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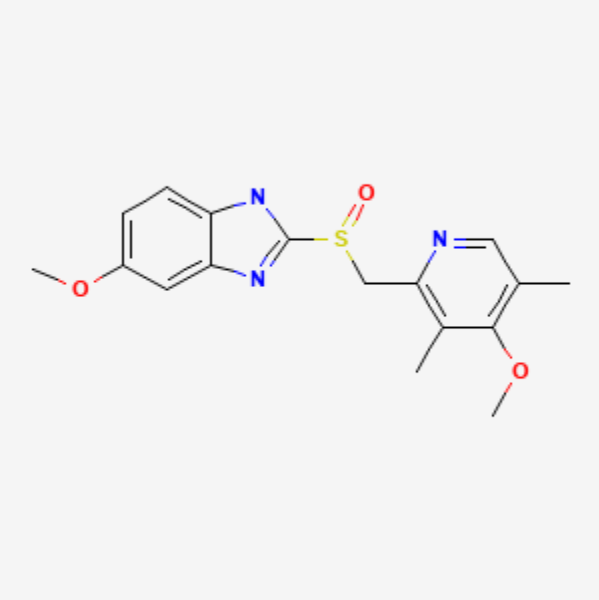
Omeprazole

Revised: May 15, 2022.

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 review article reported that a search of database from the European Pharmacovigilance Centre found 104 cases of gynecomastia, 15 cases of galactorrhea, 15 cases of breast pain and 16 cases of breast enlargement associated with omeprazole. A search of the WHO global pharmacovigilance database found 439 cases of gynecomastia, 46 cases of galactorrhea, 93 cases of breast pain and 63 cases of breast enlargement associated with omeprazole.[4]

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.[5] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

A 26-year-old woman with a kidney transplant developed galactorrhea after her kidney function decreased. She was taking tacrolimus, prednisone, amlodipine, labetalol, lovastatin, nortriptyline and pyridoxine as well as omeprazole for heartburn. Her omeprazole dose had been increased from 20 mg twice a day to 40 mg twice a day 3 months prior. A week earlier, she had been given prescriptions for naratriptan for migraine and metoclopramide for nausea at an emergency department visit. Her symptoms persisted 4 weeks later and her serum prolactin was elevated. Metoclopramide was discontinued with no improvement change in serum prolactin. Omeprazole was discontinued and calcium carbonate started. Two weeks later, her serum prolactin had normalized. Two months later, her heartburn increased and omeprazole was restarted at 20 mg daily with no increase in serum prolactin.[6] The patient's hyperprolactinemia and galactorrhea were probably caused by omeprazole.

A 26-year-old Bhutanese woman with a kidney transplant was maintained on tacrolimus 2 mg twice daily, prednisolone 5 mg once daily, leflunomide 20 mg once daily, nifedipine 40 mg twice daily, and hydralazine 50 mg three times daily. She came to the emergency room with a complaint of abdominal pain. Her tacrolimus dose was adjusted, and oral omeprazole was begun. After 3 days, she experienced milk production from her left breast. According to the patient she had experienced the same reaction 7 years prior when she had her kidney transplant. Omeprazole was stopped and milk production ceased 3 days later. The authors rated the galactorrhea as definitely being caused by omeprazole.[7]

Alternate Drugs to Consider

Antacids, Cimetidine, Famotidine, Pantoprazole, Sucralfate

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Substance Identification

Substance Name

Omeprazole

CAS Registry Number

73590-58-6

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Ulcer Agents

Gastrointestinal Agents

Proton Pump Inhibitors