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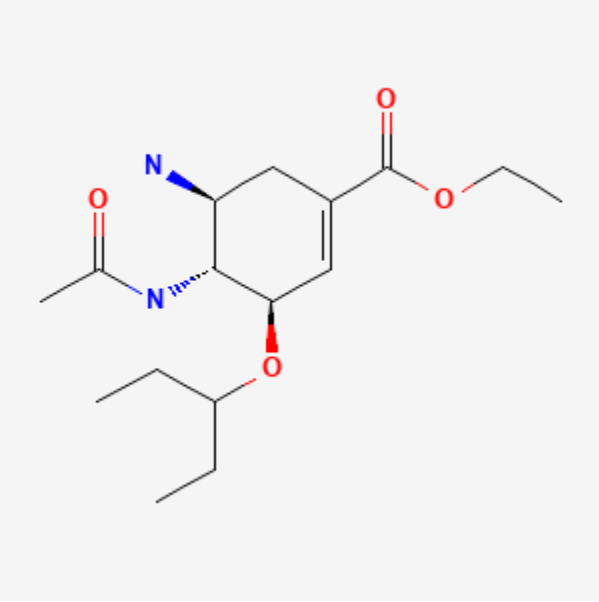
Oseltamivir

Revised: February 15, 2024.

CASRN: 196618-13-0



Drug Levels and Effects

Summary of Use during Lactation

Limited data indicate that oseltamivir and its active metabolite are poorly excreted into breastmilk. Maternal dosages of 150 mg daily produce low levels in milk and would not be expected to cause any adverse effects in breastfed infants. Infants over 2 weeks of age can receive oseltamivir directly in doses much larger than those in breastmilk.

Drug Levels

Maternal Levels. A nursing mother who was 9 months postpartum was given oseltamivir 75 mg by mouth twice daily for 5 days. She collected 8 milk samples within 30 minutes of taking an oseltamivir dose and 2 after the last

dose. Milk was analyzed for oseltamivir and its carboxylate metabolite. Oseltamivir milk concentrations fluctuated depending on the time of the milk sample, but oseltamivir carboxylate concentrations were generally higher and reached a steady-state between 37 to 39 mcg/L after 3 days of therapy. The authors calculated that at worst, the infant would receive 0.012 mg/kg daily, compared to the dosage for infants over 2 weeks of age of 3 mg/kg daily. The dose in milk corresponded to 0.5% of the mother's weight-adjusted dosage.[1]

Seven postpartum women who were bottle feeding their infants donated milk samples at the time of and 0.5, 1, 2, 4, 8, 12, and 24 hours after a single 75 mg oral dose of oseltamivir. Both oseltamivir and its metabolite, oseltamivir carboxylate were measured in milk samples. The average peak milk level of oseltamivir of 26.9 mcg/L occurred at an average of 3.4 hours after the dose and the average peak milk level of oseltamivir carboxylate of 41.9 mcg/L occurred at an average of 18.9 hours after the dose. Using area under the curve (AUC) data reported in the paper and the standardized milk intake of 150 mL/kg daily, a fully breastfed infant would receive daily dosages of about 0.9 mcg/kg of oseltamivir and 3.6 mcg/kg of oseltamivir carboxylate. These values would be doubled with the usual dosage of 75 mg twice daily, but the sum of these entities is far below the dose reportedly used in infants of 3 mg/kg daily.[2]

Six women with influenza were receiving oseltamivir 75 mg twice daily for 5 days. Oseltamivir and its active metabolite oseltamivir carboxylate were measured in breastmilk at 0, 1, 2, 4, 6, 8, 10, and 12 hours after the seventh dose of the drug. The peak oseltamivir concentration was found at 1.3 hours after the dose and was 69.5 mcg/L. Its half-life in milk was 2.1 hours. The peak oseltamivir carboxylate concentration was found at 5.3 hours after the dose and was 38.4 mcg/L. Its half-life in milk was 12.5 hours. Although the study was not powered to measure colostrum and breastmilk separately, the study found no significant difference in the pharmacokinetics between colostrum collected within 5 days of birth in 3 women and breastmilk from 3 women who were 13 days postpartum.[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.

Alternate Drugs to Consider

Zanamivir

References

1. Wentges-van Holthe N, van Eijkeren M, van der Laan JW. Oseltamivir and breastfeeding. Int J Infect Dis 2008;12:451. PubMed PMID: 18243025.
2. Greer LG, Leff RD, Rogers VL, et al. Pharmacokinetics of oseltamivir in breast milk and maternal plasma. Am J Obstet Gynecol 2011;204:524.e1-4. PubMed PMID: 21457910.
3. Fodor E, Nagy RN, Nógrádi A, et al. An observational study on the pharmacokinetics of oseltamivir in lactating influenza patients. Clin Pharmacol Ther 2024;115:318-23. PubMed PMID: 37975276.

Substance Identification

Substance Name

Oseltamivir

CAS Registry Number

196618-13-0

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents

Antiviral Agents

Neuraminidase Inhibitors