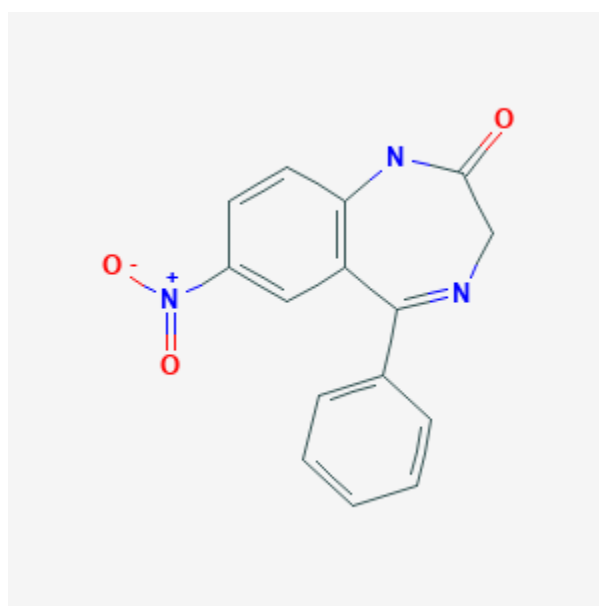




## Nitrazepam

Revised: December 3, 2018.

CASRN: 146-22-5



## Drug Levels and Effects

### Summary of Use during Lactation

Nitrazepam is not approved for marketing in the United States by the U.S. Food and Drug Administration. It is excreted into breastmilk in small amounts. Because of its long half-life of about 30 hours, it may accumulate in the serum of breastfed infants with repeated doses. Other agents are preferred, especially while nursing a newborn or preterm infant.

### Drug Levels

*Maternal Levels.* Five women received radioactively tagged nitrazepam 5 mg at 8 pm daily for 5 days. Milk samples were collected daily at 9 am and 5:45 pm. The authors estimated that an infant would receive about 5 to 10 mcg/L of nitrazepam per 100 mL of milk ingested.[1]

Ten mothers were given oral nitrazepam 5 mg for sleep in the first 5 nights postpartum if they requested it. One of the mothers did not produce enough milk to measure the drug. Of the remaining 9 mothers, between 4 and 8 took the medication nightly. Milk nitrazepam levels were measured at 6 am the following day, 6 to 8 hours after the previous dose. Average milk concentrations were about 8.4 mcg/L on day 1 and 14 mcg/L on day 5. The authors calculated that a breastfed infant would receive an average of between 1 and 1.5 mcg per 100 mL of milk ingested or a maximum of 2 mcg per 100 mL.[2] This is equivalent to about 2.6% of the maternal weight-adjusted dose.[3]

*Infant Levels.* One mother took nitrazepam 5 mg orally at bedtime for sleep nightly for 5 nights while breastfeeding her newborn. On day 5 of life, nitrazepam was undetectable (<2.8 mcg/L) in the infant's serum.[2]

## Effects in Breastfed Infants

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

## Effects on Lactation and Breastmilk

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

## References

1. Rieder J, Wendt G. Pharmacokinetics and metabolism of the hypnotic nitrazepam. In, Garattini S, Mussini E, Randall LO, eds. The benzodiazepines. New York: Raven Press. 1973;99-127.
2. Matheson I, Lunde PK, Bredesen JE. Midazolam and nitrazepam in the maternity ward: milk concentrations and clinical effects. Br J Clin Pharmacol. 1990;30:787-93. PubMed PMID: 2288825.

## Substance Identification

### Substance Name

Nitrazepam

### CAS Registry Number

146-22-5

### Drug Class

Breast Feeding

Lactation

Hypnotics and Sedatives

Anti-Anxiety Agents

Benzodiazepines