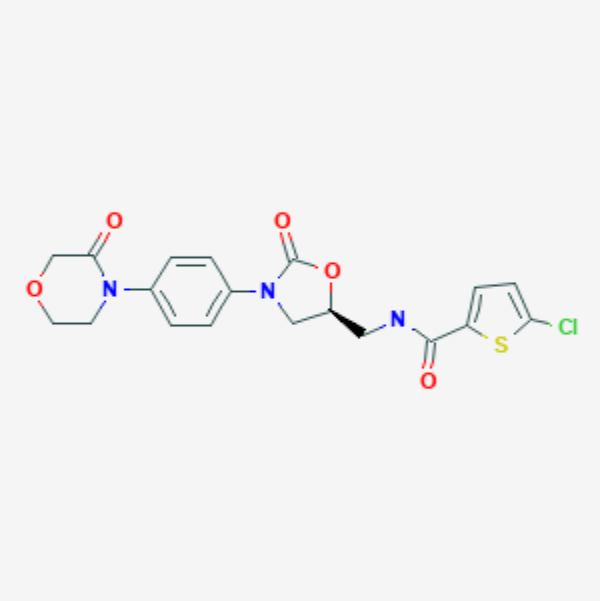
U.S. National Library of Medicine
National Center for Biotechnology Information

NLM Citation: Drugs and Lactation Database (LactMed) [Internet]. Bethesda (MD): National Library of Medicine (US); 2006-. Rivaroxaban. [Updated 2020 Jan 20].
Bookshelf URL: https://www.ncbi.nlm.nih.gov/books/

Rivaroxaban

Revised: January 20, 2020.

CASRN: 366789-02-8



Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that a maternal dose of rivaroxaban of 30 mg daily produces low levels in milk. If rivaroxaban is required by the mother, it is not a reason to discontinue breastfeeding. However, until more data become available, an alternate drug may be preferred, especially while nursing a newborn or preterm infant.[1,2]

Drug Levels

Maternal Levels. A 40-year-old woman developed bilateral pulmonary embolism and peripartum cardiomyopathy following cesarean section. She initially received enoxaparin, but was switched to oral rivaroxaban 15 mg twice daily after 2 days. On day 3 of rivaroxaban, complete milk collections from both breasts were obtained before and at 3, 6, and 10 hours after the morning dose. Blood samples were taken at the same

times. The authors calculated that a fully breastfed infant would receive 2.4 mcg/kg over the 10-hour period, which would be 1.3% of the maternal weight-adjusted dosage.[3]

A 38-year-old woman woman with antiphospholipid syndrome began rivaroxaban 15 mg (0.19 mg/kg) daily at 5 days postpartum for prophylaxis of deep vein thrombosis. On two separate days, 7 samples of milk were taken over a 24-hour period. Values were similar at the same times on each day. A mean peak value of 53.9 mcg/L occurred at 6 hours after the dose and the average milk concentration was 22.7 mcg/L. The half-life in milk was 4.7 hours. The estimated daily dose that a fully breastfed infant would receive was 3.4 mcg/kg daily, which corresponded to 1.8% of the maternal weight-adjusted dosage.[4]

Two postpartum women were prescribed rivaroxaban, one for stroke and the other for a pulmonary embolism. Each began therapy with 15 mg twice daily for 21 days, then 20 mg daily. Both patients provided several steady-state milk samples over the dosage interval during each regimen. After the 15 mg dose, a mean peak value of 300 mcg/L occurred 1 hour after the dose and the average milk concentration was 160 mcg/L. The estimated daily dose that a fully breastfed infant would receive was 10 mcg/kg every 12 hours, which corresponded to 5% of the maternal weight-adjusted dosage. After the 20 mg dose, the mean peak value of 260 mcg/L occurred 2 hours after the dose and the average milk concentration was 70 mcg/L. The estimated daily dose that a fully breastfed infant would receive was 10 mcg/kg daily, which corresponded to 4% of the maternal weight-adjusted dosage.[5]

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

Effects in Breastfed Infants

A 38-year-old woman woman with antiphospholipid syndrome began rivaroxaban 15 mg (0.19 mg/kg) daily at 5 days postpartum for prophylaxis of deep vein thrombosis. She partially breast-fed her infant (at least 50%). No apparent evidence of bleeding was noted in the infant at 1- and 3-month check-ups and development was normal at 18 months of age.[4]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Acenocoumarol, Dalteparin, Enoxaparin, Heparin, Warfarin

References

1. Bates SM, Greer IA, Middeldorp S, et al. VTE, thrombophilia, antithrombotic therapy, and pregnancy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2012;141 (2 Suppl):e691S-736S.
2. Cohen H, Arachchillage DR, Beyer-Westendorf J, et al. Direct oral anticoagulants and women. Semin Thromb Hemost. 2016;42:789–97. PubMed PMID: 27706531.
3. Wiesen MH, Blaich C, Muller C, et al. The direct factor Xa inhibitor rivaroxaban passes into human breast milk. Chest. 2016;150:e1–4. PubMed PMID: 27396794.
4. Saito J, Kaneko K, Yakuwa N, et al. Rivaroxaban concentration in breast milk during breastfeeding: A case study. Breastfeed Med. 2019;14:748–51. PubMed PMID: 31746638.
5. Muysson M, Marshall K, Datta P, et al. Rivaroxaban treatment in two breastfeeding mothers: A case series. Breastfeed Med. 2020;15:41–3. PubMed PMID: 31532233.

Substance Identification

Substance Name

Rivaroxaban

CAS Registry Number

366789-02-8

Drug Class

Breast Feeding

Lactation

Anticoagulants