known to be taking prescribed medicines for these conditions, particularly for patients older than 60 years and patients who receive daily oral doses of more than 30 mg*
d. *Domperidone should be avoided in patients who are taking concomitant medication known to cause QT prolongation (eg, ketoconazole or erythromycin)*
e. *Patients should be advised to seek prompt medical attention if symptoms such as syncope or tachyarrhythmias appear during treatment*

3. **Enquiry answer 2012** - *Further to your enquiry regarding domperidone use for increasing lactation I have located the following information:*
    a. *Domperidone is included in the Adult Lothian Joint Formulary for augmentation of lactation.*
    b. *The relevant information is as follows:*
        i. *Dose - domperidone tablet 10mg. Starting dose 10mg 3 times a day and if no response after 1 week increase to 20mg three times a day for a maximum of 8 weeks*
        ii. *Prescribing Notes - Domperidone should only be used after non-pharmacological support (assessment of breastfeeding technique/frequency, mechanical expression technique/frequency and active management of breastfeeding) has been inadequate in augmenting breastfeeding. The use of domperidone in this indication is 'off label', a referral letter containing key relevant information should be sent to GPs for those women who have been discharged from hospital but require domperidone to augment lactation. Domperidone must be used in combination with non-pharmacological breastfeeding support and with regular assessment and review at a breastfeeding support clinic in Lothian.*
    c. *There is also a guideline in production 'Domperidone for augmentation of lactation Maternity Services Pan Lothian – secondary and primary care'. This is still in draft format, and I*

understand that it is still being worked on, therefore I have not sent the draft guideline. I understand there may be changes regarding the withdrawal, with inclusion of details on how this may be done. The dosing information and duration will not change. Details are as follows:

i. *Dose: 10mg three times daily orally for a week. Review and if there is response continue for 3-4 weeks and then withdraw slowly over a week. If no response after a week increase dose to 20mg three times daily. Monitor weekly, if there is no response after a further 4 weeks then stop slowly over a week.*
ii. *Duration: Use for the shortest effective period but for not for more than 8 weeks unless advised by a consultant obstetrician with collaboration with Infant Feeding Advisor and a specialist Pharmacist (if required).*
iii. *Response: It may take three to four days to notice a significant effect (although some mothers notice an effect within 24 hours) and most take 2-3 weeks to get maximal effect. Continual assessment of efficient milk removal, positioning and attachment is essential to obtain and maintain increased milk yield.*

d. *The guideline also includes practical information regarding breastfeeding, and also includes the usual main contraindications and cautions to treatment with domperidone as follows:*
   i. *Avoid in women with known cardiac disease and those with a diagnosis or known family history of premenopausal breast cancer. Ketoconazole & erythromycin can reduce domperidone metabolism and concomitant use should be avoided to reduce any probable risk of QT prolongation. Patients should be advised to seek prompt medical attention if symptoms such as syncope or tachyarrhythmia appear during treatment.*
   ii. *Further information in final version of guidelines (pending approval):*
      1. *Start with domperidone 10mg three times a day (Review after 1 week). If response, continue for maximum of 8 weeks. To taper dose: reduce to 10mg twice daily for 2days and then 10mg once a day for 2 days and stop.*
      2. *If no response after 1 week the dose may be increased to 20mg three times a day. Assess after 1 week for response. (Dose can be reduced to*

10mg three times during the 8 week period based on response). If continued at 20mg three times a day then to taper: reduce to 10mg three times daily for 3 days then 10mg twice a day for 2 days, then 10mg once a day for 2 days and then stop.

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at www.itspublicknowledge.info/Appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the FOI Reviewer at the email address at the head of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: https://org.nhslothian.scot/FOI/Pages/default.aspx

Yours sincerely

ALISON MACDONALD
Executive Director, Nursing
Cc: Chief Executive

Group	Obstetrics
Condition	Lactation

Pathway 1	Suppression of lactation

/1

No treatment is recommended, see prescribing notes.

Prescribing notes	• No treatment is recommended; bromocriptine should not be prescribed. • Cabergoline can be prescribed in hospital only, to suppress the initiation of lactation in women with a foetal loss after 24 weeks.

Pathway 2	Augmentation of lactation

/1

Non-pharmacological breast-feeding support, including advice from specialists such as Health Visitors and Breastfeeding support teams.

/2

Domperidone	Domperidone 10mg tablets (UI)	10mg 3 times a day for 1 week, then review.

Prescribing notes	• Domperidone should only be used after non-pharmacological support (assessment of breastfeeding technique/frequency, mechanical expression technique/frequency and active management of breastfeeding) has been inadequate in augmenting breastfeeding. • The use of domperidone in this indication is 'off label', a referral letter containing key relevant information should be sent to GPs for those women who have been discharged from hospital but require domperidone to augment lactation. • Domperidone must be used in combination with non-pharmacological breastfeeding support and with regular assessment and review at a breastfeeding support clinic. • For further information in NHS Lothian refer to Breastfeeding: Insufficient supply – RefHelp.

	• For further information in NHS Borders and NHS Fife see Using domperidone for low milk supply – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice.

Group	Obstetrics
Condition	Lactation

Pathway 1	Suppression of lactation

/1

No treatment is recommended, see prescribing notes.

Prescribing notes	• No treatment is recommended; bromocriptine should not be prescribed. • Cabergoline can be prescribed in hospital only, to suppress the initiation of lactation in women with a foetal loss after 24 weeks.

Pathway 2	Augmentation of lactation

/1

Non-pharmacological breast-feeding support, including advice from specialists such as Health Visitors and Breastfeeding support teams.

/2

Domperidone	Domperidone 10mg tablets (UI)	10mg 3 times a day for a maximum of 1 week.

Prescribing notes	• Domperidone should only be used after non-pharmacological support (assessment of breastfeeding technique/frequency, mechanical expression technique/frequency and active management of breastfeeding) has been inadequate in augmenting breastfeeding. • The use of domperidone in this indication is 'off label', a referral letter containing key relevant information should be sent to GPs for those women who have been discharged from hospital but require domperidone to augment lactation. • Domperidone must be used in combination with non-pharmacological breastfeeding support and with regular assessment and review at a breastfeeding support clinic.

East Region Formulary

NHS SCOTLAND

Formulary Amendment Form

Please read the supporting guidance that is available on the formulary website before completing.

Medicine Information *(medicine details can be checked on the dm+d browser)*

Amendment type	Choose an item.
Name of medicine	Domperidone
Formulation	10mg tablets
Route of administration	Oral
Indication	Augmentation of Lactation

Place on Formulary

Therapeutic area	Obstetrics, gynaecology, and urinary-tract disorders
Will this medicine replace another formulary medicine?	No
Which medicine?	If yes, which medicine will it replace?
Rationale for change	Update of domperidone for augmentation of lactation to allow further supply beyond 1 week if necessary. Mainly with aim of facilitating slow wean off domperidone if abrupt stop has caused drop in supply, to support lactation in line with UKDILAS advice. Formulary text to be changed to 'for 1 week and then review' vs. 'for 1 week maximum' as per https://apps.nhslothian.scot/refhelp/guidelines/pregnancy/breast-feeding-problems/breastfeeding-insufficient-supply/. Would also like to add link in prescribing notes to SPS/UKDILAS information for NHS Fife & Borders staff who do not have access to NHS Lothian guideline https://www.sps.nhs.uk/articles/using-domperidone-for-low-milk-supply/.
Cost implications	Anticipated to be minimal – majority of patients should only require 1 week's treatment (no change to status quo). Some patients may require additional supplies at a cost of ~56p per 30 x 10mg domperidone tablets. Aim is to support breastfeeding to continue which has recognised health benefits and associated cost savings for both breastfeeding parent and breastfed infant.
Proposed position	Second choice within a treatment pathway *(Contact us for support on amending or creating pathways)*

Rationale for position	Non-pharmacological breast-feeding support, including advice from specialists such as Health Visitors and Breastfeeding support teams, should be in place before considering use of domperidone.
Formulary flags	☐ - None ☐ SI Specialist Initiation ☐ SUO Specialist Use Only ☐ UM Unlicensed Medicine ☒ UI Unlicensed Indication
Rationale for flags	Unlicensed indication
Has a local clinical management guideline been developed/updated?	Yes (If yes, please attach a copy of the guideline with this application)
Has an implementation plan been produced?	No *(If yes, please attach a copy of the plan with this application)*

Additional Information

Support for this formulary amendment from NHS Borders, NHS Fife and NHS Lothian	Application from NHS Lothian staff. NHS Fife REDACT Pharmacist for Women and Children: I agree that this is an appropriate change to make and I'm happy for you to submit this formulary amendment form. NHS Borders REDACT, Lead Pharmacist, Borders General Hospital: Yes this amendment seems perfectly reasonable. Happy to support the amendment to the ERF. I will share the guideline with our maternity team.
Additional information	Guideline has been updated to be in line with advice/evidence summary produced by UK Drug in Lactation Advisory Service (UKDILAS) which can be viewed at https://www.sps.nhs.uk/articles/using-domperidone-for-low-milk-supply/.

Applicant Details & Declaration of Interests (last 3 years)

First name	REDACT
Surname	REDACT
Health Board	NHS Lothian

Position held	Lead Infant Feeding Advisor
Email address	REDACT

Do you have a **personal specific** interest to declare? No

If yes, enter the nature of the interest being declared here.

Do you have a **personal non-specific** interest to declare? No

If yes, enter the nature of the interest being declared here.

Do you have a **non-personal specific** interest to declare? No

If yes, enter the nature of the interest being declared here.

Do you have a **non-personal non-specific** interest to declare? No

If yes, enter the nature of the interest being declared here.

- **I declare** that the information I have given is correct and complete.
- **I understand** that if I knowingly provide false information this may result in disciplinary action and I may be liable for prosecution and civil recovery proceedings.
- **I understand** this form is a public record, and it will be made available for audit or other inspection, or disclosure under the Freedom of Information Act.

Name: REDACT Date: 22/04/2025

Supporting Pharmacist Details & Declaration of Interests (last 3 years)

First name	REDACT
Surname	REDACT
Health Board	NHS Lothian
Position held	Specialist Pharmacist – Women's & Neonatal Services
Email address	REDACT

Do you have a **personal specific** interest to declare? No

If yes, enter the nature of the interest being declared here.

Do you have a **personal non-specific** interest to declare?	No
If yes, enter the nature of the interest being declared here.	
Do you have a **non-personal specific** interest to declare?	No
If yes, enter the nature of the interest being declared here.	
Do you have a **non-personal non-specific** interest to declare?	No
If yes, enter the nature of the interest being declared here.	

- **I declare** that the information I have given is correct and complete.
- **I understand** that if I knowingly provide false information this may result in disciplinary action and I may be liable for prosecution and civil recovery proceedings.
- **I understand** this form is a public record, and it will be made available for audit or other inspection, or disclosure under the Freedom of Information Act.

Name: REDACT Date: 22/04/2025

The applicant should return the form by email to eos.prescribing@nhs.scot copying in the supporting Pharmacist.

For internal use only

Additional Information

Additional information for Formulary Committee reviewer:	Additional information for formulary committee reviewer.

Formulary Committee Decision

Formulary status:	What is the status of this application?
Rationale:	What is the rationale for this status?
Other comments/actions:	Capture any comments or actions required here.
Date:	Select a date.
Additional information:	Capture any additional information here (e.g. details provided by clinical team.)

FORMULARY APPLICATION FORM 3
UNLICENSED / OFF-LABEL MEDICINES

For information, refer to the ADTC 'Policy for the Use of Unlicensed (and Off-label use) Medicines in NHS Lothian' (available at www.ljf.scot.nhs.uk).

Requests to initiate unlicensed / off-label medicines in groups of patients should first be submitted by the responsible clinician, with the support of the appropriate clinical pharmacist, to the relevant Drug and Therapeutics Committee (e.g. LUHD DTC, GPPC) for provisional categorisation. The request will then be forwarded by the DTC to the Formulary Committee which will assign the drug to one of the following categories:

Red:	**Specialist use only**
Amber:	**General use with restrictions**
Green:	**Unrestricted general use**
Black:	**Not approved for use**

Section 1: Background information

Generic name of medicine: Domperidone

Brand name (if available): Motilium®

Manufacturer: Sanofi-Aventis

Formulation: Tablet and oral suspension

Route: Oral

Proposed indication: augmentation of lactation

Dosing information: 10-20mg three a day for a maximum of 8 weeks

Details of the proposed prescriber: General Practitioners

UK license status of the medicine (in terms of its proposed clinical use): Off-label

Details of the medicine's availability: Both generic and proprietory brands available in UK

Completed by:
REDACTED

Approved by:
Clinical Director (Women's Services) REDACTED
Signature:_____ **DATE:**_____

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Section 2: Place of unlicensed/off-label medicine in therapy in Lothian

Please estimate for ALL Lothian use:
Prevalence (number of patients with condition): 200
Incidence (number of new patients per annum): 200
Number of patients to be treated with the medicine per annum: 200

Has a local Lothian protocol been developed? **Yes** [√] **No** [ ]

If yes, please attach a copy of the protocol with this report. (attached)

If no, please summarise in the boxes below how it is proposed that the medicine will be used in Lothian.
Please indicate proposed place of medicine in the LJF:

- Add to the LJF as first or second choice*** first [ ] second [√]
  - Add to the LJF as a prescribing note [√]

*** **non-pharmaceutical breast feeding support is first line (see guideline)**.

Please specify prescribing (primary care, secondary care or if shared care protocol (SCP) is considered appropriate): Primarily in Primary Care by General Practitioners unless if woman is an inpatient

- Add to the Additional List (i.e. useful in some patients after LJF medicines ineffective, not tolerated, LJF medicines contra-indicated, or specialist practice) [ ]
- Non-formulary: 'Not preferred' as effective alternatives available [ ]
- Unsure - leave to FC discretion [ ]

Please specify place in therapy in relation to existing medicines:

There are no licensed galactagogues in UK. Domperidone is the galactagogue of choice based on its safety and efficacy. It is not a panacea but it can be effective in augmentation of lactation when used in combination with established non-pharmacological support and breastfeeding measures and only after these measures have been failed to increase breast milk adequately.

Section 3 *(to be completed if "Add to LJF as first or second choice" has been ticked in section 2 above)* Place of medicine in the Lothian Joint Formulary (www.ljf.scot.nhs.uk)

In which section of the Lothian Joint Formulary should this medicine be placed?
Should this medicine replace one already recommended in the Lothian Joint Formulary? *(please tick appropriate box)*:

YES [ ] **NO [√]

** There is no recommended galactagogue in LJF currently

If YES, specify medicine to be replaced:
Is this medicine proposed as *(please tick appropriate box)*:
(a) first choice (b) second choice

Section 4: Summary of evidence on clinical effectiveness issues

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What are the principal trials supporting the indication(s) described above and the overall results regarding outcomes (e.g. absolute or relative risk reduction or NNT) and efficacy? Please state what the principal outcome measures are and provide copies of up to 3 (max) relevant references.

There has widespread use and recommendations for over 30 years and several small studies[1-7] have investigated the effectiveness of domperidone for this off label indication for the augmentation lactation. Several reviews [8-11] have addressed its place within this clinical context. Despite certain limitations, domperidone is considered the first line galactagogue based on its safety and efficacy in the UK and in many other countries.

Petralgia et al in 1985 did a double-blinded trial in 32 women[1]. Oral domperidone 10mg three times for 4 days was given to achieve initiation of lactation in 8 out of 15 multiparous women (group 1) and for 10 days for augmentation of lactation in 9 out of 17 primigravid women (group 2). Milk yield was four times that of placebo in group1 and continued for a month in these 8 women. The milk yield almost doubled in the 9 prims and again this continued for a month compared to none in the placebo group. No side effects were reported in mothers or infants. Apart from sample size, another limiting factor in this study was that mothers were only breastfeeding 6-7 times a day and that is generally not considered optimal to produce to sufficient milk supply. Orlando da Silva et al (2001) [2] in a randomised, double blinded trial studied the effect of oral domperidone 10mg three times a day for 7 days in 16 women. Milk production was significantly higher in domperidone group and began about 48 hours after start of dosing and returned to normal after 10 days. The calculated infant dose based on measured milk level and a daily milk intake of 150ml/kg/day would be 200nanogram/kg/day well below dosage used clinically in neonates. In 1983, Hopmeyer GJ et al[3] had also reported that only small amounts of domperidone was excreted in breast milk using the same dose. A similar response in milk production was found in two other placebo controlled double blinded trial (n=20)[4,5] using the same dose as da Silva. A randomised, crossover double blinded trial[6] using dosage of 10-20mg three times a day for 1-2 weeks in women who had preterm births (n=6) found that about 66% of women had a three-fold increase in milk production using the double dose. Mean infant dose was about 0.01% at both doses. Reported side effects were dry mouth, headaches, abdominal cramps and depressed mood and these were dose related[6-7]. Wan[6] the first to address the proposed dosage range, the key limitation of this study was the small sample size. Women had non-pharmacological breastfeeding support in most of these studies and hence the pragmatic recommendation that it should be used with continued reassessment and review and for the shortest possible duration (maximum of 8 weeks) to help promote effective breast milk supply.

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References

1 Petralgia F et al. Domperidone in defective and insufficient lactation. Eur J Obstet Gynae Reprod Biol 1985;19:281-7

2 Da Silva OP, Knoppert DC, Angelini MM, Forret PA. Effect of domperidone on milk production in mothers of premature newborns: a randomised, double-blinded, placebo controlled trail. CMAJ 2001;164(1):17-21.

3 Hopmeyer GJ, van Idelekinge B. Domperidone and lactation (letter). Lancet 1983:1:647

4 Gabay MP. Galactagogues: Medication that induce lactaion. J Human Laction 2002;18:274-9

5 Campbell-Yeo ML et al. Effect of domperidone on the composition of preterm human breast milk. Pediatrics 2010;125:e107-114

6 Wan EWX et al. Dose effect study of domperidone as a galactagogue in preterm mothers with insufficient milk supply and its transfer into milk. Br J Clin Pharmacol 2008;66(2):283-289

7 Wendy Jones, Sharon Breward. Use of domperidone to enhance lactation: what is the evidence? Community Practitioner 2011;84(6):35-37 (East Hampshire Primary Care Trust)

8 **UKMi Q&A 73-**3 Drug treatment of inadequate lactation. 20 April 2010. http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Drug-treatment-of-inadequate-lactation/ accessed December 2011

9 Anderson PO, Valdes. A critical review of pharmaceutical galactagogues. Breastfeeding Medicine 2007;2:229-42.

10 Christine Betzold. Is domperidone safe for breastfeeding mothers? A review. J Midwifery & Women Health 2004;49:151-4.

Section 5:Summary of evidence on comparative efficacy

What are the advantages of this medicine compared to other treatments? Consider medicines already recommended in the Lothian Joint Formulary or others in the same therapeutic class.

Breastfeeding is recognised worldwide as the optimal form of nutrition for term and preterm infants [1-3]. Apart from the nutritional and psychological benefits, breastfeeding has been shown to protect against sudden infant death syndrome, insulin-dependent diabetes, Crohn's disease, ulcerative colitis, necrotizing enterocolitis, lymphoma, leukaemia, and allergic disease. There is therefore a need to consider the place of this galactogagues to support breastfeeding.

Antipsychotic agents such as chloropromazine and sulpiride have been used but safety profile is poor. Metoclopramide has a comparable efficacy to domperidone [4] but the extrapyramidal side effects as well as depression are of major concerns in this patient group. Domperidone is considered the drug of choice due to its better safety and efficacy based on short-term trials over the past 30 years [4-8]. As it is highly protein bound (90%) and has a relatively high molecular weight, transfer into milk is likely to be low (about 0.01% of maternal dose) and this has been confirmed [6-8]. Although optimal dose and duration of treatment is not known some mothers can respond in 24 hours and most within 2-3 days [6,7]. Use of domperidone is appropriate to support breastfeeding in mothers who are unwell and have preterm babies or those who wish to breast feed but have low milk supply accompanied by weight loss in their babies despite continued use of non-pharmacological measures and support. Before initiating domperidone, it is necessary to assess breastfeeding technique (including milk expressing/emptying as milk stasis inhibits milk production) and then institute corrective breastfeeding support such as use of appropriate electric pump. Stress can also play a role in these mothers so again that needs to be addressed by use relaxation or similar techniques. Domperidone should not be used alone and as first-line management. It can be useful and have a place in augmentation of lactation in combination with non-pharmacological support and measures and only after they have failed and with regular reassessment and support thereafter.

References

1 Department of Health. Infant feeding recommendation. London.2003

2 Kramer MS, Kakuma R. (2002). Optimal duration of exclusive breastfeeding. Cochrane Database Syst Rev (1) 2002:CD003517

3 Hoddinott P, Tappin D, Wright C. Breast feeding. BMJ 2008;336:881

4 Ingram J, Taylor H, Churchill C, *et al.* Metoclopramide or domperidone for increasing maternal breast milk output:a randomised controlled trial. *Arch Dis Child Fetal Neonatal Ed* 2011:F1-5

5 Anderson PO, Valdes. A critical review of pharmaceutical galactagogues. Breastfeeding Medicine 2007;2:229-42.

6 Wan EWX et al. Dose effect study of domperidone as a galactagogue in preterm mothers with insufficient milk supply and its transfer into milk**.** Br J Clin Pharmacol 2008;66(2):283-289

7 **UKMi Q&A 73-**3 Drug treatment of inadequate lactation. 20 April 2010. http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Drug-treatment-of-inadequate-lactation/ accessed December 2011

8 Wendy Jones, Sharon Breward. Use of domperidone to enhance lactation: what is the evidence? Community Practitioner 2011;84(6):35-37 (East Hampshire Primary Care Trust)

Section 6: Summary of evidence on comparative safety

Are there any safety issues regarding this medicine in comparison to existing medicines?

Antipsychotic agents such as chloropromazine and sulpiride have been used but safety profile is very poor. Metoclopramide can be effective [1] but the risk of extrapyramidal side effects and depression are of major concerns especially in this patient group. Reports of fatal cardiac arrhythmias, in very ill adults, using the intravenous domperidone has led to the warning from the FDA[2] not to use domperidone for this purpose. Despite 30 years experience of the oral domperidone, no cardiac side effects have been reported. This is not surprising as there is marked first pass loss and low oral bioavailability resulting in peak plasma concentration 60-80 fold lower compared to the intravenous route [3,4]. Nevertheless, on theoretical grounds it should be avoided in women with known cardiac disease[3-5] and possibly in those with a diagnosis or known family history of premenstrual onset of breast cancer [6]. It is best to avoid concomitant use with potent CYP34A inhibitors such as ketoconazole and erythromycin as these can reduce its metabolism and may potentially cause QT prolongation [3,4]. There are also theoretical concerns about long-term effects on the maturation of central dopamine mechanism in the newborn. To limit any possible unknown safety

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issues and enhance efficacy its combined used with non-pharmacological measures such as corrective breastfeeding techniques and appropriate use of pump (milk stasis can inhibit milk production) must be advocated. Typical duration of therapy will usually be 2-4 weeks and limited to a maximum of 8 weeks and with regular (possibly weekly) monitoring of milk production and baby's weight gain. In mothers whose response is short lived or have had no response, it is essential to check other possible causes of poor milk production such as FBC (anaemia), TSH (hypothyroidism), hCG (retained placenta) and serum prolactin to exclude pituitary disease[3,5,6] .

References

1 Ingram J, Taylor H, Churchill C, *et al.* Metoclopramide or domperidone for increasing maternal breast milk output:a randomised controlled trial. *Arch Dis Child Fetal Neonatal Ed* 2011:F1-5
2 Food and Drug Administration (FDA). Domperidone. www.fda.gov/Safety/Alertsfor HumanMedicalProducts/ucm154914.htm accessed November 2011
3 **UKMi Q&A 73-**3 Drug treatment of inadequate lactation. 20 April 2010. http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Drug-treatment-of-inadequate-lactation/ accessed December 2011
4 http://www.medicines.org.uk/EMC/medicine/20011/SPC/Motilium+10/#PHARMACOKINETIC_PROPS accessed Jan 2012
5 Wendy Jones, Sharon Breward. Use of domperidone to enhance lactation: what is the evidence? Community Practitioner 2011;84(6):35-37 (East Hampshire Primary Care Trust)
6 Harvey JA et al. Increase in mammographic breast density associated with the use of domperidone. The Breast J 2004;10 (3):256-8 (case report)
7 Christine Betzold. Is domperidone safe for breastfeeding mothers? A review. J Midwifery & Women Health 2004;49:151-4.

Section 7: Summary of evidence on cost effectiveness

Please provide information on the cost effectiveness of this medicine in terms of absolute risk reduction and cost per QALY.

The health benefits of breastfeeding is considerable[1-4] ranging from physiological, psychological and long term health benefits therefore it is essential to evaluate the safety and efficacy of any treatment that can support this activity. The cost effectiveness would be difficult to assess and good quality evidence of public health interventions is limited. NICE considered interventions to be cost-effective at an incremental cost effectiveness ratio of between £20,000 and £30,000 per QALY[5]. A recent estimate from the USA was that if 90% of mothers were to breastfeed exclusively for 6 months, the United States would save $13 billion per year and prevent an excess 911 deaths, nearly all of which would be in infants ($10.5 billion & 741 deaths at 80% compliance). Such data supports that selective and appropriate use of domperidone can have considerable financial and health gains benefits.

References

1 Department of Health. Infant feeding recommendation. London.2003
2 Kramer MS, Kakuma R. (2002). Optimal duration of exclusive breastfeeding. Cochrane Database Syst Rev (1);2002:CD003517
3 National Institute for Clinical Health and Excellence. The effectiveness of public health interventions to promote the duration of breastfeeding. May 2005 www.nice.org.uk accessed November 2011).
4 Hoddinott P, Tappin D, Wright C. Breast feeding. BMJ 2008;336:881
5 National Institute for Clinical Health and Excellence. Maternal and Child Nutrition programme Economic Appraisal (NCC-WCH). Modelling the Cost-effectiveness of breastfeeding support. http://www.nice.org.uk/nicemedia/live/11677/34695/34695.pdf
6 Bartick M, Reinhold A. The Burden of Suboptimal Breastfeeding in the United States: A Pediatric Cost Analysis. Pediatrics 2010;125(5):1048-56

Section 8: Guidelines

Please include the appropriate sections from any relevant local or national guidelines e.g. SIGN, NICE

There are no national guidelines. The Breastfeeding Network (Paisley)[1] and Ayrshire & Arran (2009) guidelines advocate a similar dosage and also stress the need for it to be used in conjunction with breastfeeding support. In England, there are several guidelines but the most robust is from Somerset by the Academy of Breastfeeding Medicine[2] and again the message is comparable to our guideline.

References

1 The Breastfeeding Network**.** Domperidone use during breastfeeding http://www.breastfeedingnetwork.org.uk/pdfs/dibm/Domperidone_and_Breastfeeding_Jan_2012.pdf
2 The Academy of Breastfeeding Medicine (Protocol 9): Use of galactagogues in initiating or augmenting maternal milk supply.. http://www.bfmed.org/ace-files/protocol/prot9galactogoguesEnglish.pdf . Accessed January 2012

Section 9: Information on similar use elsewhere (peer support)

RELEASED FOI

There is over 30 years experience with the off label use of domperidone within UK and worldwide[1,2]. For many years, use of domperidone for augmentation of lactation has been advocated by Jack Newman[3], a well recognised Canadian breastfeeding specialist[1] but the dosage and duration appears to be led by opinion rather that evaluated published studies. Guidelines from Canada[4] and New Zealand[5] are more in line with UK practice. The message is the same that it should be considered as the first line galactagogue. It is not a substitute for effective breastfeeding measures and support but should be used at the lowest effective dose in combination with these measures for 4-8 weeks and with the opportunity for regular review as this must be a mother and baby not a drug led activity.

References

1. Wendy Jones, Sharon Breward. Use of domperidone to enhance lactation: what is the evidence? Community Practitioner 2011;84(6):35-37 (East Hampshire Primary Care Trust)
2. **UKMi Q&A 73-**3 Drug treatment of inadequate lactation. 20 April 2010. http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Drug-treatment-of-inadequate-lactation/ accessed December 2011
3. NewmanJ, Kernerman E. Domperidone, getting started. www.drjacknewman.com/help/Domperidone/Getting/20started.asp accessed November 2011
4. Zuppa AA, Sindico P, Orchi C, Carducci C et al. Safety and Efficacy of Galactogogues: Substances that Induce, Maintain and Increase Breast Milk Production. J Pharm Pharmaceut Sci (www.cspsCanada.org) 2010: 13(2) 162-174
5. http://www.adhb.govt.nz/newborn/guidelines/maternal/domperidoneandbreastfeeding accessed November 2011

Section 10: Financial Information for the use of *[Domperidone (Motilium®)* in Lothian

		No. of patients in Lothian eligible for treatment per annum	Cost per annum (£) per patient	Cost per annum (£) ALL patients**
Secondary Care	Lothian	50	REDACT	REDACT
	Non-Lothian			
Primary Care	Lothian	150	REDACT	REDACT
	Non-Lothian			
SUB-TOTAL (secondary care and primary care):				
Cost of replaced therapy	Secondary Care			
	Primary Care			
TOTAL NET COST:		200		REDACT
Other Cost Implications	e.g. Additional Medicine Therapy, X-rays, Lab Tests, etc.			

† *Note*. For Cancer medicines (SCAN) please insert separate rows for Lothian, Fife, Borders and Dumfries & Galloway. Refer also to the NHS Scotland Regional Cancer Advisory Group document '*Financial Planning of Cancer Medicines likely to be SMC approved*'.

REDACT for FOI

****It is anticipated that prescribing will be mainly GP lead for outpatients and that most (99%) patients will have access to established "walk in" breastfeeding clinics within Lothian**.
http://www.nhslothian.scot.nhs.uk/Services/A-Z/BreastfeedingSupport/Pages/default.aspx

Section 11: **Conclusions & Comments**

Breastfeeding has many well-recognised health, psychological and financial benefits. Although domperidone is not a panacea for women with breastfeeding issues, it is acknowledge worldwide that it is the galactagogue of choice as benefits outweigh risks. Domperidone can contribute to augmentation of breastfeeding but it must be used in conjunction with effective breastfeeding techniques, measures and support. As this is an off label use of this drug, GPs are naturally concerned about it use especially as a "P" medicine. It can also be of concern if women were to try to purchase it from community pharmacies without the appropriate support. Lothian already has a range of breastfeeding support teams and clinics (see attachment above) and the opportunity to also utilise oral domperidone appropriately would be very beneficial. The approval of domperidone for the augmentation of lactation would therefore further facilitate seamless care and shared information across Lothian to provide a safe and effective patient-centred approach to breastfeeding.

Section 12: Declaration of Interests

LOTHIAN FORMULARY COMMITTEE
(Area Drug and Therapeutics Committee)
Policy on Declaration of Involvement and Competing Interests with the Pharmaceutical Industry

The lead clinician(s) and pharmacist(s) responsible for completing FAF3, and/or providing information to the Formulary Committee, are asked to declare and describe to the Chairman, Formulary Committee, any involvement that they may have with the relevant pharmaceutical company, or with the manufacturers of any comparator products.

1. Personal interests over the last 12 months
This involves payments* (or other support) from any one company to an individual member or their spouse/partner/cohabittee or close relative, as defined in section 22 of the Lothian Standing Financial Instructions. The main examples are consultancies, fee-paid work, travel grants or pharmaceutical company shares. (The amount of money involved does not have to be declared).

Company	**Nature or purpose of support from the company**	**Period of support From**	**To**
None			
Name of Clinician: REDACT	**Date:**		
Name of Pharmacist: REDACT	**Date:**		

* for practical purposes, payments and/or support to a value in excess of £100 annually should be declared. (Threshold of £100 chosen locally to exclude amounts for trivial items such as pens, post-its, books, etc)

2. Non-Personal interests over the last 12 months

REDACT for FOI

This implies support* from any one company for your unit or place of work, as defined in section 22 of the Lothian Standing Financial Instructions. It may be financial or in kind, e.g. funding of a nurse, colleague, building or piece of equipment. (The amount of money involved does not have to be declared).

Company	Nature or purpose of support from the company	Period of support From	To
None – N/A			
Name of Clinician: REDACT	**Date:**		
None - N/A			
Name of Pharmacist: REDACT	**Date:**		

* for practical purposes, payments and/or support to a value in excess of £1000 annually should be declared. (Threshold of £1,000 chosen to concord with Scottish Medicines Consortium guidance.)

Please submit this form to the relevant Drug and Therapeutics Committee (e.g. LUHD DTC, GPPC) for provisional categorisation

Please then email the completed form, along with a note of the provisional categorisation, to prescribing@nhslothian.scot.nhs.uk

Please also post the completed form and signed declaration of interests to:

Lothian Formulary Committee
C/o Medicines Management Team
Stevenson House
555 Gorgie Road
Edinburgh
EH11 3LG

REDACT for FOI

Note **This document is regularly reviewed with the aim of ensuring that it is as user-friendly as possible. Please email any comments on the documentation to prescribing@nhslothian.scot.nhs.uk**