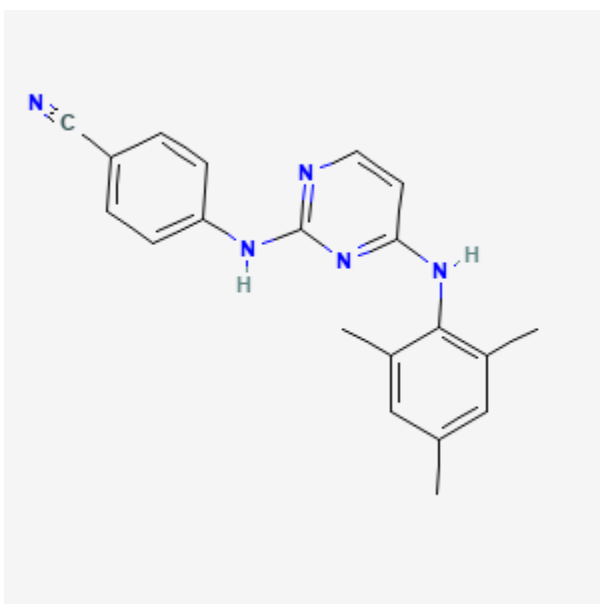




Dapivirine

Revised: February 15, 2024.

CASRN: 244767-67-7



Drug Levels and Effects

Summary of Use during Lactation

Dapivirine is investigational in the United States, but available overseas as a vaginal ring for pre-exposure prophylaxis of HIV infections (PrEP). In this dosage form, it is acceptable to use during breastfeeding.

Drug Levels

Maternal Levels. Sixteen lactating women who had weaned their infants used the dapivirine vaginal ring for 14 days and provided milk, blood and cervicovaginal fluid samples for analysis. Milk samples were obtained on days 0, 1, 7 and 14 during use of the insert and on day 16, two days after its removal. The mean breastmilk

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concentration was 676 ng/L (range 297 to 1,420 ng/L). This translated to an estimated average infant dosage of 74.3 ng/kg daily. The average half-life in milk was 45.8 hours.[1]

A clinical trial compared the dapivirine vaginal ring 25 mg monthly to emtricitabine and tenofovir disoproxil fumarate as prophylaxis against HIV infection. In women randomized to dapivirine (n = 148), dapivirine concentrations in breastmilk averaged 698.3 ng/L during the first week of use and trended downward to 596.1 ng/L in the third month of use. At 2 weeks after discontinuation, milk dapivirine averaged 50.1 ng/L.[2]

Infant Levels. A clinical trial compared the dapivirine vaginal ring 25 mg monthly to emtricitabine and tenofovir disoproxil fumarate as prophylaxis against HIV infection. In the infants of women randomized to dapivirine (n = 148), dapivirine was detected in 15% of infants' serum after 2 weeks of use, with an average concentration of 14.5 ng/L. In the third month of use, the drug was detectable in the serum of only 5.1% of infants with an average concentration of 10.7 ng/L. At 2 weeks after drug discontinuation, no infants had detectable dapivirine in their serum.[2]

Effects in Breastfed Infants

A study compared the dapivirine vaginal ring to emtricitabine plus tenofovir for prophylaxis of HIV infections. Of 148 mother-infant pairs who received the dapivirine vaginal ring, no adverse effects in infants were attributed to dapivirine.[3]

Effects on Lactation and Breastmilk

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

References

1. Noguchi LM, Hoesley C, Kelly C, et al. Pharmacokinetics of dapivirine transfer into blood plasma, breast milk, and cervicovaginal fluid of lactating women using the dapivirine vaginal ring. *Antimicrob Agents Chemother* 2019;63:e01930-18. PubMed PMID: 30602513.
2. Owor M, Noguchi L, Horne E, et al. Dapivirine ring safety and drug detection in breastfeeding mother-infant pairs. In *Special Issue: Abstracts From CROI 2023 Conference on Retroviruses and Opportunistic Infections*. *Top Antiviral Med* 2023;31:314.
3. Noguchi L, Owor M, Gati B, et al. Phase 3B, randomized, open-label, safety study of dapivirine vaginal ring and oral emtricitabine 200mg/tenofovir disoproxil fumarate 300 mg tablet in breastfeeding mother-infant pairs. *J Int AIDS Soc* 2022;25 (Suppl 3):e25935. PubMed PMID: 35916394.

Substance Identification

Substance Name

Dapivirine

CAS Registry Number

244767-67-7

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents

Antiviral Agents

Anti-HIV Agents

Anti-Retroviral Agents

Reverse Transcriptase Inhibitors