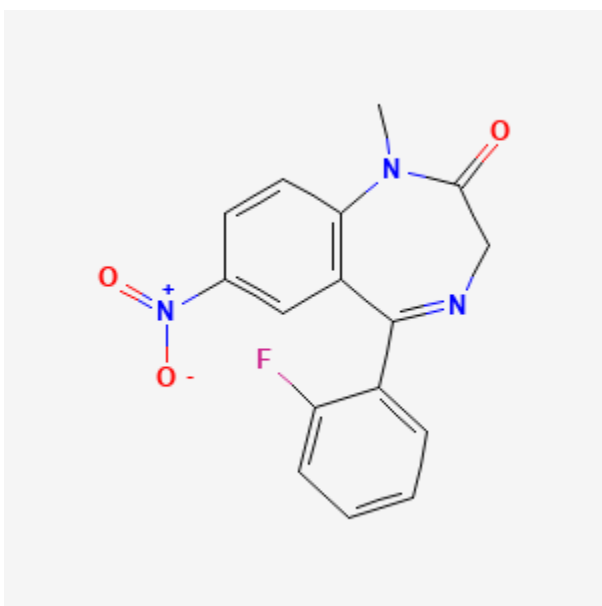




Flunitrazepam

Revised: January 15, 2024.

CASRN: 1622-62-4



Drug Levels and Effects

Summary of Use during Lactation

Flunitrazepam is not approved for marketing in the United States by the U.S. Food and Drug Administration. It is excreted into breastmilk and, because of its long half-life of about 20 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.[1] If flunitrazepam is used long-term, monitor the infant for sedation, poor feeding and poor weight gain. After a single dose of flunitrazepam, as for sedation before a procedure, there is usually no need to wait to resume breastfeeding, although with a newborn or preterm infant, a cautious approach would be to wait a period of 6 to 8 hours before resuming nursing.

Disclaimer: Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

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Drug Levels

Flunitrazepam is metabolized to the active metabolite norflunitrazepam.

Maternal Levels. Five nursing mothers were given a single oral dose of flunitrazepam 2 mg (66 mcg/kg) at 8 pm. Milk samples were collected 11, 15 and 27 hours later. The average flunitrazepam concentrations in milk were 2 mcg/L at 11 hours after the dose, 1.7 mcg/L at 15 hours after the dose, and 0.6 mcg/L at 27 hours after the dose. Norflunitrazepam was not detectable (<0.2 mcg/L) in milk at any of these times.[2,3] From these data, it is estimated that a fully breastfed infant would receive about 1% of the maternal weight-adjusted dosage.[4]

Two women who were taking oral flunitrazepam donated milk samples between 3 and 6 days postpartum at 2 hours after a dose at the estimated peak serum concentration and just before a dose. One woman who was taking a dose of 1 mg daily had a 2-hour milk level of 2.48 mcg/L and a trough milk level of 0.524 mcg/L. The other woman was taking a dose of 2 mg daily. She had a 2-hour milk level of 4.09 mcg/L and a trough milk level of 1.48 mcg/L. Norflunitrazepam was not measured.[5]

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

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

Alternate Drugs to Consider

Lorazepam, Oxazepam, Temazepam

References

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2. Kanto J, Aaltonen L, Kangas L, et al. Placental transfer and breast milk levels of flunitrazepam. *Curr Ther Res* 1979;26:539-46.
3. Kanto JH. Use of benzodiazepines during pregnancy, labour and lactation, with particular reference to pharmacokinetic considerations. *Drugs* 1982;23:354-80. PubMed PMID: 6124415.
4. Chisholm CA, Kuller JA. A guide to the safety of CNS-active agents during breastfeeding. *Drug Saf* 1997;17:127-42. PubMed PMID: 9285203.
5. 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.

Substance Identification

Substance Name

Flunitrazepam

CAS Registry Number

1622-62-4

Drug Class

Breast Feeding

Lactation

Milk, Human

Hypnotics and Sedatives

Anti-Anxiety Agents

Benzodiazepines