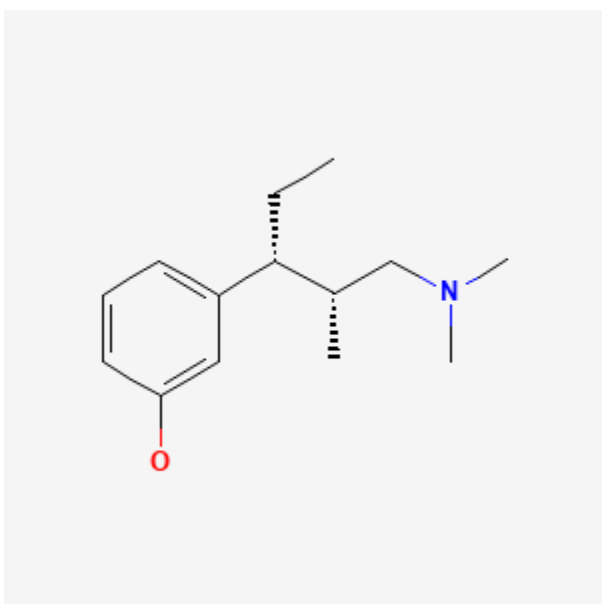




## Tapentadol

Revised: December 15, 2023.

CASRN: 175591-23-8



## Drug Levels and Effects

### Summary of Use during Lactation

Maternal use of oral opioids during breastfeeding can cause infant drowsiness, which may progress to rare but severe central nervous system depression. Newborn infants seem to be particularly sensitive to the effects of even small dosages of narcotic analgesics.[1] Little information is available on the use of tapentadol during breastfeeding. Because it has opioid agonist activity, an alternate drug is preferred, especially while nursing a newborn or preterm infant. Monitor infants for excess sedation and respiratory depression. If tapentadol is required by the mother of a newborn, it is not a reason to discontinue breastfeeding; however, once the mother's milk comes in, it is best to provide pain control with a nonnarcotic analgesic and limit maternal intake of oral tapentadol to 2 to 3 days at a low dose with close infant monitoring. If the baby shows signs of increased sleepiness (more than usual), difficulty breastfeeding, breathing difficulties, or limpness, a physician should be

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contacted immediately. Withdrawal symptoms can occur in breastfed infants when maternal administration of an opioid analgesic is stopped, or when breastfeeding is stopped.

## Drug Levels

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

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

## Effects in Breastfed Infants

The German manufacturer of tapentadol reports that they received 4 spontaneous reports of infant exposure to tapentadol in breastmilk, with no adverse reactions noted. Neither the age of the infants nor the extent of breastfeeding was reported. The dosage was known in only one of the mothers, which was 100 mg twice daily given rectally.[2]

## Effects on Lactation and Breastmilk

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

## Alternate Drugs to Consider

Acetaminophen, Butorphanol, Hydromorphone, Ibuprofen, Morphine

## References

1. Ito S. Opioids in breast milk: Pharmacokinetic principles and clinical implications. *J Clin Pharmacol* 2018;58 (Suppl 10):S151-S163. PubMed PMID: 30248201.
2. Stollenwerk A, Sohns M, Heisig F, et al. Review of post-marketing safety data on tapentadol, a centrally acting analgesic. *Adv Ther* 2018;35:12-30. PubMed PMID: 29270779.

## Substance Identification

### Substance Name

Tapentadol

### CAS Registry Number

175591-23-8

### Drug Class

Breastfeeding

Lactation

Milk, Human

Analgesic, Opioid

Narcotics