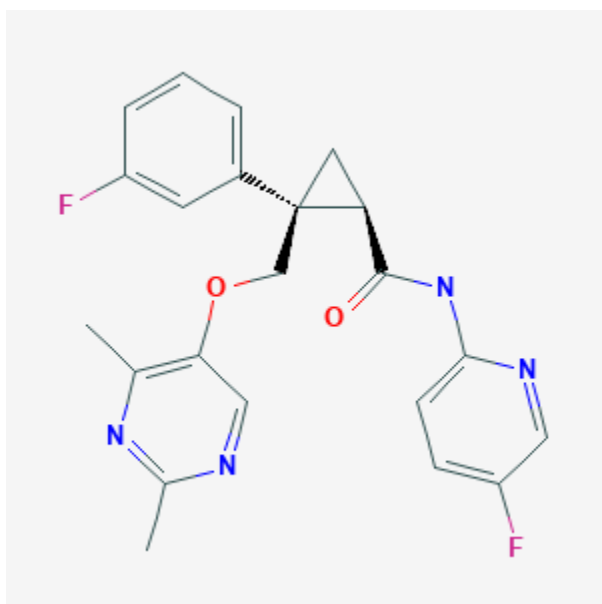




## Lemborexant

Revised: January 15, 2024.

CASRN: 1369764-02-2



## Drug Levels and Effects

### Summary of Use during Lactation

Amounts of lemborexant in milk appear to be low. If lemborexant is required by the mother, it is not a reason to discontinue breastfeeding. However, until more data become available, monitor the infant for sedation, poor feeding and poor weight gain, especially while nursing a newborn or preterm infant.

### Drug Levels

*Maternal Levels.* A woman took lemborexant 10 mg, brotizolam 0.25 mg and etizolam 0.5 mg at bedtime during pregnancy and postpartum. Five colostrum samples were taken during day 2 and 3 postpartum at times ranging from 8 to 19.6 hours after a dose. Milk concentrations ranged from 1.8 to 12.7 mcg/L, with the highest

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concentration in the sample taken 8 hours after the dose. The estimated daily infant dose via breastmilk using the highest milk level value was 1.91 mcg/kg daily, which translates to a relative infant dose of 1.21%.<sup>[1]</sup>

A manufacturer-sponsored study was done in 8 women who had breastfed for at least 5 weeks postpartum. Each was given a single 10 mg oral dose of lemborexant and complete extractions of breastmilk were collected by an electric breast pump in intervals up to 10 days after the dose. Over the 240-hour collection period a total of 0.0174 mg of the unchanged drug was collected in milk, 70% of which was from the first 24 hours of collection. The authors calculated that a fully breastfed infant would receive an average weight-adjusted relative infant dose of 1.96% of the mother's dose.<sup>[2]</sup>

*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

Zaleplon, Zolpidem

## References

1. Saito J, Ishii M, Sandaiji N, et al. Lemborexant levels in maternal serum, cord blood, and breast milk during pregnancy and lactation: A case report. *Psychiatry Clin Neurosci Rep* 2023;2:e62. doi:10.1002/pcn5.62
2. Rawal S, Brimhall D, Aluri J, et al. Lemborexant levels in breast milk after single doses in healthy, lactating women. *Br J Clin Pharmacol* 2024;90:158-63. PubMed PMID: 37565541.

## Substance Identification

### Substance Name

Lemborexant

### CAS Registry Number

1369764-02-2

### Drug Class

Breast Feeding

Lactation

Milk, Human

Hypnotics and Sedatives

Orexin Receptor Antagonists

Sleep Aids, Pharmaceutical