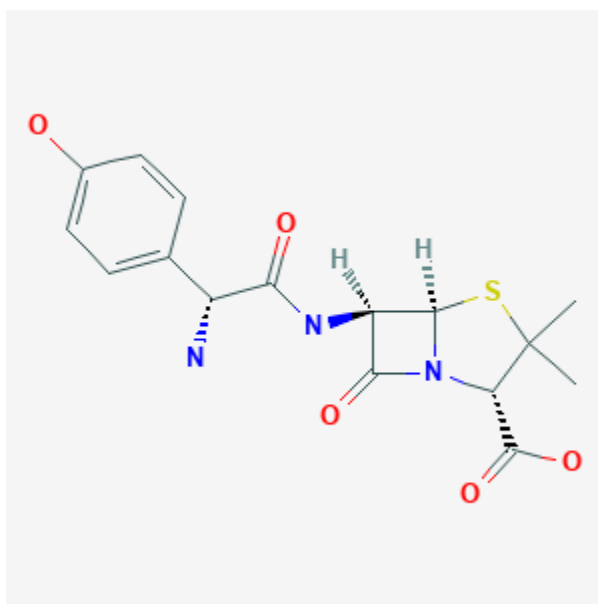




Amoxicillin

Revised: October 31, 2018.

CASRN: 26787-78-0



Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that amoxicillin produces low levels in milk that are not expected to cause adverse effects in breastfed infants. Occasionally, rash and disruption of the infant's gastrointestinal flora, resulting in diarrhea or thrush, have been reported, but these effects have not been adequately evaluated. Amoxicillin is acceptable in nursing mothers. Amoxicillin powder for suspension reconstituted with breastmilk is absorbed as well as the powder reconstituted with water.[1]

Drug Levels

Maternal Levels. After a single 1 gram oral dose of amoxicillin in 6 women, peak milk amoxicillin levels occurred 4 to 5 hours after the dose. Average milk levels were 0.69 mg/L (range 0.46 to 0.88 mg/L) at 4 hours and 0.81 mg/L (range 0.39 to 1.3 mg/L) at 5 hours after the dose.[2] Using these data, an exclusively breastfed infant

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would be expected to receive a maximum daily dosage of about 0.1 mg/kg of amoxicillin with a maternal dose of 500 mg three times daily. This amounts to 0.25 to 0.5% of a typical infant amoxicillin dosage.

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

Effects in Breastfed Infants

In a telephone follow-up study, 25 nursing mothers reported taking amoxicillin (dosage unspecified). Three mothers reported diarrhea in their infants. No rashes or candidiasis were reported among the exposed infants. [3]

In contrast, a small, controlled, prospective study had mothers 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 the related antibiotics, ampicillin or ampicillin-clavulanate.[4]

A prospective, controlled study asked mothers who called an information service about adverse reactions experienced by their breastfed infants. Of 40 infants exposed to amoxicillin in breastmilk, 2 developed diarrhea and 1 developed a rash.[5]

A study compared the breastfed infants of mothers taking amoxicillin to those taking a macrolide antibiotic. Adverse reactions occurred in 8.3% of the infants exposed to amoxicillin which was similar to the rate in macrolide-exposed infants. Reactions included rash and somnolence.[6]

A 2-month-old infant breastfed since birth. His mother had taken many medications during pregnancy, but she did not recall their identity. She developed mastitis and was treated with amoxicillin/clavulanic acid 1 gram orally every 12 hours and gentamicin 160 mg intramuscularly once daily. The infant was breastfed for 10 minutes starting 15 minutes after the first dose of both drugs. About 20 minutes later, the infant developed a generalized urticaria which disappeared after 30 minutes. A few hours later, the infant breastfed again and the urticaria reappeared after 15 minutes and disappeared after an hour. After switching to formula feeding and no further infant exposure to penicillins, the reaction did not reappear with follow-up to 16 months of age. The adverse reaction was probably caused by the antibiotics in breastmilk. The drug that caused the reaction cannot be determined, but it was most likely the amoxicillin/clavulanic acid.[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

Amoxicillin

CAS Registry Number

26787-78-0

Drug Class

Breast Feeding

Lactation

Anti-infective Agents

Antibacterial Agents

Penicillins