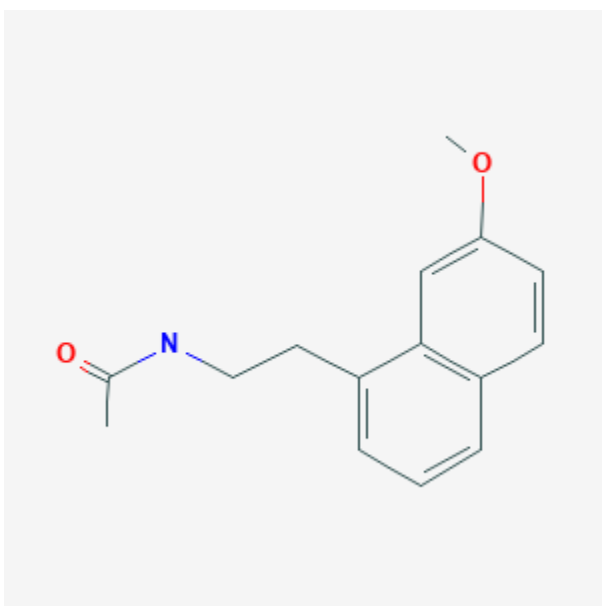




Agomelatine

Revised: August 15, 2023.

CASRN: 138112-76-2



Drug Levels and Effects

Summary of Use during Lactation

Agomelatine is not approved for marketing in the United States by the U.S. Food and Drug Administration (FDA), but is available in other countries. Some follow-up data reported possible drowsiness and developmental concerns in one infant, but no problems in 16 other breastfed infants. A minimal amount of information indicates that exposure and adverse effects can be avoided in breastfed infants if breastfeeding is held for 4 hours after a dose.

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Drug Levels

Maternal Levels. A woman who was taking quetiapine 200 mg daily for postpartum psychosis had agomelatine 25 mg daily added after 1 week of therapy because of depressive symptoms. A mixture of fore- and hindmilk samples were collected 10 min before and 30, 60, 90, 120, and 240 minutes after each dose for the first 3 days of agomelatine therapy. Peak agomelatine milk levels of 0.78 to 2 mcg/L occurred at 60 to 120 minutes after the dose. On all 3 days, the milk concentration was undetectable (<0.1 mcg/L) at 240 minutes after the dose.[1]

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

Effects in Breastfed Infants

A woman with severe postpartum depression was given agomelatine 25 mg daily at bedtime. She breastfed her infant for 12 weeks, taking the dose after her last breastfeeding of the day and then pumping her milk in the morning before resuming breastfeeding. Her use of formula, if any, was not mentioned. She breastfed normally during the day. Her infant developed normally and had no abnormal laboratory values or adverse effects during the 12-week period.[2]

A prospective study followed 14 mothers taking agomelatine from birth and their 16 breastfed infants. The women were taking an average dose of 25 mg daily, with a range of 25 mg twice weekly to 50 mg daily. Infants were breastfed for an average of 7.4 months. Thirteen mothers did not report any short- or long-term adverse effects. One mother reported a possible adverse reaction of drowsiness in her baby in the first few weeks after birth which she attributed to agomelatine. She was taking agomelatine in an unspecified dose with duloxetine 90 mg daily and continued breastfeeding her baby until 9 months of age. She reported some developmental concerns of speech and low muscle tone in her baby who was 9 months of age at the time of follow-up.[3]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Nortriptyline, Paroxetine, Sertraline

References

1. Schmidt FM, Lichtblau N, Uribe MM, et al. Agomelatine in breast milk. *Int J Neuropsychopharmacol* 2013;16:497-9. PubMed PMID: 22781637.
2. Xiao L. Agomelatine for postpartum depression and breastfeeding. *Ther Adv Psychopharmacol* 2021;11.
3. Kwok S, Cupitt D, Kennedy D. Breastfeeding exposure to agomelatine – Preliminary findings from an Australian observational cohort study. *Neurotoxicol Teratol* 2023;98:16-7. doi:10.1016/j.ntt.2023.107222

Substance Identification

Substance Name

Agomelatine

CAS Registry Number

138112-76-2

Drug Class

Breast Feeding

Lactation

Milk, Human

Antidepressants