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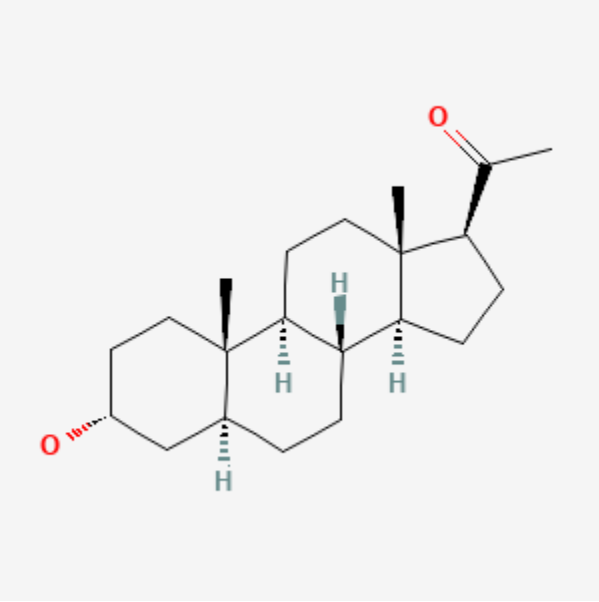
Brexanolone

Revised: August 15, 2023.

CASRN: 516-54-1



Drug Levels and Effects

Summary of Use during Lactation

Because of the low amounts of brexanolone in milk and low oral bioavailability, brexanolone would not be expected to cause any adverse effects in breastfed infants. If brexanolone is required by the mother, it is not a reason to discontinue breastfeeding. Because excessive sedation or sudden loss of consciousness can occur during brexanolone infusion, it is suggested that patients provide a separate caregiver for any child who is present during the infusion.[1]

Drug Levels

Brexanolone is the pharmaceutical name for the naturally occurring hormone allopregnanolone. Brexanolone has an oral bioavailability of less than 5% in adults.

Maternal Levels. Twelve healthy women who were less than 6 months postpartum received an intravenous infusion of brexanolone titrated to a maximum of 90 mg/kg per hour then tapered down over 60 hours at various study sites. Breastmilk was collected at random times, but at least every 12 hours, daily for 7 days. Peak milk levels occurred between hours 24 and 48 of the infusion when the maximum dosage was being infused. The average peak allopregnanolone breastmilk level was 125 mcg/L. Milk levels fell below the limit of detection (5 mcg/L) in most women by about 3 days after the end of the infusion. These data were incorporated into a population pharmacokinetic model that predicted that 95% of patients have milk allopregnanolone levels <10 mcg/L at 36 hours after the end of the infusion. The predicted median weight-adjusted percent of maternal dosage was 0.69% and the maximum was 1.3%.[2]

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

Effects in Breastfed Infants

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

Effects on Lactation and Breastmilk

In a study of 12 healthy women given a 60-hour infusion of brexanolone, there were no reports of effects on milk production according to the manufacturer.

Alternate Drugs to Consider

Nortriptyline, Paroxetine, Sertraline, Zuranolone

References

1. Rosen-Carole C, Ito S. Using brexanolone for postpartum depression must account for lactation. Matern Child Health J 2021;25:1007-9. PubMed PMID: 34019187.
2. Wald J, Henningsson A, Hanze E, et al. Allopregnanolone concentrations in breast milk and plasma from healthy volunteers receiving brexanolone injection, with population pharmacokinetic modeling of potential relative infant dose. Clin Pharmacokinet 2022;61:1307-19. PubMed PMID: 35869362.

Substance Identification

Substance Name

Brexanolone

CAS Registry Number

516-54-1

Drug Class

Breastfeeding

Lactation

Milk, Human

Antidepressants

Antidepressive Agents

GABA Agents

Hormones

Progesterone Congeners