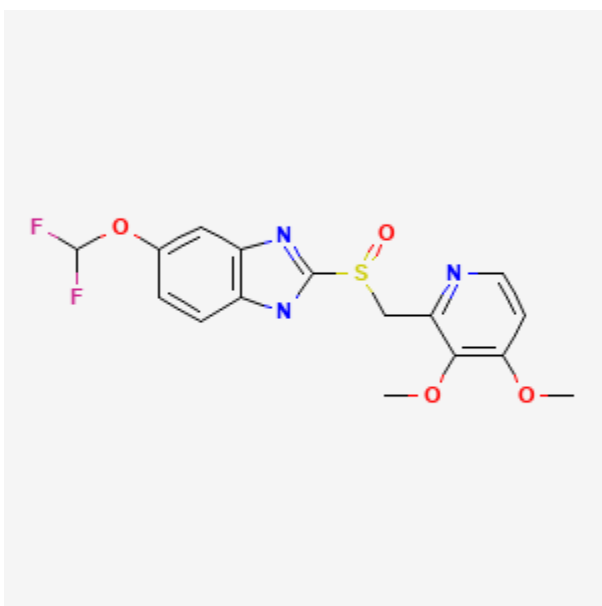




Pantoprazole

Revised: May 15, 2022.

CASRN: 102625-70-7



Drug Levels and Effects

Summary of Use during Lactation

Maternal pantoprazole doses of 40 mg daily produce low levels in milk and would not be expected to cause any adverse effects in breastfed infants.

Drug Levels

Maternal Levels. A mother who was 10 months postpartum and partially nursing her infant was given a single 40 mg dose of oral pantoprazole. Pantoprazole was detectable in milk only 2 and 4 hours after the dose with milk levels of 36 mcg/L and 24 mcg/L, respectively, at those times. It was not detectable (<10 mcg/L) in milk at 6, 8

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and 24 hours after the dose. The authors estimated that a fully breastfed infant would receive 0.14% of the maternal weight-adjusted dosage.[1]

Twelve lactating women were given oral pantoprazole 40 mg daily for one week. Maternal blood and breastmilk samples were obtained 7 times over the 12 hours following the dose on both days. The mean pantoprazole concentration in breastmilk was 62 mcg/L on day 1 and 153 mcg/L on day 7. Overall, 21 of 97 breastmilk samples contained detectable (>30 mcg/L) pantoprazole. On day 1, 21% of milk samples contained measurable pantoprazole and on day 7, 22% contained measurable pantoprazole.[2] Further description of the time course was not contained in the abstract.

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

Effects in Breastfed Infants

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

Effects on Lactation and Breastmilk

A retrospective claims database study in the United States found that users of proton pump inhibitors had an increased risk of gynecomastia.[3]

A review article reported that a search of database from the European Pharmacovigilance Centre found 48 cases of gynecomastia, 3 cases of galactorrhea, 14 cases of breast pain and 4 cases of breast enlargement associated with pantoprazole. A search of the WHO global pharmacovigilance database found 97 cases of gynecomastia, 13 cases of galactorrhea, 35 cases of breast pain and 16 cases of breast enlargement associated with pantoprazole.[4]

Alternate Drugs to Consider

Antacids, Cimetidine, Famotidine, Omeprazole, Sucralfate

References

1. Plante L, Ferron GM, Unruh M, et al. Excretion of pantoprazole in human breast. *J Reprod Med.* 2004;49:825–7. PubMed PMID: 15568407.
2. Bor S, Karacaoglu S, Ergun P, et al. The levels of pantoprazole in human breast milk and plasma: Two compartment model. *Neurogastroenterol Motil* 2017;29:79-80. Abstract. doi:10.1111/nmo.13180
3. He B, Carleton B, Etminan M. Risk of gynecomastia with users of proton pump inhibitors. *Pharmacotherapy.* 2019;39:614–8. PubMed PMID: 30865318.
4. Ashfaq M, Haroon MZ, Alkahraman YM. Proton pump inhibitors therapy and risk of hyperprolactinemia with associated sexual disorders. *Endocr Regul.* 2022;56:134–47. PubMed PMID: 35489049.

Substance Identification

Substance Name

Pantoprazole

CAS Registry Number

102625-70-7

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Ulcer Agents

Gastrointestinal Agents

Proton Pump Inhibitors