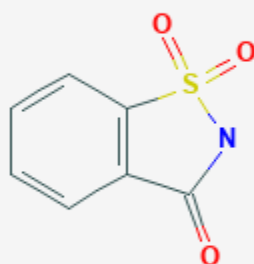




## Saccharin

Revised: February 7, 2019.

CASRN: 81-07-2



## Drug Levels and Effects

### Summary of Use during Lactation

Because of the low levels of saccharin in breastmilk, amounts ingested by the infant after typical maternal intake are small and would not be expected to cause any adverse effects in breastfed infants. However, some authors suggest that women may wish to limit the consumption of nonnutritive sweeteners while breastfeeding because their effect on the nursing infants are unknown.[1][2]

### Drug Levels

*Maternal Levels.* Six lactating women were given 126 mg of saccharin in the form of a 356 mL (12 fluidounces) soft drink every 6 hours for 9 doses. Plasma and breastmilk were sampled at 9 time points between 0 and 6 hours after the first and ninth doses. The peak milk concentration occurred 2 hours after both the first and ninth doses. Milk concentrations varied widely, ranging from <0.2 to 1.06 mg/L after the first dose up to as high as 1.8 mg/L

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after the ninth dose. The area under the milk concentration-time curve increased from 54% to 72% of the simultaneous serum concentration-time curve between the first and ninth doses, indicating some accumulation in milk over time. The average elimination half-life from milk was 15 hours on day 1 and 18 hours on day 3, although individual values varied widely.[3] Using the highest milk concentration in this study of 1.8 mg/L, an exclusively breastfed infant would receive a dose of 0.27 mg/kg daily which is much lower than the 5 mg/kg daily limit suggested by the United States Food and Drug Administration.

Twenty lactating women completed background questionnaires about breastfeeding and the intake of nonnutritive sweeteners in the prior 24 hours. Each then donated a milk sample that was analyzed for the presence of nonnutritive sweeteners. Sweetener intake was primarily from diet sodas and sweetener packets. Of the 14 women who reported intake of a nonnutritive sweetener, 4 had saccharin detectable in their breastmilk in concentrations ranging from 0.01 to 1.42 mg/L.[1]

*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

Aspartame

## References

1. Sylvetsky AC, Gardner AL, Bauman V et al. Nonnutritive sweeteners in breast milk. J Toxicol Environ Health A. 2015;78:1029-32. PubMed PMID: 26267522.
2. Rother KI, Sylvetsky AC, Schiffman SS. Non-nutritive sweeteners in breast milk: Perspective on potential implications of recent findings. Arch Toxicol. 2015;89:2169-71. PubMed PMID: 26462668.
3. Egan PC, Marx CM, Heyl PS et al. Saccharin excretion in mature human milk. Drug Intell Clin Pharm. 1984;18:511. Abstract.

## Substance Identification

### Substance Name

Saccharin

### CAS Registry Number

81-07-2

### Drug Class

Breast Feeding

Lactation

Artificial Sweeteners

Sweetening Agents