

DOMPERIDONE

Trade:

Can/Aus/UK: Motilium, Motilidone

Uses: Gastrokinetic agent, galactagogue

LRC: L1

AAP: Maternal Medication Usually Compatible with Breastfeeding

Domperidone (Motilium) is a peripheral dopamine antagonist (similar to Reglan) generally used for controlling nausea and vomiting, dyspepsia, and gastric reflux. It blocks peripheral dopamine receptors in the GI wall and in the CRTZ (nausea center) in the brain stem and is currently used in Canada as an antiemetic.[1] Unlike metoclopramide (Reglan), it does not enter the brain compartment and it has few CNS effects such as depression. It is also known to produce significant increases in prolactin levels and has proven useful as a galactagogue. Serum prolactin levels have been found to increase from 8.1 ng/mL to 124.1 ng/mL in non-lactating women after one 20 mg dose.[2] Concentrations of domperidone reported in milk vary according to dose. But following a dose of 10 mg three times daily, the average concentration in milk was only 2.6 µg/L.[3] In a study by da Silva, 16 mothers with premature infants and low milk production (mean= 112.8 mL/d in domperidone group; 48.2 mL/d in placebo group) were randomly chosen to receive placebo (n= 9) or domperidone (10 mg TID) (n= 7) for 7 days.[4] Milk volume increased from 112.8 to 162.2 mL/d in the domperidone group and 48.2 to 56.1 mL/d in the placebo group. Prolactin levels increased from 12.9 to 119.3 µg/L in the domperidone group and 15.6 to 18.1 µg/L in the placebo group. On day 5, the mean domperidone concentration was 6.6 ng/mL in plasma and 1.2 µg/L in breastmilk of the treated group (n= 6). No adverse effects were reported in infants or mothers. In a new study just released, a group of 6 breastfeeding women were placed in a double blind randomized crossover trial to compare doses of domperidone.[5] In this trial, mothers were studied in a run-in phase (no drug treatment), 30 mg, or 60 mg domperidone daily doses (10 or 20 mg every 8 hours). Milk volume created per hour, and plasma prolactin levels were monitored. With milk production, two mothers did not respond to domperidone treatment. Four other mothers showed a significant increase from 8.7 g/hour in the run-in phase to 23.6 g/h for the 30 mg/d dose, to 29.4 g/h for the 60 mg dose. While plasma prolactin levels were increased by domperidone treatment, there was no significant difference between levels at 30 mg and 60 mg doses. Median domperidone concentrations in milk were 0.28 ug/L and 0.49 ug/L for the 30 mg and 60 mg doses respectively. The mean Relative Infant Dose was 0.012% at 30 mg daily and 0.009% at the 60 mg/day dose. The usual oral dose for controlling GI distress is 10-20 mg three to four times daily although for nausea and vomiting the dose can be higher (up to 40 mg). The galactagogue dose is suggested to be 10-20 mg orally 3-4 times daily. The prior studies clearly suggest that doses of 10-20 mg three to four times daily elevate prolactin levels to levels more than adequate to produce milk. Doses higher than this should be avoided in breastfeeding mothers. Recently the US FDA issued a warning on this product stating that it could induce arrhythmias in patients. These claims were derived from data many years old where domperidone was used intravenously as an antiemetic during cancer chemotherapy (20 mg stat followed by 10 mg/kg/24 h).[6] Many of these patients were undergoing extensive chemotherapy, were extremely ill, and hypokalemic to begin with. In addition, intravenous domperidone produces plasma levels many times higher than oral use. Thus far, we do not have any recent published data suggesting that domperidone used orally in breastfeeding mothers is arrhythmogenic, although its use in women who are already arrhythmic is not recommended.

Pregnancy Risk Category:

C

Lactation Risk Category:

L1

Adult Concerns: Dry mouth, skin rash, itching, headache, thirst, abdominal cramps, diarrhea, drowsiness. Seizures have occurred rarely. Could induce arrhythmias in hypokalemic patients, or patients subject to arrhythmias.

Pediatric Concerns: None reported in breastfed infants. Considered the ideal galactagogue.

Drug Interactions: Cimetidine, famotidine, nizatidine, ranitidine (H-2 blocker) plasma levels may be reduced by domperidone. Prior use of bicarbonate

reduces absorption of domperidone.

Theoretic Infant Dose: 0.18 ug/Kg/Day

Relative Infant Dose: 0.0%

Adult Dose: 10-20 mg 3-4 times daily

Alternatives: Metoclopramide

T_{1/2} = 7-14 hours	M/P = 0.25
PHL =	PB = 93%
Tmax = 30 minutes	Oral = 13-17%
MW = 426	pKa =
Vd =	

References:

1. Hofmeyr GJ, van Iddekinge B. Domperidone and lactation. Lancet 1983; 1(8325):647.
2. Brouwers JR, Assies J, Wiersinga WM, Huizing G, Tytgat GN. Plasma prolactin levels after acute and subchronic oral administration of domperidone and of metoclopramide: a cross-over study in healthy volunteers. Clin Endocrinol (Oxf) 1980; 12(5):435-440.
3. Hofmeyr GJ, van Iddekinge B, Blott JA. Domperidone: secretion in breast milk and effect on puerperal prolactin levels. Br J Obstet Gynaecol 1985; 92(2):141-144.
4. da Silva OP, Knoppert DC, Angelini MM, Forret PA. Effect of domperidone on milk production in mothers of premature newborns: a randomized, double-blind, placebo-controlled trial. CMAJ 2001; 164(1):17-21.
5. Wan E W-X, Davey K, Page-Sharp M, Hartmann PE, Simmer K, Ilett KF. Dose-effect study of domperidone as a galactagogue in preterm mothers with insufficient milk supply, and its transfer into milk. British Journal of Clinical Pharmacology 2008; (in press 9 April 2008).
6. Osborne RJ, Slevin ML, Hunter RW, Hamer J. Cardiac arrhythmias during cytotoxic chemotherapy: role of domperidone. Hum Toxicol 1985 Nov; 4(6):617-26.

Yes

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