

LACTATION PROMOTION USING GALACTAGOGUES TO IMPROVE SUPPLY AND SUSTAIN BREASTFEEDING - CHW

PRACTICE GUIDELINE[®]

DOCUMENT SUMMARY/KEY POINTS

- Mothers who are breastfeeding may experience difficulties in maintaining their supply of breast milk when their infant is hospitalised or they are unwell.
- The use of Galactagogues (medications or herbal substances) is to increase breast milk supply for breast feeding mothers at CHW
- Galactagogues should only be prescribed when all other contributing factors have been addressed and a low supply persists.
- The medication may have an effect after 24 hours but more often the effect may not be noted for three or four days.
- Most potential side effects occur in less than 1% of women although some occur in up to 2%.
- Some medication will pass through to the breast milk – there are no reports of any harmful side effects when the medication is taken at the recommended levels.

Key Performance Indicator

- That prior to commencement of galactagogues a full assessment of maternal breast milk supply and of the effectiveness of milk transfer has been documented.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1 st May 2014	Review Period: 3 years
Team Leader:	Clinical Nurse Consultant	Area/Dept: Child & Family Health CHW

Date of Publishing: 12 February 2014

Date of Printing:

Page 1 of 11

K:\CHW P&P\Policy\Apr 14\Lactation Promotion_Galactagogues_Sustain Breastfeeding - CHW.docx

This Guideline may be varied, withdrawn or replaced at any time.

CHANGE SUMMARY

- The changes to this document include
 - Additions to the list of known drug interactions
 - Update weaning regime
 - Parent information re missed doses
 - Updating of the Reference List

READ ACKNOWLEDGEMENT

- This document is relevant for any NSW Health staff member who care for breast feeding or formula feeding babies and their mothers, or who may be called on to do so. It is also relevant to any NSW Health staff members who may handle expressed breast milk.
- The above mentioned staff should read and acknowledge they understand the contents of this document.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1 st May 2014	Review Period: 3 years
Team Leader:	Clinical Nurse Consultant	Area/Dept: Child & Family Health CHW

Date of Publishing: 12 February 2014

Date of Printing:

Page 2 of 11

K:\CHW P&P\Policy\Apr 14\Lactation Promotion_Galactagogues_Sustain Breastfeeding - CHW.docx

This Guideline may be varied, withdrawn or replaced at any time.

TABLE OF CONTENTS

1	Galactagogues	4
2	Guideline	4
	<i>Commonly available galactagogues include:</i>	<i>5</i>
3	Drug of Choice Administration	5
3.1	Domperidone (Motilium®).....	5
	<i>Contra-indications (mother)</i>	<i>6</i>
	<i>Possible side effects of Domperidone</i>	<i>6</i>
	<i>Known drug interactions</i>	<i>6</i>
3.2	Metoclopramide	7
3.3	Further Information	7
4	References and Bibliography	8
	<i>References</i>	<i>8</i>
	<i>Bibliography</i>	<i>8</i>
	<i>Acknowledgment</i>	<i>8</i>
	Appendix 1: Possible side effects of Domperidone	9
	Appendix 2: Parent Information Sheet	10
	Use of Domperidone (Motilium) Tablets to Increase Milk Production	10
	Motilium Regime.....	11

1 Galactagogues

Mothers who are breastfeeding may experience difficulties in maintaining their supply of breast milk when their infant is hospitalised or they are unwell. Separation from their infant or the infant who is not feeding effectively may also contribute to the disruption of their supply of milk. Mothers of infants unable to breast feed and who are expressing milk by hand or with a pump may often experience a decline in milk production after several weeks.

At times the use of a medication may be required in addition to other measures (see point 2 below) to further assist in increasing the production of milk. Galactagogues (or lactagogues) are medications or herbal substances believed to assist in initiation, maintenance, or augmentation of maternal milk production. These medications are dopamine antagonists which, through interaction with the hypothalamus and anterior pituitary, increase prolactin secretion thereby increasing milk production¹.

2 Guideline

1. Galactagogues should only be prescribed by a Medical Officer when all other contributing factors have been addressed and a low breast milk supply persists.
2. It is imperative that a Lactation Specialist, Medical Officer or delegated RN conducts a full assessment of a mother's current milk supply and the effectiveness of milk transfer and documents this in the patient's file prior to starting any medication. This assessment will include:
 - taking a full feeding history from the mother
 - ensuring feed frequency and duration is appropriate
 - establishing correct attachment where by milk is transferred efficiently to the baby
 - correcting sucking problems
 - increasing breast stimulation through milk expression after feeds
 - reducing or eliminating inappropriate supplementation
 - reducing mother infant separation (if possible)
 - educating mothers re maternal self-care – adequate rest, balanced diet and fluid intake appropriate to her thirst.
3. Women should be fully informed by the Lactation Specialist, Medical Officer or delegated RN about the efficacy, safety and timing of use of galactagogues.
4. Prior to commencing a course of galactagogues, maternal screening should be undertaken by the Lactation Specialist, Medical Officer or delegated RN to ensure there are no contraindications for the use of a particular medication. The woman should be advised about possible/potential side effects of the medication.
5. The Lactation Specialist and/or Medical Officer are obligated to ensure appropriate follow-up, of both mother and infant regarding milk supply and any side effects.

6. The Galactagogue should be prescribed by a Medical Officer following the dosage regime (see below) and using an out of hospital (external) prescription. An information sheet should be given to the mother and discussed with her and a full assessment should be carried out. Documentation should occur in the patients' notes by the Medical or Nursing staff who have discussed galactagogues with the mother.
7. Any mother who is being prescribed Domperidone should be provided with the Parent Information Sheet ([Appendix 2](#))

Commonly available galactagogues include:

- Domperidone (Motilium[®])
- Metoclopramide (Maxolon[®], Pramin[®])
(*Note: not the drug of choice at CHW because of documented side effects*)
- Herbal preparations
(*Note: there is no scientific evidence to support the use of herbal galactagogues and these are not discussed further in this document*).

3 Drug of Choice Administration

3.1 Domperidone (Motilium[®])

- The medication may have an effect from 24 hours but more often the effect may not be noted for three or four days.
- Maximum effect noted in **2 - 3 weeks however this can sometimes** take 4 or more weeks.
- Commencing dosage - **20mg (two 10mg tablets) 3 times a day before meals for two weeks** (may be continued at this dose if necessary for another 2 weeks after discussion with Lactation Specialist)
- Once milk supply has increased sufficiently dosage should be reduced by one tablet each week, using the following plan²:
 - **Step 1:** Decrease to 5 tablets per day – 2 tablets in the morning, 1 tablet at midday and 2 tablets at night. Remain on this dosage for up to 1 week and if milk supply has not decreased, proceed to the next step.
 - **Step 2:** Decrease to 4 tablets – 1 tablet in the morning, 1 tablet at lunch time and 2 tablets at night. Continue for up to 1 week and if milk supply has not decreased then proceed to the next step.
 - **Step 3:** Decrease to 3 tablets per day – 1 tablet in the morning and 1 tablet at lunch time and 1 tablet at night. Continue for up to 1 week and if milk supply has not decreased proceed to the next step.

- **Step 4:** Decrease to 2 tablets per day – 1 tablet in the morning and 1 tablet at night. Continue for up to 1 week and if milk supply has not decreased proceed to the next step.
- **Step 5:** Decrease to 1 tablet per day – 1 tablet at night. Continue for up to 1 week and if milk supply has not decreased then cease medication.
- The reduction regime should be halted if the milk supply has lessened, and the mother should be advised to return to her previous effective dosage and remain at that dosage for 1 – 2 weeks. If the milk supply continues to be adequate during the initial phase of reduction, the regime for decreasing may proceed more quickly².
- Domperidone should be trialled for at least four to six weeks before deciding that it is not working and ceasing it².

Contra-indications (mother)

- Prolactin releasing pituitary tumours
- Concomitant oral ketoconazole, erythromycin or other potent CYP3A4 inhibitors which prolong QTc interval – e.g. fluconazole, voriconazole, clarithromycin, amiodarone telithromycin.
- Where gastrointestinal (GI) motility stimulation may be dangerous e.g. GI haemorrhage, mechanical obstruction, perforation (e-MIMS)

Possible side effects of Domperidone

Mother:

Most potential side effects occur in less than 1% of women although some may occur in up to 2%. Refer to [Appendix 1](#) for a full list of known potential side effects.

Baby:

Some medication will pass through to the breast milk however there are no reports of any harmful side effects when the medication is taken at the recommended dose.

Known drug interactions

(See also [contra-indications](#) above)

- | | |
|----------------------|-----------------------------|
| ● Cimetidine | ● Codeine |
| ● Famotidine | ● Methadone |
| ● Nizatidine | ● Antihypertensive |
| ● Ranitidine | ● Phenytoin |
| ● CNS depressants | ● Tricyclic antidepressants |
| ● Sodium bicarbonate | ● Antacids |

All these medications may interact with domperidone. If, after taking the medication for 2 weeks and continuing stimulation of the milk supply (through frequent feeding and expressing) there has not been a significant increase in the milk supply it may be worth continuing the current dosage for a further 2 weeks then reviewing again.

Metoclopramide

This may be used as an alternative when Domperidone has been contra-indicated. The recommended dose is 10mg three times per day for 7 – 15 days. Metoclopramide represents a small risk to the nursing infant with maternal doses of 45mg or less per day³.

3.2 Further Information

Further information can be obtained from the Child and Family Health CNC for general ward areas or the CNS Lactation and Breast Feeding for Grace Centre for Newborn Care and PICU.

Information can also be obtained from Mothersafe ph. 93826539 (Monday to Friday).

4 References and Bibliography

References

1. Mannel, R; Martens, P; Walker, M (Eds) 2008. *Core Curriculum for Lactation Consultant Practice*. Jones and Bartlett Publishers, Sudbury, Massachusetts. 2nd Edition: p 580
2. Knoppert, D; Page, A; Warren, J; Carr, M; Angelini, M; Killick, D; DaSilva, O. The Effect of Two Different **Domperidone** Dosages on Maternal Milk Production. *J Hum Lact*, 0890334412438961, first published on May 3, 2012. Available from <http://jhl.sagepub.com/>
3. Briggs, G.B., Freeman, R.K. Yaffe, S.J. *Drugs in pregnancy and lactation*, 7th Edition 2005. (Lippincott, Williams and Wilkins)
4. https://www.mimsonline.com.au.acs.hcn.com.au/Search/FullPI.aspx?ModuleName=ProductInfo&searchKeyword=Domperidone&PreviousPage=~/Search/QuickSearch.aspx&SearchType=&ID=5500001_2 (Accessed 12th February 2014.)

Bibliography

5. Hale TW, *Medications and Mother's milk* 14th Edition (2010) Hale Publishing Amarillo, Texas
6. Hale Publishing (Available Reading Material) - www.iBreastfeeding.com accessed 21st November 2012
7. The Academy of Breastfeeding Medicine – www.bfmed.org/ace-files/protocol/prot9galactagoguesEnglish.pdf (accessed November 2012)
8. Newman, J; Pitman, T. *The Ultimate Breastfeeding Book of Answers* 2006. Three Rivers Press New York.
9. Campbell-Yeo, ML., Allen, AC., Joseph, KS., Ledwidge, JM., Allen, VM and Dooley, KC. Study Protocol: A double blind placebo controlled trial examining the effect of Domperidone on the composition of Breast milk. *BMC Pregnancy and Childbirth* 2006.
10. Flanders, D., Lowe, A., Kramer, M., Da Silva, O., Dobrich, C., Campbell-Yeo, M., Kernerman, E and Newman, J. A Consensus Statement on the use of Domperidone to support Lactation. May, 2012.

Acknowledgment

Policy for the use of Domperidone from the following hospitals:

- Royal North Shore Hospital
- Westmead Hospital
- Royal Prince Alfred Hospital
- Royal Hospital for Women, Victoria
- NSW Health Increasing your supply of Breastmilk. August 2011

Copyright notice and disclaimer:

The use of this document outside Sydney Children's Hospitals Network (SCHN), or its reproduction in whole or in part, is subject to acknowledgement that it is the property of SCHN. SCHN has done everything practicable to make this document accurate, up-to-date and in accordance with accepted legislation and standards at the date of publication. SCHN is not responsible for consequences arising from the use of this document outside SCHN. A current version of this document is only available electronically from the Hospitals. If this document is printed, it is only valid on the date of printing.

Appendix 1: Possible side effects of Domperidone

The possible side effects marked * are reported to occur in 1 – 2 % of women, whilst the remaining side effects are reported in less than 1% of women⁴.

Central nervous system <ul style="list-style-type: none"> ○ Dry mouth* ○ Headache* ○ Insomnia ○ Nervousness ○ Dizziness ○ Thirst ○ Lethargy ○ Irritability ○ Extrapyramidal reactions (rare) 	Gastrointestinal <ul style="list-style-type: none"> ○ Abdominal cramps ○ Diarrhoea ○ Regurgitation ○ Changes in appetite ○ Nausea ○ Heartburn ○ Constipation
Dermatological <ul style="list-style-type: none"> ○ Rash ○ Pruritis ○ Urticaria 	Urinary <ul style="list-style-type: none"> ○ Urinary frequency ○ Dysuria
Cardiovascular <ul style="list-style-type: none"> ○ Oedema ○ Palpitations 	Musculoskeletal <ul style="list-style-type: none"> ○ Leg cramps ○ Asthenia
Immunological <ul style="list-style-type: none"> ○ Allergic reaction (very rare) 	Reproductive <ul style="list-style-type: none"> ○ Amenorrhoea
Other <ul style="list-style-type: none"> ○ Conjunctivitis ○ Stomatitis ○ Drug intolerance ○ Galactorrhea (rare) ○ Gynaecomastia (rare) 	

Appendix 2: Parent Information Sheet

Use of Domperidone (Motilium) Tablets to Increase Milk Production

Domperidone increases the production of the milk making hormone Prolactin and this, along with regular breastfeeding and/or expressing, should increase your milk supply.

Before you start Domperidone:

It is extremely important that the doctor who is writing the prescription for you is aware of whether you suffer (or have suffered in the past) with any of the following conditions:

- Any known allergies
- A history of heart arrhythmia (irregular heart beat) or heart condition
- Any medical condition (e.g. diabetes, thyroid conditions, renal disease, asthma, depression or others)

It is also very important that the doctor writing your prescription knows if you are on any medications (particularly for high blood pressure or gastro-oesophageal reflux)

Using domperidone:

- **Take 20 mg (two 10mg tablets) 3 times a day for two weeks.** This may be extended for longer if necessary.
- Once the supply of milk has increased sufficiently, the dose of tablets can be decreased by 1 tablet each week.
- It can take up to eight weeks to finish the course (see attached Domperidone regime).

After starting domperidone, it may take three or four days before you notice any effect, although some mothers notice an increase in their milk supply within 24 hours. It is reasonable to give domperidone a trial of at least six weeks before deciding it is not working.

How long to take domperidone?

- If there has not been a decrease in your milk supply, or if there has been a small decrease that does not affect the breastfeeding and baby's weight gain you can continue with the regime as suggested.
- If, however, your supply decreases significantly, return to the previous effective dose and do not decrease the number of tablets that you are taking for one week. It is important that you speak to a Lactation Specialist at this point.
- You may find that you have to continue a certain dose to maintain your milk supply.
If after six weeks of taking the domperidone you still do not see an improvement in your milk supply, consult a Lactation Specialist.

Side effects of domperidone on the Mother:

Most side effects occur in less than 1% – 2% of women.

Some side effects (very uncommon):

- Headache, which disappeared when the dose was reduced
- dry mouth
- alteration of menstrual periods
- If you experience anything unusual or if you begin to feel unwell after commencing your course of Domperidone you should tell you doctor, lactation consultant or pharmacist.

Side effects on the Baby:

A small amount of the tablet will pass through to the breast milk but there are no reports of side effects if the medication is taken at the recommended dose.

Remember:

Domperidone will work better if you do the following:

- Increase breast stimulation by increasing the number of times that you feed and/or express.
- Use breast compression and massage to assist with milk drainage and ultimately milk production.
- Ensure positioning and attachment is correct.
- Try to drink adequate fluids, eat a well-balanced diet and get some rest.

What if you miss a dose:

If you miss a dose it should be taken as soon as you remember unless it is almost time for your next dose. In this case skip the dose you missed and take the next dose as planned. Do not double dose to try to make up for the dose you missed.

Motilium Regime

<u>Week 1 and Week 2</u> <ul style="list-style-type: none"> ○ Breakfast 2 tablets ○ Lunch 2 tablets ○ Dinner 2 tablets 	<u>Week 5</u> <ul style="list-style-type: none"> ○ Breakfast 1 tablet ○ Lunch 1 tablet ○ Dinner 1 tablet
<u>Week 3</u> <ul style="list-style-type: none"> ○ Breakfast 2 tablets ○ Lunch 1 tablet ○ Dinner 2 tablets 	<u>Week 6</u> <ul style="list-style-type: none"> ○ Breakfast 1 tablet ○ Lunch 0 tablet ○ Dinner 1 tablet
<u>Week 4</u> <ul style="list-style-type: none"> ○ Breakfast 1 tablet ○ Lunch 1 tablet ○ Dinner 2 tablets 	<u>Week 7</u> <ul style="list-style-type: none"> ○ Breakfast 0 tablet ○ Lunch 0 tablet ○ Dinner 1 tablet
	<u>Week 8</u> <ul style="list-style-type: none"> • Motilium Course finished.

If at any time your milk supply decreases whilst you are on the medication please go back to the previous dose of Motilium that you were on before the decrease and speak to a lactation consultant.