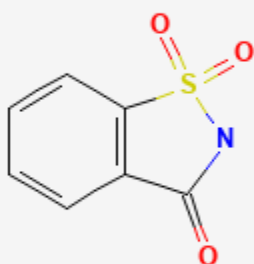




Saccharin

Revised: July 18, 2022.

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 and not likely to reach an intake greater than the acceptable daily intake.[1] Ingestion of diet drinks containing low-calorie sweeteners might increase the risk of vomiting 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.[2,3]

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Drug Levels

Maternal Levels. Six lactating women were given 126 mg of saccharin in the form of a 356 mL (12 fluid ounces) 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 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.[4] 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.[2]

Forty-nine women consumed a beverage containing 20 mg of saccharin. Normal and overweight women were about equally represented in the sample. Breastmilk samples were collected before the beverage and at 30, 60, 120, 180, 240, 300, and 360 minutes after the beverage. The average peak milk level in 46 of the women was 81.5 mcg/L and it occurred at 4 hours after the beverage.[5]

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

Effects in Breastfed Infants

A cross-sectional survey assessed the dietary history of US mothers nursing infants between 11 and 15 weeks of age. The survey was used to estimate the amount of diet soda and fruit drinks consumed by the women. There were no statistically significant differences in infants' weight or z-scores based on low calorie sweetener exposure. However, infants exposed to low calorie sweetener in milk once or less per week had a statistically significantly higher risk of vomiting than those who were not exposed. Greater exposure was not associated with vomiting. It was not possible to assess the effects of specific sweeteners.[6]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Aspartame

References

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Substance Identification

Substance Name

Saccharin

CAS Registry Number

81-07-2

Drug Class

Breast Feeding

Lactation

Milk, Human

Artificial Sweeteners

Sweetening Agents