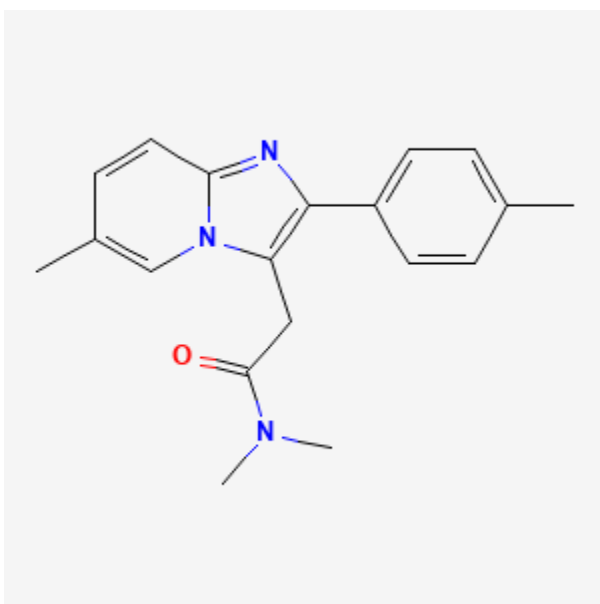




Zolpidem

Revised: February 15, 2023.

CASRN: 82626-48-0



Drug Levels and Effects

Summary of Use during Lactation

The levels of zolpidem in breastmilk are low and is somewhat rapidly eliminated from milk, so it would not be expected to cause any adverse effects in older breastfed infants who does not breastfeed during the night after the mother's dose. The manufacturer states that excess sedation in infants exposed to zolpidem through breastmilk has been reported, although details are lacking. Some expert opinion recommends against zolpidem use during breastfeeding, primarily because of minimal documentation.[1] Monitor the infant for sedation, poor feeding and poor weight gain.

Disclaimer: Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

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Drug Levels

Maternal Levels. Five nursing mothers who were 3 to 4 days postpartum were given a single oral dose of zolpidem 20 mg. Milk collected 3 hours after the dose contained between 0.76 and 3.88 mcg of zolpidem. This corresponded to 0.004 to 0.019% of the maternal dosage. The drug was undetectable (<0.5 mcg/L) in milk 13 and 16 hours after the dose. The authors estimated the half-life in milk to average 2.6 hours.[2]

A woman was taking zolpidem 5 mg nightly for sleep. Breastmilk concentrations were measured at 3 times postpartum: day 1 at 8.2 hours after a dose the concentration was 12.8 mcg/L; day 2 at 9 hours after the dose the concentration was 6.4 mcg/L; day 3 at 2.2 hours after the dose the concentration was 26.5 mcg/L. The authors estimated the maximum infant dose to be 4 mcg/kg daily based on the day 3 value.[3]

Two pregnant women took zolpidem 5 mg doses daily during pregnancy and postpartum. One woman had a breastmilk zolpidem concentration of 10.1 mcg/L at 6.5 hours after a dose on day 6 postpartum. The other woman had milk zolpidem concentrations ranging from 0.6 mcg/L mcg/L at 18.1 hours after a dose on day 2 postpartum to 4.8 mcg/L at 10.1 hours after a dose on day 3 postpartum. A third woman who took a 5 mg dose as needed had a milk level of 3.4 mcg/L at 17.2 hours after a dose on day 1 postpartum. On day 7, 105 hours after a dose, zolpidem was undetectable in milk.[4]

Infant Levels. Three infants were breastfed by mothers taking zolpidem 5 mg daily (n = 2) or as needed (n = 1). The infants were breastfed 4 to 6 times daily. All of the infants had undetectable (< 0.05 mcg/L) serum levels of zolpidem.[4]

Effects in Breastfed Infants

The mother of a newborn was taking 5 to 10 mg of zolpidem nightly. At the one-month checkup, no adverse effects were noted by the patient's pediatrician.[3]

Three infants were breastfed by mothers taking zolpidem 5 mg daily (n = 2) or as needed (n = 1). No abnormalities were found at the one-month checkup.[4]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Zaleplon

References

1. Uguz F. A new safety scoring system for the use of psychotropic drugs during lactation. *Am J Ther.* 2021;28:e118–e126. PubMed PMID: 30601177.
2. Pons G, Francoual C, Guillet P, et al. Zolpidem excretion in breast milk. *Eur J Clin Pharmacol.* 1989;37:245–8. PubMed PMID: 2612539.
3. Saito J, Tachibana Y, Sano Wada Y, et al. Presence of hypnotics in the cord blood and breast milk, with no adverse effects in the infant: A case report. *Breastfeed Med.* 2022;17:349–52. PubMed PMID: 34935466.
4. Saito J, Tachibana Y, Kawasaki H, et al. Transfer of zolpidem to cord blood and breast milk: A case series evaluating zolpidem serum levels and outcomes in birth and suckling infants. *Breastfeed Med.* 2022;17:1034–8. PubMed PMID: 36301249.

Substance Identification

Substance Name

Zolpidem

CAS Registry Number

82626-48-0

Drug Class

Breast Feeding

Lactation

Milk, Human

Hypnotics and Sedatives