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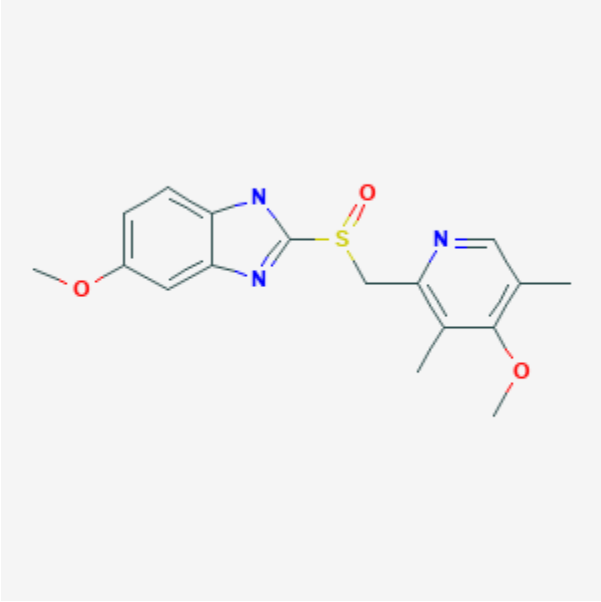
Omeprazole

Revised: June 3, 2019.

CASRN: 73590-58-6



Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that maternal omeprazole doses of 20 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 woman taking oral omeprazole 20 mg daily for gastroesophageal reflux had omeprazole measured in her milk 3 weeks postpartum. The milk omeprazole level was not detectable for 90 minutes after the dose and then reached a peak of 20 mcg/L at 3 hours after the dose.[1] Using the peak milk level in this patient, the maximum dose that an exclusively breastfed infant would receive in breastmilk would be 3 mcg/kg daily or about 0.9% of the maternal weight-adjusted dosage. For comparison, doses of 1 mg/kg daily have been used in neonates.

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

Effects in Breastfed Infants

One mother taking oral omeprazole 20 mg daily pumped and discarded her milk once each day 4 hours after her morning dose. She breastfed her infant the remainder of the day for 3 months before weaning. The infant remained well at 12 months of age.[1]

Effects on Lactation and Breastmilk

The Spanish pharmacovigilance system found 20 cases of gynecomastia reported in patients taking omeprazole during the time period of 1982 to 2006.[2] A retrospective claims database study in the United States found that users of proton pump inhibitors had an increased risk of gynecomastia.[3]

A 13-year-old girl was placed on omeprazole 20 mg twice daily by mouth for dyspepsia caused by mefenamic acid and a *Helicobacter pylori* infection. After 2 days of therapy, she developed bilateral galactorrhea and elevated serum prolactin. Three weeks after discontinuing omeprazole, galactorrhea and hyperprolactinemia resolved. Six weeks later, she was rechallenged with omeprazole and her serum prolactin rose from 27 to 70 mcg/L. Prolactin returned to normal 2 weeks after omeprazole discontinuation. Over the next 6 months, she was given domperidone on one occasion and lansoprazole on another. With both drugs, she developed galactorrhea and hyperprolactinemia which returned to normal after drug discontinuation.[4] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Alternate Drugs to Consider

Antacids, Cimetidine, Famotidine, Nizatidine, Pantoprazole, Ranitidine, Sucralfate

References

1. Marshall JK, Thompson AB, Armstrong D. Omeprazole for refractory gastroesophageal reflux disease during pregnancy and lactation. Can J Gastroenterol. 1998;12:225-7. PubMed PMID: 9582548.
2. Carvajal A, Macias D, Gutierrez A et al. Gynaecomastia associated with proton pump inhibitors: A case series from the Spanish Pharmacovigilance System. Drug Saf. 2007;30:527-31. PubMed PMID: 17536878.
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. Jabbar A, Khan R, Farrukh SN. Hyperprolactinaemia induced by proton pump inhibitor. J Pak Med Assoc. 2010;60:689-90. PubMed PMID: 20726208.

Substance Identification

Substance Name

Omeprazole

CAS Registry Number

73590-58-6

Drug Class

Breast Feeding

Lactation

Anti-Ulcer Agents

Gastrointestinal Agents

Proton Pump Inhibitors