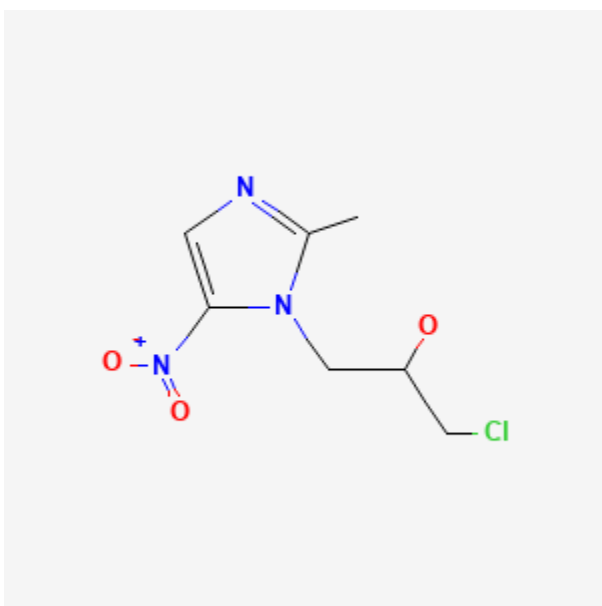




Ornidazole

Revised: December 15, 2023.

CASRN: 16773-42-5



Drug Levels and Effects

Summary of Use during Lactation

Ornidazole is not approved for marketing in the United States by the U.S. Food and Drug Administration, but is available in other countries. The amount of ornidazole in milk is low after administration of 3 doses totaling 2 grams intravenously perinatally. Measurements of infant plasma levels during breastfeeding have not been reported. No studies have evaluated adverse effects of ornidazole on the infant during breastfeeding, but presumably they are similar to those of the closely related drug, metronidazole, such as increased risk of oral and rectal *Candida* infections.

As with metronidazole, concern has been raised about exposure of healthy infants to ornidazole via breastmilk, [1] because of possible mutagenicity and carcinogenicity. Opinions vary among experts on the advisability of

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using ornidazole during longer-term therapy while breastfeeding, but avoidance of breastfeeding for 3 days after a single dose should allow milk levels to drop to negligible values because its half-life is similar to tinidazole.[2] Other drugs are available for bacterial vaginosis, and can be given vaginally, which should result in lower amounts in breastmilk.

Drug Levels

Maternal Levels. Seventy-seven mothers who had a cesarean section and received ornidazole as one preoperative dose of 1000 mg and two postoperative doses of 500 mg each within 24 hours contributed 123 colostrum and milk samples for analysis. These values were used to create a population pharmacokinetic model of ornidazole excretion into milk. Simulated milk levels with this dosage regimen found the median peak milk levels to be 5.4 mg/L at 27 hours after delivery in patient with normal total bilirubin (<17 micromol/L) and 6.2 mg/L at 33 hours after delivery in patients with abnormal bilirubin (>17 micromol/L).[3]

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

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

References

1. American Academy of Pediatrics Committee on Drugs. The transfer of drugs and other chemicals into human milk. *Pediatrics* 2001;108:776-89. PubMed PMID: 11533352.
2. Evaldson GR, Lindgren S, Nord CE, Rane AT. Tinidazole milk excretion and pharmacokinetics in lactating women. *Br J Clin Pharmacol* 1985;19:503-7. PubMed PMID: 4039599.
3. Li S, Cao M, Zhou Y, et al. Ornidazole transfer into colostrum and assessment of exposure risk for breastfeeding infant: A population pharmacokinetic analysis. *Pharmaceutics* 2023;15:2524. PubMed PMID: 38004504.

Substance Identification

Substance Name

Ornidazole

CAS Registry Number

16773-42-5

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents

Antibacterial Agents

Antiprotozoal Agents

Nitroimidazoles