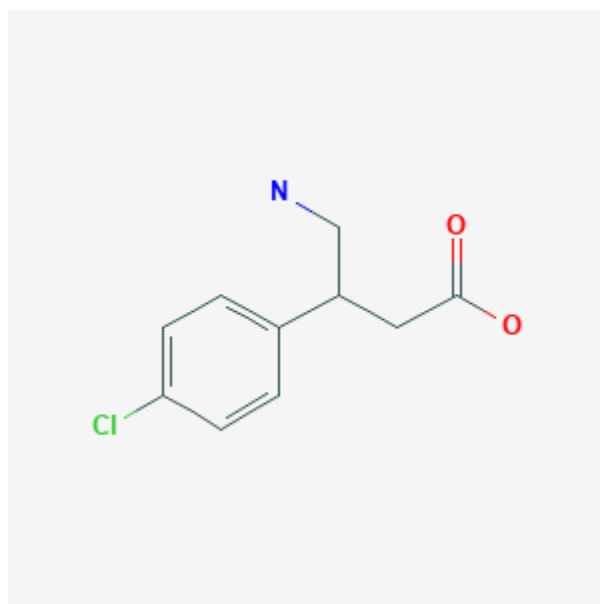




Baclofen

Revised: June 3, 2019.

CASRN: 1134-47-0



Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that orally administered baclofen appears in low levels in milk and would not be expected to cause any adverse effects in breastfed infants, especially if the infant is older than 2 months. Monitor newborn infants for signs of sedation. Low intrathecal doses and topical application produce even lower milk levels and are unlikely to affect the nursing infant.

Drug Levels

Maternal Levels. A woman with spastic paraplegia was given a single oral 20 mg dose of baclofen 14 days postpartum. A peak milk level of about 0.13 mg/L occurred 4 hours after the dose. The half-life in milk was 5.6 hours. The authors estimated that the total amount recovered in breastmilk over 26 hours was 22 mcg.[1]

A woman with spinal cord injury was taking baclofen 20 mg four times at evenly spaced intervals between 0600 and 2200 daily during pregnancy and postpartum. Breast milk samples were collected at estimated trough (0530) and peak (2400) times on 3 consecutive days postpartum. Trough levels averaged 0.297 mg/L (range 0.28 to 0.32 mg/L). Peak levels averaged 0.343 mg/L (range 0.32 to 0.38 mg/L).[2] Using the average of the peaks and troughs, a fully breastfed infant would receive a daily dosage of 0.048 mg/kg, which would be 3.6% of the maternal weight adjusted dosage.

A woman with long-standing spasticity and flexion myopathy from a head injury was given continuous baclofen infusion via intrathecal pump during pregnancy and postpartum at a dose of 330 mcg daily. One postpartum sample of breastmilk was analyzed and found to contain 0.617 mcg/L of baclofen.[3]

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

Effects in Breastfed Infants

An infant was born after exposure to baclofen in utero. The mother was taking baclofen 10 mg twice daily plus clonazepam 1 mg orally twice daily and sustained-release oxycodone 50 mg daily in divided doses. The infant was breast and bottle fed while the mother continued taking baclofen. Neonatal withdrawal symptoms necessitated phenobarbital administration. The infant also received baclofen 0.5 mg/kg daily in 4 divided doses that was weaned and decreased by day 9 of life. Neurologic examination was normal at discharge on day 16 and at 6-weeks of age.[4]

A woman with spinal cord injury was taking baclofen 20 mg four daily during pregnancy and postpartum. After birth, the infant received an initial baclofen dosage of 0.1 mg/kg daily for 4 days, plus about 1/3 of the diet as breastmilk containing baclofen (about 0.016 mg/kg daily), followed by a daily decrease of 0.01 mg/kg daily until discontinuation of the baclofen on the 13th day of life. Breastmilk intake was eventually increased to 50% of the infant's diet. Daily assessment for neonatal abstinence syndrome (NAS) was performed using the modified Finnegan NAS scoring system. Of 82 modified Finnegan NAS scores obtained in the first 16 days of life, the mean score was 2. The maximum NAS score of 9 was observed on the 13th day of life. At no point were there three consecutive NAS scores of 8 or greater, indicating no need for further pharmacological intervention. The infant was discharged 3 days after the taper ended.[5]

Effects on Lactation and Breastmilk

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

References

1. Eriksson G, Swahn CG. Concentration of baclofen in serum and breast milk from a lactating woman. *Scand J Clin Lab Invest.* 1981;41:185-7. PubMed PMID: 7313501.
2. Lin HH, Barton N, Wiegand TJ. Baclofen distribution into breast milk-a potential for toxicity? *J Med Toxicol.* 2014;10:86. Abstract. DOI: [10.1007/s13181-013-0376-x](https://doi.org/10.1007/s13181-013-0376-x).
3. Hara T, Nakajima M, Sugano H et al. Pregnancy and breastfeeding during intrathecal baclofen therapy - A case study and review. *NMC Case Rep J.* 2018;5:65-8. PubMed PMID: 30023142.
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5. Lin HH, Barton N, Wiegand TJ. Prevention of neonatal abstinence syndrome in the setting of intrauterine baclofen exposure. *J Med Toxicol.* 2014;10:85-6. Abstract. DOI: [10.1007/s13181-013-0376-x](https://doi.org/10.1007/s13181-013-0376-x).

Substance Identification

Substance Name

Baclofen

CAS Registry Number

1134-47-0

Drug Class

Breast Feeding

Lactation

GABA Agonists

Muscle Relaxants, Central