

clarithromycin milk level was 0.85 mg/L at 2.2 hours after the dose; the peak 14-hydroxyclearithromycin level was 0.63 mg/L at 2.8 hours after the dose. Respective trough values were 0.21 and 0.36 mg/L. The half-lives of the drug and metabolite were 4.3 hours 9 hours, respectively.[1] Using the milk level data from this study, an exclusively breastfed infant would receive an estimated average of about 136 mcg/kg daily of drug plus metabolite with a maternal dosage of 500 mg daily. This dosage is less than 1% of the recommend pediatric (<6 months) dosage, and is about 1.7% of the maternal weight-adjusted dosage.

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

Effects in Breastfed Infants

A cohort study of infants diagnosed with infantile hypertrophic pyloric stenosis found that affected infants were 2.3 to 3 times more likely to have a mother taking a macrolide antibiotic during the 90 days after delivery. Stratification of the infants found the odds ratio to be 10 for female infants and 2 for male infants. All of the mothers of affected infants nursed their infants. Most of the macrolide prescriptions were for erythromycin, but only 1.7% were for clarithromycin. However, the authors did not state which macrolide was taken by the mothers of the affected infants.[2]

A study comparing the breastfed infants of mothers taking amoxicillin to those taking a macrolide antibiotic found no instances of pyloric stenosis. However, most of the infants exposed to a macrolide in breastmilk were exposed to roxithromycin. Only 6 of the 55 infants exposed to a macrolide were exposed to clarithromycin. Adverse reactions occurred in 12.7% of the infants exposed to macrolides which was similar to the rate in amoxicillin-exposed infants. Reactions included rash, diarrhea, loss of appetite, and somnolence.[3]

A retrospective database study in Denmark of 15 years of data found a 3.5-fold increased risk of infantile hypertrophic pyloric stenosis in the infants of mothers who took a macrolide during the first 13 days postpartum, but not with later exposure. The proportion of infants who were breastfed was not known, but probably high. The proportion of women who took each macrolide was also not reported.[4]

Two meta-analyses failed to demonstrate a relationship between maternal macrolide use during breastfeeding and infantile hypertrophic pyloric stenosis.[5][6]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Azithromycin, Erythromycin

References

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Substance Identification

Substance Name

Clarithromycin

CAS Registry Number

81103-11-9

Drug Class

Breast Feeding

Lactation

Anti-Bacterial Agents

Anti-Infective Agents

Macrolides