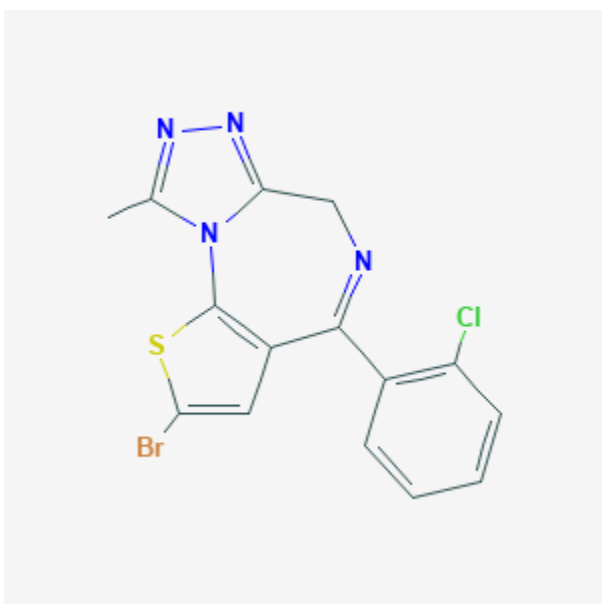




Brotizolam

Revised: January 15, 2024.

CASRN: 57801-81-7



Drug Levels and Effects

Summary of Use during Lactation

Brotizolam is not approved for marketing in the United States by the U.S. Food and Drug Administration. Very little information is available on the passage of brotizolam into milk, although amounts in milk appear to be very low. An alternate drug might be preferred, especially while nursing a newborn or preterm infant. If brotizolam is used, monitor the infant for sedation, poor feeding and poor weight gain.

Drug Levels

Maternal Levels. A woman who was taking oral brotizolam 0.25 mg daily donated milk samples between 3 and 6 days postpartum 1 to 1.5 hours after a dose at the estimated peak serum concentration and just before a dose.

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She had a peak milk level of 0.589 mcg/L. Her trough milk levels was less than the lower limit of quantification of 0.25 mcg/L.[1]

A woman with bipolar disorder received brotizolam 0.25 mg, alprazolam 0.4 mg, and trazodone 50 mg daily during pregnancy and postpartum. She also received sertraline 25 mg daily, which was increased gradually to 100 mg twice daily. On day 5 postpartum, the brotizolam concentration in milk was 0.12 mcg/L at 7.1 hours after the dose. Milk samples at 16.4, 19.2 and 29 hours after the dose had undetectable (<0.05 mcg/L) levels of brotizolam.[2]

A woman with dissociative disorder and persistent dysthymic depression was treated during pregnancy with brotizolam 0.25 mg daily, propericiazine 10 mg daily, and zolpidem 5 mg daily. Zolpidem was discontinued at week 28 and sulpiride 100 mg daily was begun at week 33. On postpartum day 5, alprazolam 0.4 mg daily was begun. Milk samples were taken at 7.5 and 11.5 hours after the previous dose on day 9 postpartum. Brotizolam was undetectable (<0.1 mcg/L) in both milk samples.[3]

Infant Levels. A woman with bipolar disorder received brotizolam 0.25 mg, alprazolam 0.4 mg, and trazodone 50 mg daily during pregnancy and postpartum. She also received sertraline 25 mg daily, which was increased gradually to 100 mg twice daily. The infant was admitted to the neonatal ICU and was given 40 to 100 mL of pumped breastmilk plus 100 to 220 mL of formula daily. Brotizolam was undetectable (<0.05 mcg/L) in infant serum on 5 occasions over the first 5 days postpartum.[2]

Effects in Breastfed Infants

A woman with bipolar disorder received brotizolam 0.25 mg, alprazolam 0.4 mg, and trazodone 50 mg daily during pregnancy and postpartum. She also received sertraline 25 mg daily, which was increased gradually to 100 mg twice daily. The infant was admitted to the neonatal ICU for neonatal abstinence syndrome and was discharged on day 8 of life. The mother exclusively breastfed her infant for 3 months while taking brotizolam 0.25 mg daily, sertraline 50 mg twice daily, alprazolam 0.4 mg daily and zolpidem 10 mg daily. No drug-related adverse effects were detected at the 1-, 3-, or 6-month checkups.[2]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Lorazepam, Oxazepam, Temazepam

References

1. Nishimura A, Furugen A, Umazume T, et al. Benzodiazepine concentrations in the breast milk and plasma of nursing mothers: Estimation of relative infant dose. *Breastfeed Med* 2021;16:424-31. PubMed PMID: 33449825.
2. Saito J, Ishii M, Miura Y, et al. Brotizolam during pregnancy and lactation: Brotizolam levels in maternal serum, cord blood, breast milk, and neonatal serum. *Breastfeed Med* 2021;16:579-82. PubMed PMID: 33666494.
3. Saito J, Tachibana Y, Wada YS, et al. Transfer of brotizolam, periciazine, and sulpiride in cord blood and breast milk, and alprazolam in breast milk: A case report. *J Pharm Health Care Sci* 2022;8:10. PubMed PMID: 35361275.

Substance Identification

Substance Name

Brotizolam

CAS Registry Number

57801-81-7

Drug Class

Breast Feeding

Lactation

Milk, Human

Hypnotics and Sedatives

Anti-Anxiety Agents

Benzodiazepines