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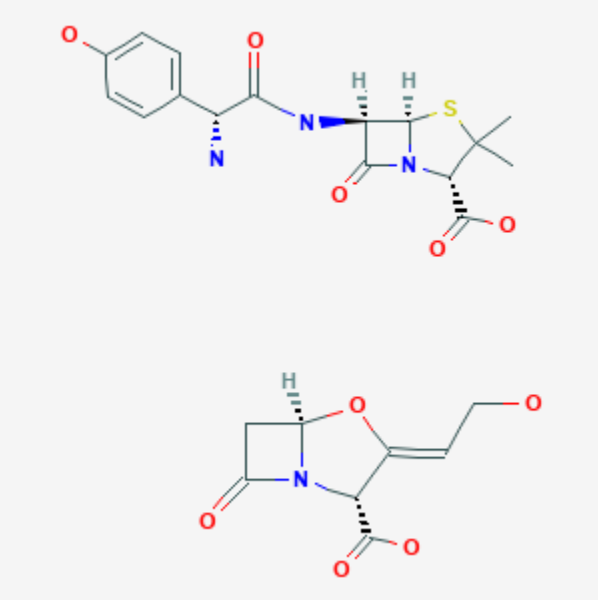
NLM Citation: Drugs and Lactation Database (LactMed) [Internet]. Bethesda (MD): National Library of Medicine (US); 2006-. Amoxicillin and Clavulanic Acid. [Updated 2018 Oct 31].
Bookshelf URL: https://www.ncbi.nlm.nih.gov/books/

Amoxicillin and Clavulanic Acid

Revised: October 31, 2018.

CASRN: 79198-29-1



Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that adverse reactions in infants are uncommon during the use of amoxicillin-clavulanic acid during nursing, with restlessness, diarrhea and rash occurring occasionally. Amoxicillin-clavulanic acid is acceptable in nursing mothers.

Drug Levels

Maternal Levels. After a single 1 g oral dose of amoxicillin (without clavulanic acid) 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.[1] Using these data, an exclusively breastfed infant would be expected to receive a maximum of about 0.1 mg/kg daily of amoxicillin

with a maternal amoxicillin-clavulanate dose of 500 mg 3 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

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 the 14 mothers taking amoxicillin-clavulanate.[2]

A prospective, controlled study asked mothers who called an information service about adverse reactions experience by their breastfed infants. Mothers were taking either amoxicillin or amoxicillin-clavulanic acid. Overall, adverse reactions in the infants were statistically more frequent in the amoxicillin-clavulanic acid group (22.3%) than in the amoxicillin group (7.5%) and the rate of adverse effects was dose-related. Amoxicillin-clavulanate reactions consisted of restlessness (8.9%), diarrhea (5.9%), rash (5.9%), and constipation (1.5%), although no single adverse effect was statistically more frequent than in the amoxicillin group. One infant whose mother was taking 1.5 g daily of amoxicillin-clavulanic acid developed mildly elevated liver enzymes (AST and ALT) during maternal therapy that returned to normal 10 days after discontinuation of the drug.[3]

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.[4]

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 and Clavulanic Acid

CAS Registry Number

79198-29-1

Drug Class

Breast Feeding

Lactation

Anti-infective Agents

Antibacterial Agents

Penicillins