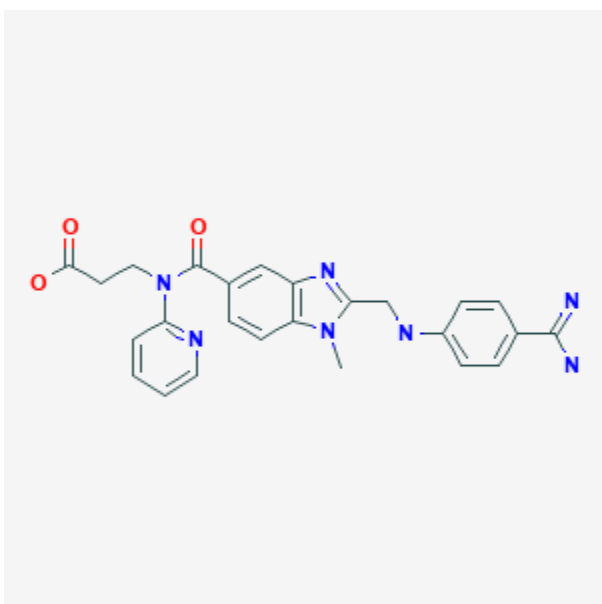




Dabigatran

Revised: January 20, 2020.

CASRN: 211914-51-1



Drug Levels and Effects

Summary of Use during Lactation

In adults, less than 7% of dabigatran is absorbed orally in its prodrug form of dabigatran etexilate mesylate; dabigatran itself is not absorbed orally. Preliminary data from 2 individuals indicate that dabigatran is poorly excreted into breastmilk and unlikely to affect the breastfed infant. However, because no information is available on the effect in breastfed infants, some expert opinion (given prior to the study on the drug excretion into milk) suggests that an alternate drug is preferred while nursing a newborn or preterm infant.[1,2]

Drug Levels

Maternal Levels. In preliminary results from a study on dabigatran in breastmilk, two patients received oral dabigatran etexilate 220 mg (2.5 and 2.7 mg/kg dabigatran). Dabigatran was first detectable in milk 2 to 3 hours after the dose. Peak milk levels occurred at 7 hours after the dose in one subject and at an estimated 171 hours in

the other subject. Milk concentrations at this time were 8.2 mcg/L and 52.6 mcg/L, respectively. These peak values represent maximum weight-adjusted percentages of maternal dose of 0.05% and 0.29%. Average maximum estimated doses were 0.35 and 2.7 mcg/kg, respectively.[3]

Infant Levels. Measurements of dabigatran in infant plasma after breastfeeding have not been made. However, if the amount present in breastmilk after a 200 mg dose of oral dabigatran etexilate were completely absorbed by a breastfed infant, investigators estimate that infant plasma levels would be less than 0.01 ng/L on days 1, 3 and 5 postpartum.[3]

Effects in Breastfed Infants

Samples of newborn and preterm infant blood spiked with the concentrations of dabigatran found in breastmilk after a 220 mg dose of dabigatran etexilate indicate that no effect on coagulation would occur.[3]

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. Vanassche T, Vandenbrielle C, Peerlinck K, et al. Pharmacotherapy with oral Xa inhibitors for venous thromboembolism. *Expert Opin Pharmacother.* 2015;16:645–58. PubMed PMID: 25554350.
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. Ayuk P, Kampouraki E, Truemann A, et al. Investigation of dabigatran secretion into breast milk: Implications for oral thromboprophylaxis in post-partum women. *Am J Hematol.* 2020;95:E10–E13. PubMed PMID: 31599003.

Substance Identification

Substance Name

Dabigatran

CAS Registry Number

211914-51-1

Drug Class

Breast Feeding

Lactation

Anticoagulants

Antithrombins