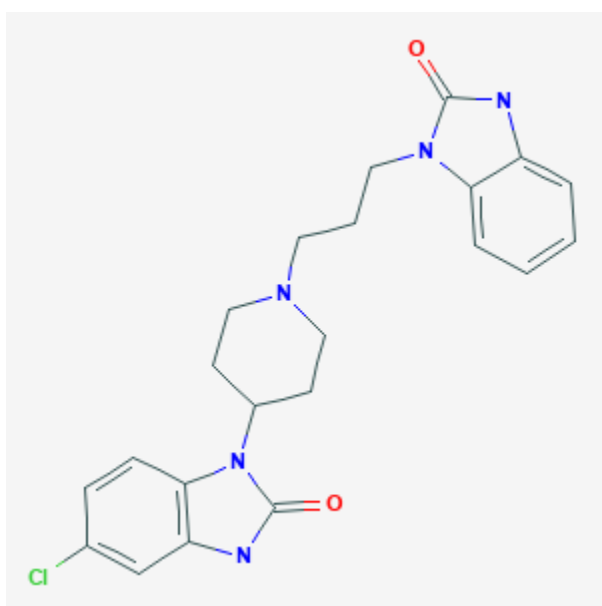




## Domperidone

Revised: March 16, 2020.

CASRN: 57808-66-9



## Drug Levels and Effects

### Summary of Use during Lactation

Domperidone is not approved for marketing in the United States by the U.S. Food and Drug Administration (FDA), but is available in other countries. Domperidone may also be available from some compounding pharmacies in the US. The quality of such products cannot be assured, and the FDA has warned against their use.[1,2]

Data available from 4 small studies on the excretion of domperidone into breastmilk are somewhat inconsistent, but infants would probably receive less than 0.1% of the maternal weight-adjusted dosage. No adverse effects have been found in a limited number of published cases of breastfed infants whose mothers were taking domperidone.

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Domperidone is sometimes used as a galactagogue to increase milk supply.[3] Galactagogues should never replace evaluation and counseling on modifiable factors that affect milk production.[4] Most mothers who are provided instruction in good breastfeeding technique and breastfeed frequently are unlikely to obtain much additional benefit from domperidone. Whether domperidone has any benefit as a galactagogue in women who continue to have insufficient milk production after nursing technique and frequency have been optimized has not been adequately studied. A meta-analysis of 3 studies that compared domperidone to placebo or no treatment concluded that domperidone increased milk production.[5] However, another meta-analysis of the 2 studies of domperidone in the aforementioned meta-analysis that met strict inclusion criteria for treatment of demonstrated lactation insufficiency in mothers of preterm infants at more than 2 weeks postpartum found that although domperidone increased milk supply acutely, it might not improve long-term outcomes of breastfeeding in this population.[6] Results of a more recent meta-analysis in mothers of preterm infants appears to support this conclusion.[7] Other reviewers concluded that improvement of breastfeeding practices seems more effective and safer than off-label use of domperidone.[8,9] A recent meta-analysis of domperidone use as a galactagogue reviewed 5 double-blinded, placebo-controlled studies of mothers with insufficient milk production. The meta-analyses found an average of 94 mL of increased daily milk production.[10]

Domperidone has no officially established dosage for increasing milk supply. Most published studies have used domperidone in a dosage of 10 mg 3 times daily for 4 to 10 days. Two small studies found no statistically significant additional increase in milk output with a dosage of 20 mg 3 times daily compared to a dosage of 10 mg 3 times and that women who failed to respond to the low dosage did not respond to the higher dosage. [11,12] Dosages greater than 30 mg daily may increase the risk of arrhythmias and sudden cardiac death in patients receiving domperidone,[13] although some feel that the risk is less in nursing mothers because of their relatively younger age.[14] In one case, domperidone use uncovered congenital long QT syndrome in a woman who developed loss of consciousness, behavioral arrest, and jerking while taking domperidone.[15] Mothers with a history of cardiac arrhythmias should not receive domperidone and all mothers should be advised to stop taking domperidone and seek immediate medical attention if they experience signs or symptoms of an abnormal heart rate or rhythm while taking domperidone, including dizziness, palpitations, syncope or seizures.[13] Maternal side effects of domperidone reported in galactagogue studies and cases reported to the FDA include dry mouth, headache, dizziness, nausea, abdominal cramping, diarrhea, palpitations malaise, and shortness of breath. Some of these were more frequent with dosages greater than with 30 mg daily.[11,12,16-18] A survey of women taking domperidone for lactation enhancement found gastrointestinal symptoms, breast engorgement, weight gain, headache, dizziness, irritability, fatigue were the most common side effects reported.[19] Drug withdrawal symptoms consisting of insomnia, anxiety, and tachycardia were reported in a woman taking 80 mg of domperidone daily for 8 months as a galactagogue who abruptly tapered the dose over 3 days.[20] Another mother took domperidone 10 mg three times daily for 10 months as a galactagogue and stopped abruptly. After discontinuation, she experienced severe insomnia, severe anxiety, severe cognitive problems and depression.[21] A third postpartum woman began domperidone 90 mg daily, increasing to 160 mg daily to increase her milk supply. Because her milk supply did not improve, she stopped nursing at 14 weeks and began to taper the domperidone dosage by 10 mg every 3 to 4 days. Seven days after discontinuing domperidone, she began experiencing insomnia, rigors, severe psychomotor agitation, and panic attacks. She restarted the drug at 90 mg daily and tapered the dose by 10 mg/day each week. At a dose of 20 mg daily, the same symptoms recurred. She required sertraline, clonazepam and reinstatement of domperidone at 40 mg daily, slowly tapering the dose over 8 weeks. Three months were required to fully resolve her symptoms.[22] In a fourth case, a mother took domperidone 20 mg four times daily for 9 months to stimulate breastmilk production. She stopped breastfeeding and domperidone at that time. Two weeks later, she presented with insomnia, anxiety, nausea, headaches and palpitations. The drug was restarted at a dosage of 20 mg three times daily and began to taper the daily dosage by 10 mg every week, but after one week she complained of insomnia. Tapering was reduced to 5 mg every week, but whenever she stopped the drug, symptoms returned. She was able to discontinue domperidone after tapering the daily dosage by 2.5 mg weekly over 10 months.[23]

## Drug Levels

*Maternal Levels.* Thirty breastmilk samples were obtained from 6 mothers taking domperidone 10 mg 3 times daily and 28 milk samples were obtained from 5 mothers taking domperidone 20 mg 3 times daily. Average concentrations of the drug in breastmilk were 0.28 mcg/L with the lower dosage and 0.49 mcg/L with the higher dosage. The authors estimated that a fully breastfed infant would receive daily dosages of 0.04 and 0.07 mcg/kg daily, respectively, at these maternal dosages. The estimated weight-adjusted maternal dosages were 0.012% and 0.009%, respectively.[11]

A double-blind, controlled trial compared two dosages of domperidone for increasing milk supply in mothers of preterm infants. Mothers received either 10 mg or 20 mg three times daily. Drug concentrations in breastmilk were measured once between days 10 and 15 three hours after a dose. Milk domperidone concentrations were 3.4 mcg/L with the 10 mg dose (n = 4) and 6.9 mcg/L with the 20 mg dose (n = 3).[12]

*Infant Levels.* Relevant published information was not found as of the revision date.

## Effects in Breastfed Infants

One paper reported 2 studies. In one, 8 women received domperidone 10 mg 3 times daily from day 2 to 5 postpartum. In the other, 9 women received domperidone 10 mg 3 times daily for 10 days from week 2 postpartum. No side effects were reported in any of the breastfed (extent not stated) infants.[24,25]

Eleven women took domperidone 10 mg 3 times daily for 7 days to increase the supply of pumped milk for their preterm neonates. No side effects were reported in their infants.[26]

In a study of 90 mothers who received domperidone 10 mg three times daily for 2 or 4 weeks while providing milk for their preterm infants, there was no apparent difference in the frequency or types of adverse events that occurred in their infants, whether taking the active drug or placebo.[27]

A retrospective chart review of a breastfeeding clinic in Toronto identified 1005 infants whose mothers took domperidone as a galactagogue while nursing. No serious side effects were reported among breastfed infants. Nonserious side-effects were rare and appeared to be unrelated to domperidone (diaper rash, blood in urine, constipation and one case of arrhythmia with unknown cause and time of onset).[28]

A transgender woman took and spironolactone 50 mg twice daily to suppress testosterone, domperidone 10 mg three times daily, increasing to 20 mg four times daily, oral micronized progesterone 200 mg daily and oral estradiol to 8 mg daily and pumped her breasts 6 times daily to induce lactation. After 3 months of treatment, estradiol regimen was changed to a 0.025 mg daily patch and the progesterone dose was lowered to 100 mg daily. Two weeks later, she began exclusively breastfeeding the newborn of her partner. Breastfeeding was exclusive for 6 weeks, during which the infant's growth, development and bowel habits were normal. The patient continued to partially breastfeed the infant for at least 6 months.[29]

## Effects on Lactation and Breastmilk

Domperidone increases serum prolactin in lactating and nonlactating women.[11,30-32] This effect is thought to be caused by the drug's antidopaminergic effect. In nonpregnant women, domperidone is less effective than the same dose of oral metoclopramide in raising serum prolactin; however, in multiparous women their effects are similar.[30,32] Domperidone has caused galactorrhoea in nonpregnant women and in one male infant.[33-38]

One paper, which was published twice in 2 different journals,[24,25] reported two separate small studies. In the first study, 15 women with a history of defective lactogenesis were given either oral domperidone 10 mg (n = 8) or placebo (n = 7) 3 times daily from day 2 to 5 postpartum. The patients were apparently not randomized and blinding was not mentioned in the paper. No instruction or support in breastfeeding technique was provided.

The groups had similar serum prolactin levels at the start of the study. Baseline serum prolactin levels were higher in the treated women from day 3 to 5 postpartum. Suckling-induced serum prolactin increases were higher in the treated women than in the placebo group from day 2 postpartum onward. Milk yield was calculated by weighing the infants before and after each nursing for 24 hours. Increase in milk yield were greater in the treated mothers from day 2 onward; however, the lower average milk yield in the placebo group was due to 3 women with very low milk output. Average infant weight gain was correspondingly greater in the treated group. At 1 month postpartum, all treated mothers were nursing well, but 5 of 7 untreated mothers had inadequate (not defined) lactation. No correlation was found between baseline serum prolactin or the increase in prolactin and milk production.

In the same paper(s), 17 primiparous women who had insufficient lactation (30% below normal) at 2 weeks postpartum were studied using the same methodology as above. Mothers were given either oral domperidone 10 mg (n = 9) or placebo (n = 8) 3 times daily for 10 days. The groups did not have significantly different serum prolactin levels at the start of the study. Serum prolactin levels were higher in the treated than untreated women from day 2 onward and milk production was higher in the treated group from day 4 onward. At the end of the study no untreated woman had an increase in milk supply from day 1. One month after the beginning of the study, all treated women had adequate milk production. No correlation was found between serum prolactin and milk production.[24]

One well-designed, but small trial was reported with domperidone. Twenty women who were pumping milk with a good quality electric pump for their preterm infants were given either oral domperidone 10 mg (n = 11) or placebo (n = 9) 3 times daily for 7 days in a randomized, double-blind, trial. The mothers averaged 32 to 33 days postpartum. All had failed to produce sufficient milk for their infant after extensive counseling by lactation consultants. By day 5 of therapy, the serum prolactin levels of the treated mothers had increased by 119 mcg/L in the treated group compared to 18 mcg/L in the placebo group. Serum prolactin decreased to baseline levels in both groups 3 days after discontinuation of the study medications. Although the (partially imputed) baseline milk production was greater in the domperidone group (113 mL daily) than in the placebo group (48 mL daily), the average daily increases in milk production on days 2 to 7 were 45% (to 184 mL) and 17% (to 66 mL) in the domperidone and placebo groups, respectively. However, 4 women in the domperidone group failed to complete the study and only the study completers were matched and found to be similar at baseline. No follow-up beyond the 7-day study period was done to evaluate the persistence of an effect of domperidone on lactation success.[26] While this study appears to offer evidence of a beneficial effect on the milk supply in the mothers of preterm infants who are pumping their milk, several factors make this conclusion questionable: a 36% drop-out rate in the active drug group, the lack of an intent-to-treat analysis, and the vast difference in baseline milk supply between the domperidone and placebo groups.

Twenty-five women who had been given domperidone 20 mg 4 times daily to increase milk supply had their dosages decreased over 2 to 4 weeks and discontinued. The duration of domperidone use was not stated in the abstract. All women had stable milk output and were nursing infants under 3 months of age who were growing normally. Of the 25 women, 23 did not increase their use of formula and all infants grew normally, indicating that domperidone can be withdrawn without a detrimental effect on infant nutrition.[39]

Six women who were unable to produce sufficient milk for their preterm infants after counseling by lactation consultants were given domperidone in dosages of 10 mg 3 times daily or 20 mg 3 times daily in a crossover fashion. Baseline serum prolactin concentrations were increased by both dosages to a similar extent. Milk production increased in only 4 of the 6 women. In the other 4 women, milk production increased from 8.7 g/hour at baseline to 23.6 g/hour with 30 mg daily and 29.4 g/hour with 60 mg daily, although there was no statistically significant difference in between the 2 dosages. Side effects in the mothers of dry mouth, abdominal cramping and headache were more frequent with the higher dosage. Severe abdominal cramping caused one

mother to drop out of the study during the run-in phase. Additionally, constipation and depressed mood were reported at the higher dosage.[11]

Mothers of preterm infants (<31 weeks) with insufficient milk supply were given either domperidone 10 mg orally 3 times daily or placebo in a randomized, double-blind study. Women who received domperidone had a greater increase in milk volume (+267%) than in the placebo group (19%) at the end of 14 days. Breastmilk calcium concentration increased in the domperidone group (+62%) and decreased (-4%) in the placebo group. Carbohydrate concentrations increased slightly in the mothers receiving domperidone (+2.7%) and decreased slightly (-2.7%) in those receiving placebo. No statistical differences were found in protein, energy, fat, sodium or phosphate concentrations between the groups.[40]

A retrospective, uncontrolled case series reported 14 mothers of preterm infants in the intensive care unit who had been given domperidone 20 mg three times daily to increase their milk supply. The pumped volume of milk increased by 48% over 14 days. However, the lack of a control group renders this report uninterpretable.[41]

Mothers who underwent cesarean section at term were randomized to receive either oral domperidone 10 mg (n = 22) or placebo (n = 23) 4 times daily in a double-blind fashion beginning within the 24 hours postpartum. Nurses collected the mothers' milk with an electric breast pump applied for 15 minutes twice daily 2 hours after the mothers nursed their infants. The volume of milk collected by this incomplete collection technique was greater at all times, including at baseline, in the domperidone group. Seven women in the domperidone group reported dry mouth, and none in the placebo group.[16] Because of the endpoint selected and inequalities at baseline, it is impossible to attribute any clinical relevance to these results.

Mothers who were expressing milk for their infants in a neonatal intensive care unit (mean gestational age 28 weeks) were given instructions on methods for increasing milk supply. If they were producing less than 160 mL of milk per kg of infant weight daily after several days, mothers were randomized to receive either domperidone or metoclopramide 10 mg by mouth 3 times daily for 10 days in a double-blinded fashion. Thirty-one mothers who received domperidone and 34 who received metoclopramide provided data on daily milk volumes during the 10 days. Milk volumes increased over the 10-day period by 96% with domperidone and 94% with metoclopramide, which was not statistically different between the groups. Some mothers continued to measure milk output after the end of the medication period. Results were similar between the 2 groups. Side effects in the domperidone group (3 women) included headache, diarrhea, mood swings and dizziness. Side effects in the metoclopramide group (7 women) included headache (3 women), diarrhea, mood swings, changed appetite, dry mouth and discomfort in the breasts.[17] The lack of a placebo group and the projection of milk volumes to impute missing data from some mothers detract from the findings of this study.

A double-blind, controlled trial compared two dosages of domperidone for increasing milk supply in mothers of preterm infants. Mothers received either 10 mg (n = 8) or 20 mg (n = 7) three times daily for 4 weeks, followed by a tapering dosage over the subsequent 2 weeks. Both dosages increased milk volume, but there was no statistically significant difference in milk volumes between the two groups.[12]

A randomized trial in Pakistan compared the effects of domperidone 10 mg to placebo 3 times daily in women who delivered at term and had 10 mL or less of milk production from both breasts per single expression on day 6 postpartum. All women were given some counseling about proper breastfeeding technique. After 7 days of drug or placebo use, women were categorized as having either 50 mL or greater milk production per single expression or less than 50 mL. Serum prolactin was not measured. Seventy-two percent of women given domperidone successfully increased their milk supply compared to 11% in the placebo group. Problems with the study included an apparent lack of blinding of the drugs, investigators and mothers as well as the questionable endpoint of a single expression at an uncontrolled time of day rather than a daily total of milk output.[42]

A retrospective study compared mothers of hospitalized preterm infants who took domperidone (n = 45) to those who did not because of its cost (n = 50). After treatment using a standard protocol, the treated mothers

showed an increase in milk supply from 125 mL/day to 415 mL/day after 30 days of treatment. Untreated mothers had a decrease in milk supply from 158 mL/day to 88 mL/day after 30 days.[43,44]

A randomized trial of domperidone (dosage not stated) in India for 7 to 14 days in 32 mothers with insufficient milk production whose infants were in a neonatal ICU found that milk output increased more (186 mL) with domperidone than with placebo (70 mL) after 7 days of therapy. There were no differences in serum prolactin between the domperidone and placebo groups on days 1 and 8 of therapy. There was also no difference in weight gain of the infants between the two groups.[45]

A randomized trial of domperidone 10 mg three times daily in Indonesia for 10 days in 50 mothers with preterm infants and insufficient milk production after 7 days of lactation counseling found that milk output increased more (182 mL) with domperidone than with placebo (72 mL) after 7 days of therapy. The increased milk volume persisted at day 10, three days after drug discontinuation.[46]

In a double-blind, multicenter study, mothers of preterm infants received either domperidone 10 mg 3 times daily for 28 days or placebo three times daily for 14 days followed by domperidone 10 mg 3 times daily for 14 days. Only mothers with documented low milk production were entered into the trial and breastfeeding support was provided to all mothers. Seventy-eight percent of mothers who received domperidone in the first 2 weeks had a 50% increase in milk supply compared to 58% who received placebo (odds ratio 2.56). At the end of 4 weeks, the values were 69% and 62%, but the difference was not statistically significant. At 6 weeks postterm gestation, there was no appreciable difference between the groups in the numbers of mothers providing milk to their infants or supplementing with formula. The authors concluded that domperidone supported more mothers to increase their milk volume as early as 8 to 21 days postdelivery; however, the gain in volume was modest.[27] In a secondary analysis of study results, the authors found no difference in response between mothers of infants born between 23 and 26 weeks of gestation and mothers of infants born between 27 and 29 weeks of gestation. [47] Other secondary analyses of the data found no difference in outcome regardless of whether domperidone was started during the period of days 8 to 14 or days 15 to 21 postpartum.[48,49]

A retrospective chart review of a breastfeeding clinic in Toronto identified 985 infants whose mothers took domperidone as a galactagogue while nursing. Sixty-three percent of patients were using formula before and 41% after domperidone treatment.[28]

Women were retrospectively studied following the birth of preterm infants of 30 weeks or less gestational age. Overall, those who received domperidone for lactation enhancement during postpartum hospitalization (n = 84) were no more likely to be nursing their infants at the time of infant discharge from the neonatal unit than mothers who did not receive domperidone (n = 114). However, among mothers weighing 70 kg or more, the use of domperidone was associated with a lower likelihood of breastfeeding on discharge.[50]

A meta-analysis of studies on domperidone use as a galactagogue in the mothers of preterm infants found 5 studies with 95 mothers randomized to domperidone and 97 to placebo. All studies used a dose of 10 mg three times daily for a duration of 5 to 14 days. The results found that domperidone use resulted in an average increase of 88 mL daily with a 95% CI of 57 to 120 mL daily.[7]

A meta-analysis of studies on domperidone use as a galactagogue in mothers who expressed their milk found 5 studies with 120 mothers randomized to domperidone and 125 to placebo. Three of the studies comprising 73 mothers randomized to domperidone and 77 randomized to placebo were included in the previously published meta-analysis ([9]). Four studies used a dose of 10 mg three times daily for a duration of 7 to 14 days, and one used 10 mg four times daily for 4 days. The results found that domperidone use resulted in an average increase of 94 mL daily with a 95% CI of 71 to 117 mL daily. A subanalysis found that using domperidone longer than 7 days provided no additional benefit in increased milk output.[10]

A study of 10 mothers of preterm infants in the neonatal intensive care unit were administered domperidone 10 mg three times daily if their milk production was either less than 300 mL or 160 mL/kg infant body weight daily after 2 weeks postpartum. The median daily milk volume was 60 mL (range 2–310 mL) initially and 176 mL (range 11–400 mL) on the 14th day. Seven of the 10 mothers had an increase in milk volume to more than 1.5 times their initial volume or greater. The median serum prolactin concentration was 46 mcg/L (range 4–128) before administration and 167 mcg/L (range 59–356) on the 14th day after administration. There was no correlation between serum prolactin and milk production and 3 mothers with elevated prolactin did not produce additional milk.

## Alternate Drugs to Consider

Metoclopramide

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## Substance Identification

### Substance Name

Domperidone

### CAS Registry Number

57808-66-9

### Drug Class

Breast Feeding

Lactation

Antiemetics

Dopamine Antagonists

Galactogogues

Gastrointestinal Agents