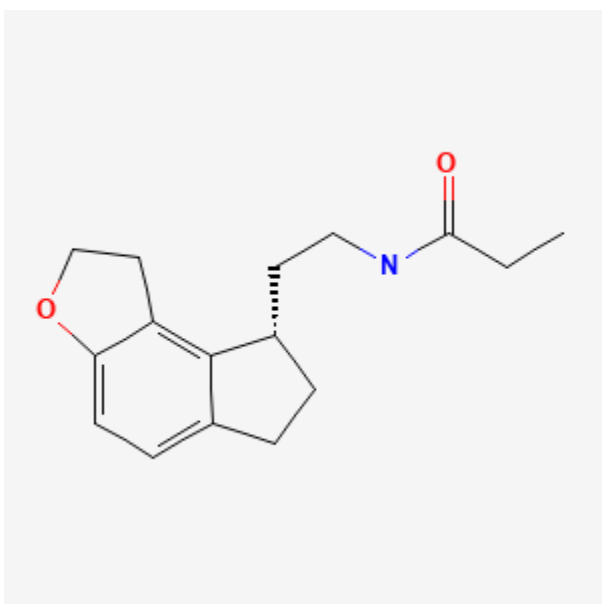




Ramelteon

Revised: April 18, 2022.

CASRN: 196597-26-9



Drug Levels and Effects

Summary of Use during Lactation

Data from one patient indicates that ramelteon and its principle active metabolite have low levels in milk. Monitor the infant for drowsiness and adequate feeding, especially while nursing a newborn or preterm infant. Until more data become available an alternate drug may be preferred.

Drug Levels

Ramelteon undergoes rapid and almost complete first-pass metabolism to several metabolites. The principle active metabolite is M-II, which has an elimination half-life of 2 to 5 hours in adults.

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.

Attribution Statement: LactMed is a registered trademark of the U.S. Department of Health and Human Services.

Maternal Levels. A woman was taking oral ramelteon 8 mg nightly for sleep during pregnancy and postpartum while nursing. Breastmilk concentrations of ramelteon and its active M-II metabolite were measured at 3 times postpartum: on day 1 at 8.2 hours after a dose, concentrations were 0.4 and 14.6 mcg/L, respectively; day 2 at 9.1 hours after the dose, concentrations were 0.2 and 7.1 mcg/L, respectively; day 3 at 2.2 hours after the dose, concentrations were 2.6 and 88.9 mcg/L, respectively. The authors calculated that the infant would receive 0.24% of the mother's weight-adjusted dosage.[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

Prolactin levels increased by 4.9 mcg/L (34%) in non-breastfeeding women with chronic insomnia who were taking ramelteon 16 mg nightly for 6 months. No clinical symptoms of hyperprolactinemia were reported.[2] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Alternate Drugs to Consider

Zaleplon, Zolpidem

References

1. 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.
2. Richardson G, Wang-Weigand S. Effects of long-term exposure to ramelteon, a melatonin receptor agonist, on endocrine function in adults with chronic insomnia. *Hum Psychopharmacol.* 2009;24:103–11. PubMed PMID: 19090503.

Substance Identification

Substance Name

Ramelteon

CAS Registry Number

196597-26-9

Drug Class

Breast Feeding

Lactation

Milk, Human

Central Nervous System Depressants