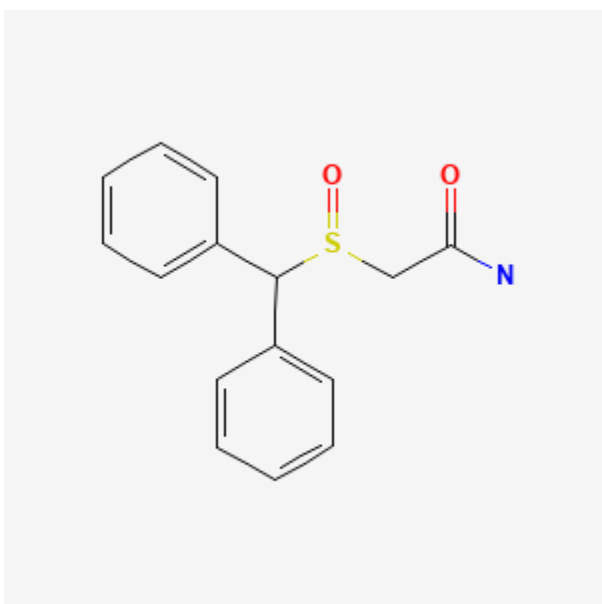




## Modafinil

Revised: May 15, 2023.

CASRN: 68693-11-8



## Drug Levels and Effects

### Summary of Use during Lactation

Little information is available on the excretion of modafinil into breastmilk. In the case reports available, only *R*-modafinil was measured. *R*-enantiomer is the predominant form (about 75%) in the blood after administration of racemic modafinil, but not measuring *S*-modafinil in those reports likely led to an underreporting of the total amount in milk and exposure in the infant.[1,2] Nevertheless, milk levels of *R*-modafinil in two nursing mothers and serum of one breastfed infant were very low. Some information from women who breastfed their infants while using modafinil found no adverse effects in the infants. Until more safety data are available, modafinil should be used with careful infant monitoring during breastfeeding, or an alternate drug may be preferred.

**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

Modafinil is a mixture of equal parts of *R*- and *S*-modafinil; *R*-modafinil alone is also available as armodafinil. The two isomers have equal potency, but the *R*-isomer has a longer half-life and therefore predominates in plasma at ratio of approximately 3 to 1. No interconversion between the two isomers occurs.

*Maternal Levels.* A woman with idiopathic hypersomnolence was treated with racemic modafinil 250 mg daily. She was also taking 75 mcg of levothyroxine daily for Hashimoto's thyroiditis, sertraline 200 mg daily for obsessive-compulsive and major depressive disorders, and inhaled albuterol as needed for mild intermittent asthma. At 19 days postpartum, milk samples were collected at 0, 1, 2, 4, 6, 8, 10, 12, and 24 hours after the dose. The trough milk *R*-modafinil level was 0.43 mg/L, with peak value of 2.3 mg/L at 2 hours after the dose. Based on the average amount of *R*-modafinil in milk of 1.2 mg/L, the daily infant dosage was estimated to be 0.18 mg/kg. All of these values may be underestimates of the pharmacologically active total drug (both *R*- and *S*-enantiomers), because *S*-modafinil was not measured.[3]

A nursing mother with narcolepsy was taking racemic modafinil 300 mg in the morning and 100 mg at noon. Eight milk samples were collected over a 26-hour period and the active isomer, armodafinil, was measured in milk. The peak milk concentrations of *R*-modafinil 3.89 and 4.07 mg/L occurred about 2 and 4 hours after the morning dose on the two days, respectively. The lowest milk level was 0.92 mg/L just before the dose on day 2. The authors estimated the *R*-modafinil infant dosage for a fully breastfed infant to be 294 mcg/kg daily. All of these values may be underestimates of the pharmacologically active total drug (both *R*- and *S*-enantiomers) because *S*-modafinil was not measured.[1,2,4]

*Infant Levels.* A nursing mother with narcolepsy was taking modafinil 300 mg in the morning and 100 mg at noon. Her exclusively breastfed infant had a blood sample taken 110 minutes after the morning dose (and 30 minutes after breastfeeding was started), which was 0.19 mg/L, which was 1.6% of the mother's simultaneous plasma level; however this may be an underestimate of the pharmacologically active total drug (both *R*- and *S*-enantiomers) because *S*-modafinil was not measured.[1,4]

## Effects in Breastfed Infants

In one case-control study of women having narcolepsy with cataplexy, some women (fewer than 6) breastfed their infants while taking modafinil. No adverse effects were noted. The authors felt that the risk from the medication is low.[5]

An infant was exclusively breastfed by a mother taking modafinil 300 mg in the morning and 100 mg at noon. The authors state that the infant had no adverse events during the 2-day study period and normal growth and development at 6 weeks postpartum.[4]

## Effects on Lactation and Breastmilk

A case control study comparing women with narcolepsy with cataplexy to a control group found that those with narcolepsy breastfed longer than those without the disease. The authors felt that the difference likely due to a lower employment rate among the women with narcolepsy.[5]

## Alternate Drugs to Consider

(Narcolepsy) [Amphetamine](#), [Armodafinil](#), [Dextroamphetamine](#), [Lisdexamfetamine](#), [Methylphenidate](#), [Oxybate Salts](#), [Pitolisant](#)

## References

1. Anderson PO. Armodafinil in milk. *J Hum Lact.* 2023;39:223. PubMed PMID: 37073877.

2. Leggett C, Ritchie U, Costi L, et al. Response to Dr. Anderson's letter to the editor: Modafinil and armodafinil in human milk. *J Hum Lact* 2023;39:224-5.
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4. Leggett C, Ritchie U, Costi L, et al. Infant exposure to armodafinil through human milk following maternal use of modafinil. *J Hum Lact*. 2022;39:218–22. PubMed PMID: 36384330.
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## Substance Identification

### Substance Name

Modafinil

### CAS Registry Number

68693-11-8

### Drug Class

Breast Feeding

Lactation

Milk, Human

Central Nervous System Stimulants

Wakefulness-Promoting Agents