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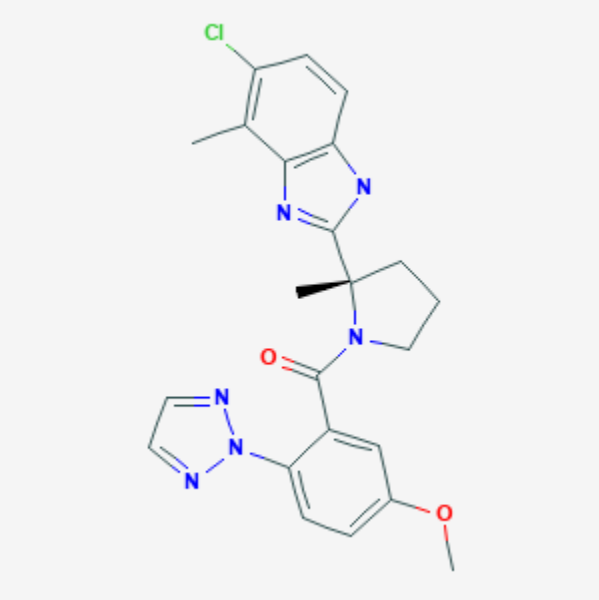
Daridorexant

Revised: June 15, 2024.

CASRN: 1505484-82-1



Drug Levels and Effects

Summary of Use during Lactation

Amounts of daridorexant in milk are very low. If daridorexant is required by the mother, it is not a reason to discontinue breastfeeding. Until more data in breastfed infants are available, monitor the infant for sedation, poor feeding and poor weight gain.

Drug Levels

Three major metabolites of daridorexant with much lower affinity to orexin receptors than the parent drug have been identified in plasma, but they do not appear to contribute to the pharmacological effect of daridorexant.[1]

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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Maternal Levels. In a manufacturer-sponsored study, 10 healthy women who were at least 2 weeks postpartum were given a single 50 mg oral dose of daridorexant. Milk was collected either every 4 or 8 hours for 3 days. The peak daridorexant milk level of 35.3 mcg/L occurred 2 hours after the dose. The metabolites M1, M3 and M10 had peak milk levels of 5.61 mcg/L, 9.1 mcg/L and 3.7 mcg/L, respectively. Peak levels of M3 and M10 occurred at 2 hours after the dose, while the peak level of M1 occurred at 6 hours after the dose. The mean daridorexant milk concentration was 6.3 mcg/L and its half-life was 7 hours. It was estimated that 9 mcg of daridorexant was excreted into milk in the first 24 hours after a dose and 10 mcg over 72 hours. The relative infant dose of daridorexant was 0.22% in the first 24 hours and 0.25% over 72 hours.[1]

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. Kaufmann P, Muehlan C, Anliker-Ort M, et al. Transfer of the dual orexin receptor antagonist daridorexant into breast milk of healthy lactating women. J Clin Pharmacol 2024. PubMed PMID: 38736033.

Substance Identification

Substance Name

Daridorexant

CAS Registry Number

1505484-82-1

Drug Class

Breast Feeding

Lactation

Milk, Human

Hypnotics and Sedatives

Orexin Receptor Antagonists

Sleep Aids, Pharmaceutical