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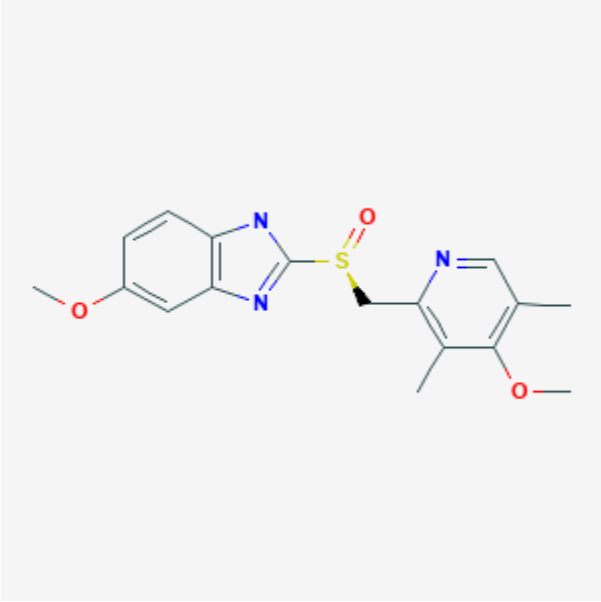
Esomeprazole

Revised: June 3, 2019.

CASRN: 119141-88-7



Drug Levels and Effects

Summary of Use during Lactation

Esomeprazole is the *S*-enantiomer of the proton-pump inhibitor, omeprazole. Limited information indicates that maternal 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

Esomeprazole is the *S*-isomer of omeprazole. Information is currently available only for racemic omeprazole. Information is currently available only for racemic omeprazole.

Maternal Levels. A woman taking omeprazole 20 mg orally 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 omeprazole 20 mg daily orally 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

Omeprazole (the racemic form) has been reported to cause gynecomastia in men[2] and a retrospective claims database study in the United States found that users of proton pump inhibitors had an increased risk of gynecomastia.[3]

One woman developed elevated serum prolactin and estradiol with bilateral galactorrhea one week after starting esomeprazole 40 mg once daily for reflux esophagitis. The galactorrhea disappeared 3 days after discontinuing esomeprazole and prolactin and estradiol returned to normal 7 days after discontinuation. One month later, the patient restarted esomeprazole and again developed bilateral galactorrhea. She was switched to lansoprazole with no galactorrhea developing.[4] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Alternate Drugs to Consider

Cimetidine, Famotidine, Nizatidine, Omeprazole, 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. Pipaliya N, Solanke D, Rathi C et al. Esomeprazole induced galactorrhea: a novel side effect. Clin J Gastroenterol. 2016;9:13-6. PubMed PMID: 26661629.

Substance Identification

Substance Name

Esomeprazole

CAS Registry Number

119141-88-7

Drug Class

Breast Feeding

Lactation

Anti-Ulcer Agents

Gastrointestinal Agents

Proton Pump Inhibitors