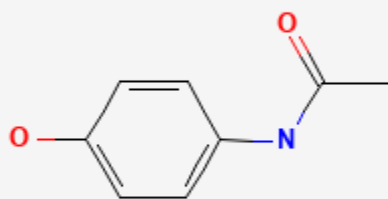




## Acetaminophen

Revised: June 15, 2024.

CASRN: 103-90-2



## Drug Levels and Effects

### Summary of Use during Lactation

Acetaminophen is a good choice for analgesia, and fever reduction in nursing mothers. Giving acetaminophen and ibuprofen on a fixed schedule for 24 hours after vaginal delivery appears to increase the breastfeeding rate. Amounts in milk are much less than doses usually given to infants. Adverse effects in breastfed infants appear to be rare.

### Drug Levels

*Maternal Levels.* A single oral dose of 650 mg of acetaminophen was given to 12 nursing mothers who were 2 to 22 months postpartum. Peak milk levels of 10 to 15 mg/L occurred between 1 and 2 hours after the dose in all

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patients. Acetaminophen was undetectable (<0.5 mg/L) in all mothers 12 hours after the dose. The authors calculated that an infant who ingested 90 mL of breastmilk every 3 hours would receive an average of 0.88 mg of acetaminophen or 0.14% (range 0.04 to 0.23%) of the mother's absolute dosage.[1] Using data from this study, an infant would receive a maximum of about 2% of the maternal weight-adjusted dosage.

Three women took a single 500 mg dose of acetaminophen. Peak milk levels averaging 4.2 mg/L occurred within 2 hours after the dose.[2] Using data from this study, an infant would receive a maximum of about 3.6% of the maternal weight-adjusted dosage.

Four women who were 2 to 8 months postpartum were given a single 1 gram dose of acetaminophen. Milk was completely emptied from one breast every 30 minutes for 3 to 3.5 hours, with a final sample from the opposite breast. Peak milk levels occurred between 1 and 2.5 hours after the dose. The acetaminophen level in the breast that was sampled only once had a lower level than the breast sampled at half-hour intervals. The authors estimated that a breastfed infant would receive an average of 1.1% and a maximum of 1.8% of the maternal weight-adjusted dosage. This dose is about 0.5% of the lowest recommended infant dose of acetaminophen.[3]

Eighteen women taking acetaminophen 500 mg orally postpartum pain donated a total of 20 milk samples for analysis at random times at 5 to 6 days postpartum. Milk concentrations ranged from 2.5 mcg/L at 68 hours after a dose to 13.5 mg/L at 0.8 hours after a dose. Levels were generally lower with increased time after a dose.[4] Note that this paper does not state the number of doses taken prior to sampling, so steady-state was not guaranteed. The pharmacokinetic analysis of samples was performed in an invalid way, and pharmacokinetic parameters reported in the paper are therefore not valid.

*Infant Levels.* No acetaminophen was detected in the urine of 12 breastfed infants aged 2 to 22 months after maternal ingestion of 650 mg of acetaminophen.[1]

Urine was collected for 1 to 3.5 hours after nursing in 6 infants aged 2 to 6 days whose mothers received 1 to 2 grams of acetaminophen 2 to 4 hours before nursing their infant. Infants excreted an average of 401 mcg of acetaminophen and its metabolites in urine during the collection interval. These neonates excreted a greater percentage of drug as acetaminophen and much less as the sulfate metabolite than in an adult comparison population.[3]

## Effects in Breastfed Infants

A maculopapular rash on the upper trunk and face of a 2-month-old infant was probably caused by acetaminophen in breastmilk. The rash occurred after 2 days of therapy in the mother at a dose of 1 gram at bedtime. It subsided when the drug was discontinued and recurred 2 weeks later after another acetaminophen dose of 1 gram was taken by the mother.[5]

Two papers report 14 women who breastfed after taking acetaminophen or its prodrug phenacetin with no adverse effects to their infants.[6,7]

In a telephone follow-up study, mothers reported no side effects among 43 infants exposed to acetaminophen in breastmilk.[8]

Two clinicians speculated that breastmilk exposure to acetaminophen during breastfeeding might be a risk factor for asthma and wheezing in the breastfed infants based on their personal observations.[9] However, these observations were uncontrolled and cannot be considered to be valid proof of an association.[10]

## Effects on Lactation and Breastmilk

A randomized study compared the use of ibuprofen 400 mg plus acetaminophen 1 gram every 6 hours for 24 hours to the same combination on demand after normal vaginal delivery. Women who received the analgesics on

a fixed schedule were more likely to breastfeed their baby (98% vs 88%) than those receiving analgesics on demand, even though their average pain scores were not different.[11]

## Alternate Drugs to Consider

Ibuprofen

## References

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## Substance Identification

### Substance Name

Acetaminophen

### CAS Registry Number

103-90-2

### Drug Class

Breast Feeding

Lactation

Milk, Human

Analgesics, Non-Narcotic