LACTATION PROMOTION USING GALACTAGOGUES TO INCREASE SUPPLY AND SUSTAIN BREASTFEEDING

PRACTICE GUIDELINE ©

DOCUMENT SUMMARY/KEY POINTS

- Currently medical staff at Sydney Children's Hospital Randwick do not prescribe galactagogues to the breastfeeding mothers of patients.
- If there is a mother of a patient at Sydney Children's Hospital Randwick who is experiencing issues with milk supply, she should be advised to see her GP, or a GP in the local area.
- Mothers who are breastfeeding may experience difficulties in maintaining their supply of breast milk when their infant is unwell or is hospitalised.
- The use of galactagogues (medications or herbal substances) is to increase breast milk supply for breast feeding mothers.
- Galactagogues are most beneficial when breast milk is being removed frequently and effectively and thus, woman should be encouraged and assisted to continue to feed or express at all stages.
- 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 3 or 4 days.
- Side effects may occur in a small number of women (less than 1%) although some may occur in up to 2% of women taking medication.
- 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 dosage.

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- Parental consent should be sought before implementing complementary or supplementary feeds.

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.

CHANGE SUMMARY

The changes to this document include:

- Update of dosage guidelines
- Addition of information regarding the Consent for Formula / Complementary, Supplementary feeds
- Addition of information regarding management of low breast milk supply for mothers at SCH Randwick
- Update of Parent information sheet
- Updating of the Reference List

READ ACKNOWLEDGEMENT

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

TABLE OF CONTENTS

1 Galactagogue 4
2 Guideline 4
Commonly available galactagogues include: 5
3 Drug of Choice Administration 5
3.1 Domperidone (Motilium®) 5
Contra-indications (mother) 6
Possible side effects of domperidone 7
Known drug interactions 7
3.2 Metoclopramide 8
3.3 Consent for Formula / Complementary, supplementary feeds 8
3.4. Further Information 8
4 References and Bibliography 9
References 9
Bibliography 9
Acknowledgment 10
Appendix 1: Possible side effects of Domperidone 11
Appendix 2: Parent Information Sheet 12
Use of Domperidone (Motilium) Tablets to Increase Milk Production 12
Motilium Regime 15
Appendix 3: Consent for formula / Complementary, supplementary feeds 16

1 Galactagogue

Mothers who are breastfeeding may experience difficulties in maintaining their supply of breast milk when their infant is hospitalised or is unwell. Separation of a mother from her infant or the infant who is not feeding effectively may also contribute to the disruption of the mother's milk supply. 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 lactogogues) 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 production[1].

2 Guideline

1. A galactagogue should only be prescribed by a Medical Officer when **all** other possible 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 electronic medical record 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. Prior to commencing on a galactagogue women should be fully informed by the Lactation Specialist, Medical Officer or delegated RN regarding the efficacy and safety of the medication and the timing of doses.
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 or delegated RN 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 must be made in the child's electronic medical record by the Medical or Nursing staff member who has discussed the use of the galactagogue with the mother.
7. Any mother who is being prescribed a galactagogue (usually domperidone) should be provided with the Parent Information Sheet (Appendix 2)
8. At the Randwick campus, if a mother experiences problems with breast milk supply she should be advised to consult a local GP for lactation advice.

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 - **one 10mg tablet 3 times a day before meals for two weeks**

  If there has been no improvement in milk supply the dose may be increased to **20 mg (2 tablets) 3 times per day or** may be continued at the same 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 appropriate plan as follows:[2]:
  - **If taking one 10 mg tablet each dose :**
- Step 1: reduce from 3 tablets per day to 2 tablets per day (1 tablet in the morning and 1 tablet in the evening). Continue for up to 1 week and if milk supply has not decreased proceed to the next step.

- Step 2: reduce the dosage to 1 tablet per day: 1 tablet to be taken in the evening. Continue for up to 1 week and if milk supply has not decreased proceed to the next step.
- Step 3: cease medication.

If taking 2 tablets 3 times per day:

- **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 may 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 quickly[2].
- Domperidone should be trialled for at least four to six weeks before deciding that it is not working and ceasing it[2].

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:

Possible side effects may occur in less than 1% of women although some may occur in up to 2% of women. 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
- Famotidine
- Nizatidine
- Ranitidine
- CNS depressants
- Sodium bicarbonate
- Codeine
- Methadone
- Antihypertensive
- Phenytoin
- Tricyclic antidepressants
- 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/or 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.

3.2 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 with dosage tapering off after this time.. There is a small risk to the nursing infant if Metoclopramide is taken at up to 45 mgs per day[3]

3.3 Consent for Formula / Complementary, supplementary feeds

The Sydney Children's Hospital Network is committed to promoting, protecting and supporting breastfeeding. However when an infant requires formula/complementary or supplementary feeds due to their medical condition or to assist with their growth and development, parental consent should be sought. **Supplementary feeds** are additional liquids which are provided in place of breastfeeding itself for example formula or specialised formula.

Complementary feeds are when additional liquid and / or powder is given along with breast milk to help meet the infant's nutritional requirements for example calories and formula.

Reasons that an infant may require formula/complementary or, supplementary feeds include:

- Medical conditions (for example metabolic disorders, confirmed allergies/intolerances, malabsorption, chylothorax, hypoglycaemia (low blood sugar), jaundice, dehydration
- Weight loss or poor weight gain
- Low birth weight or prematurity

Reasons that may prevent or limit the ability to breastfeed and when formula/complementary or, supplementary feeds may be required include:

- Maternal illness (for example childbirth complications eg. post-partum haemorrhage, sepsis or a past history of breast surgery)
- Insufficient breast milk supply is rare
- Medications which are contraindicated with breastfeeding (for example anti-epileptic drugs, strong pain relief, chemotherapy)

It is still important for mothers to continue expressing regularly *(approximately every 3 hours in the young infant or in place of normal breastfeeds in the older infant)* to help stimulate and/or maintain your milk supply. If you require assistance to establish or return to breastfeeding please contact nursing staff or the Dietitian.

If extra calories are required a nutrition assessment will be conducted by a Dietitian.

Reasons the infant may cease supplementary/complementary feeding:

• Sufficient milk supply and infant's full daily feed requirement is being met
• Infant gaining adequate weight
• Medical condition has resolved and the infant can resume full breast milk feeds/breastfeeding

3.4. Further Information

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

At the Randwick campus, mothers needing advice regarding low milk supply should be advised to see a local GP.

The Australian Breastfeeding Association website provides information for breastfeeding mothers

https://www.breastfeeding.asn.au

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

4 References and Bibliography

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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

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 women[4].

Central nervous system o Dry mouth* o Headache* o Insomnia o Nervousness o Dizziness o Thirst o Lethargy o Irritability o Extrapyramidal reactions (rare)	**Gastrointestinal** o Abdominal cramps o Diarrhoea o Regurgitation o Changes in appetite o Nausea o Heartburn o Constipation
Dermatological o Rash o Pruritis o Urticaria	**Urinary** o Urinary frequency o Dysuria
Cardiovascular o Oedema o Palpitations	**Musculoskeletal** o Leg cramps o Asthenia
Immunological o Allergic reaction (very rare)	**Reproductive** o Amenorrhoea
Other o Conjunctivitis o Stomatitis o Drug intolerance o Galactorrhea (rare) o 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 frequent 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 any medications you are taking (particularly for high blood pressure or gastro-oesophageal reflux) and 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 other heart condition
- Any medical condition (e.g. diabetes, thyroid conditions, renal disease, asthma, depression or others)

- **Using domperidone:** 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 - **one 10mg tablet 3 times a day before meals for two weeks** If there has been no improvement in the milk supply the dose may be increased to 20 mgs (2 tablets) 3 times per day or may be continued at the same 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 appropriate plan as follows:[2]:

If taking only one tablet per day:

- Step 1: reduce by one tablet per day to 1 tablet in the morning and 1 tablet in the evening. Continue for up to 1 week and if milk supply has not decreased proceed to the next step.
- Step 2: reduce by a further one tablet per day: one tablet to be taken in the evening Continue for up to 1 week and if milk supply has not decreased proceed to the next step.

  Step 3: cease medication.

If taking 2 tablets 3 times per day:

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 quickly[2].
- Domperidone should be trialled for at least four to six weeks before deciding that it is not working and ceasing it[2].

How long to take domperidone?

- When reducing the dosage, if your supply has not decreased, or if only a small decrease has occurred that has not caused any issues with breastfeeding or baby's weight gain, the reduction regime can continue as planned. 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 a further 1 week. It is important that you speak to a Lactation Specialist throughout this point.
- You may find that you have to continue a particular 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, a further consultation with a Lactation Specialist is advised.

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
- Stomach upset
- If you experience anything unusual or if you begin to feel unwell after commencing your course of Domperidone you should cease the medication and advise your doctor, lactation specialist or pharmacist.

Side effects on the Baby:

A small amount of the medication will pass through to the baby via the breast milk but there are no reports of side effects for the baby 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 to ultimately improve milk production.
- Ensure positioning and attachment of the baby at the breast 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 simply take the next dose as planned. Do not double dose to try to make up for the dose you missed.

Storage:

Medications should be stored at room temperature (15-30 ° C) away from heat and light. Do not store in the bathroom.

Motilium Regime

If taking 1 tablet 3 times per day:

Week 1: 1 tablet 3 times per day
Week 2: 1 tablet 3 times per day
Week 3: 1 tablet in the morning and 1 tablet at night
Week 4: 1 tablet at night
Week 5: Cease medication

If taking 2 tablets 3 times per day:

Week 1 and Week 2 o Breakfast 2 tablets o Lunch 2 tablets o Dinner 2 tablets	**Week 5** o Breakfast 1 tablet o Lunch 1 tablet o Dinner 1 tablet
Week 3 o Breakfast 2 tablets o Lunch 1 tablet o Dinner 2 tablets	**Week 6** o Breakfast 1 tablet o Lunch 0 tablet o Dinner 1 tablet
Week 4 o Breakfast 1 tablet o Lunch 1 tablet o Dinner 2 tablets	**Week 7** o Breakfast 0 tablet o Lunch 0 tablet o Dinner 1 tablet
	Week 8 • Motilium Course finished.

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

Appendix 3: Consent for formula / Complementary, supplementary feeds

http://intranet.schn.health.nsw.gov.au/files/scn020050_0.pdf