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**Sulbactam and Durlobactam** 

Revised: August 15, 2023.

CASRN: 68373-14-8; 1467829-71-5

SID: 390610971; 394527098

# **Drug Levels and Effects**

# Summary of Use during Lactation

Sulbactam produces low levels in milk that are not expected to cause adverse effects in breastfed infants. It is likely that durlobactam produces similar levels in milk. 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. Sulbactam-durlobactam is acceptable in nursing mothers.

### **Drug Levels**

Maternal Levels. No information is available about the passage of durlobactam into milk.

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.[1]

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.[2] It is unclear whether some of the patients in this report were the same as those in reference[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.

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## **Effects on Lactation and Breastmilk**

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

#### References

- 1. Foulds G, Miller RD, Stankewich JP, et al. The pharmacokinetics of subactam and ampicillin in postpartum women. In, Spitzy KH, Karrer K, eds. Proc 13th Int Congress Chemother 1983;1:23/17-23/22.
- 2. Foulds G, Miller D, Knirsch AK, Thrupp LD. Sulbactam kinetics and excretion into breast milk in postpartum women. Clin Pharmacol Ther 1985;38:692-6. PubMed PMID: 2998677.

# **Substance Identification**

## **Substance Name**

Sulbactam and Durlobactam

# **CAS Registry Number**

68373-14-8; 1467829-71-5

# **Drug Class**

Breast Feeding Lactation Milk, Human Anti-Infective Agents Anti-Bacterial Agents Penicillins beta-Lactamase Inhibitors