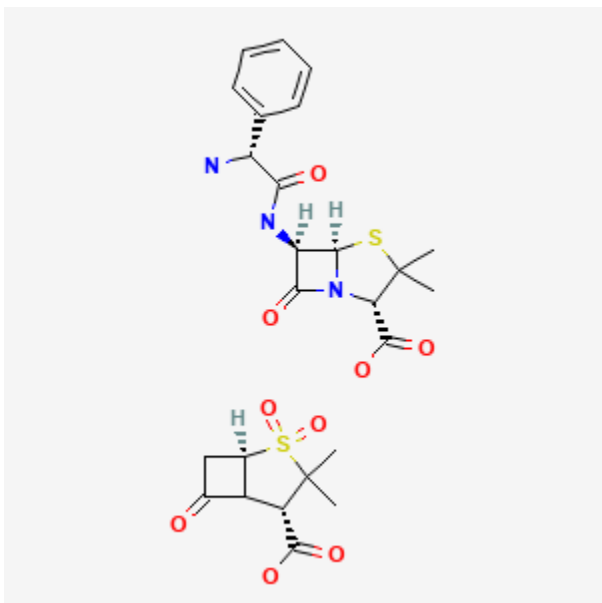




Ampicillin and Sulbactam

Revised: August 15, 2023.

CASRN: 94935-63-4



Drug Levels and Effects

Summary of Use during Lactation

Ampicillin-sulbactam produces low levels in milk that are not expected to cause adverse effects in breastfed infants. Occasionally, disruption of the infant's gastrointestinal flora, resulting in diarrhea or thrush, have been reported with penicillins, but these effects have not been adequately evaluated. Ampicillin-sulbactam is acceptable in nursing mothers.

Drug Levels

Maternal Levels. In 3 mothers who received intramuscular ampicillin 2 grams daily, milk levels ranged from 0.3 to 0.9 mg/L. In 3 mothers who received 4 grams daily intramuscularly, milk levels ranged from 0.4 to 0.9 mg/L.

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In all cases, peak milk levels occurred 3 hours after the dose. The breastfed infant was estimated to receive from 0.08 to 0.2 mg daily of ampicillin with these doses.[1]

In 15 women receiving ampicillin 500 mg 4 times daily by intramuscular injection, average milk ampicillin levels were as follows: 0.11 mg/L at 30 minutes after the injection; 0.21 mg/L at 1 hour, 0.17 at 2 hours, 0.27 mg/L at 4 hours and 0.26 mg/L at 6 hours after the injection.[2]

In 15 women given a single 2 gram dose of ampicillin intravenously, milk levels averaged 1.1 mg/L at 2 hours after the dose.[3]

A study in postpartum women with endometritis who received ampicillin 1 gram plus sulbactam 0.5 gram or ampicillin 2 grams plus 1 gram of sulbactam infused intravenously over 20 minutes found the average milk levels of ampicillin to be 1.7 mg/L with the highest level observed 3 mg/L. Sulbactam milk levels averaged 0.58 mg/L with the highest level observed 2.8 mg/L.[4]

Milk was collected at random times after 0.5 or 1 gram doses of sulbactam infused intravenously over 20 minutes. Little fluctuation occurred in milk levels over the first 8 hours after the dose with little difference in milk levels between the two dosages. Milk levels averaged 0.52 mg/L during this period with the highest level being 2.8 mg/L. Other levels from 10.5 to 20.5 hours after the dose ranged from 0.12 to 1.2 mg/L.[5] It is unclear whether some of the patients in this report were the same as those in reference[4].

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

Effects in Breastfed Infants

Relevant published information on ampicillin and sulbactam was not found as of the revision date; however, there are data on ampicillin alone. In a prospective follow-up study, 5 nursing mothers reported taking oral ampicillin (dosage unspecified). One mother reported diarrhea in her infant. No rashes or candidiasis were reported among the exposed infants.[6]

A small, controlled, prospective study had mothers taking ampicillin monitor their infants for signs of adverse effects (furring of the tongue, feeding difficulties, changes in stool frequency and consistency, diaper rash, and skin rash). Weight change and the development of jaundice were also recorded. No statistical differences in these parameters were found between the infants of the control mothers and those of mothers taking oral ampicillin.[7]

Effects on Lactation and Breastmilk

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

References

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Substance Identification

Substance Name

Ampicillin and Sulbactam

CAS Registry Number

94935-63-4

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents

Anti-Bacterial Agents

Penicillins

beta-Lactamase Inhibitors