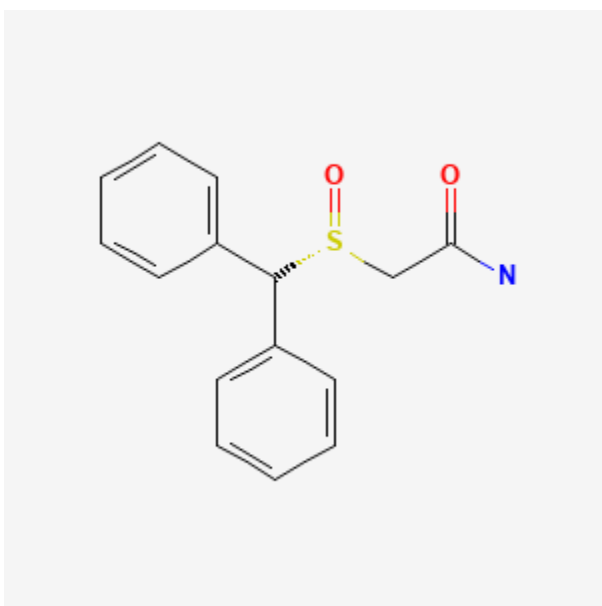




Armodafinil

Revised: May 15, 2023.

CASRN: 112111-43-0



Drug Levels and Effects

Summary of Use during Lactation

Armodafinil is the *R*-enantiomer of modafinil. Armodafinil has only been measured in the milk of mothers taking modafinil, where it is the predominant form and its milk levels were very low. Some information from women who breastfed their infant's while using racemic modafinil found no adverse effects in their infants. Until more safety data are available, armodafinil should be used with careful infant monitoring during breastfeeding, or an alternate drug may be preferred.

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Drug Levels

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.[1]

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.[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.[2,3]

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.[2]

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, Dextroamphetamine, Lisdexamfetamine, Methylphenidate, Modafinil, Oxybate Salts, Pitolisant

References

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2. 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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4. 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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Substance Identification

Substance Name

Armodafinil

CAS Registry Number

112111-43-0

Drug Class

Breast Feeding

Lactation

Milk, Human

Central Nervous System Stimulants

Wakefulness-Promoting Agents