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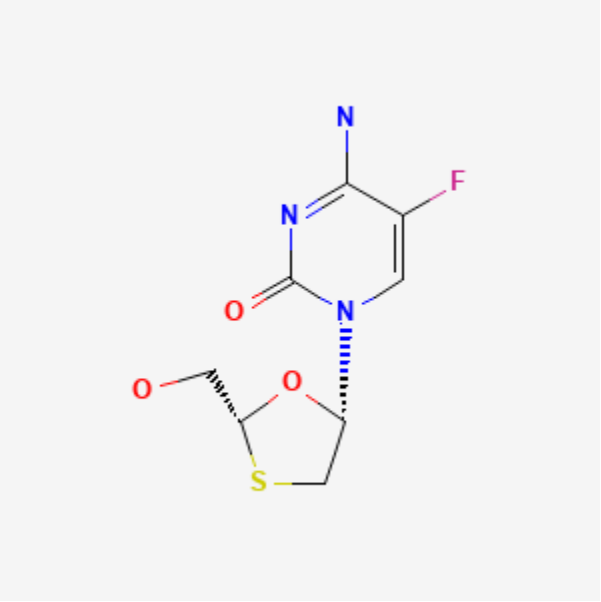
Emtricitabine

Revised: February 15, 2024.

CASRN: 143491-57-0



Drug Levels and Effects

Summary of Use during Lactation

Emtricitabine has been relatively well studied during breastfeeding and it is sometime used in treating HIV-positive mothers who are breastfeeding. Achieving and maintaining viral suppression with antiretroviral therapy decreases breastfeeding transmission risk to less than 1%, but not zero. Individuals with HIV who are on antiretroviral therapy with a sustained undetectable viral load and who choose to breastfeed should be supported in this decision. If a viral load is not suppressed, banked pasteurized donor milk or formula is recommended. [1,2]

For use in treating maternal hepatitis B, no difference exist in infection rates between breastfed and formula-fed infants born to hepatitis B-infected women, as long as the infant receives hepatitis B immune globulin and

hepatitis B vaccine at birth. Mothers with hepatitis B are encouraged to breastfeed their infants after their infants receive these preventative measures.[3,4] With HIV pre-exposure prophylaxis with tenofovir 200 mg and emtricitabine 300 mg, infants receive only about 0.5% of a therapeutic dose of emtricitabine. During long-term maternal use of emtricitabine 200 mg daily, breastfed infants usually have undetectable blood concentrations.

Drug Levels

Maternal Levels. Five exclusively breastfeeding mothers received oral emtricitabine 200 mg plus tenofovir 300 mg and nevirapine 200 mg at the start of labor, then oral emtricitabine 200 mg and tenofovir 300 mg daily for 7 days postpartum. A total of 16 concurrent maternal blood and milk samples were collected on days 1, 2, 3, and 7 postpartum between 10 minutes and 21 hours after the mothers' doses. Median peak and trough emtricitabine concentrations in breastmilk were 679 mcg/L and 177 mcg/L, respectively. The authors estimated that an exclusively breastfed infant would receive about 2% of the proposed infant dose for emtricitabine and achieve infant serum concentrations that might result in the emergence of viral resistance to emtricitabine.[5]

Fifty HIV-negative women who were nursing their infants were given pre-exposure prophylaxis daily with the combination of tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg by directly observed therapy for 10 days. On days 7 and 10 of therapy, peak milk samples were obtained 1 to 2 hours after a dose and trough samples were obtained 23 to 24 hours after the previous dose. The median peak milk emtricitabine concentration was 212.5 mcg/L and the trough concentration was 183 mcg/L. These values represent an estimated daily dosage of 27.5 to 31.5 mcg/kg, which is approximately 0.5% of the proposed infant therapeutic dosage.[6]

Emtricitabine was measured in 6 HIV-positive nursing mothers after a 300 mg dose during ongoing therapy. The peak breastmilk level was 872 mcg/L (range 696 to 1063 mcg/L) at a median of 3 hours.[7]

Sixteen Nigerian women took emtricitabine 200 mg once daily as part of a combination therapy for HIV. Expressed milk samples were taken before the dose and at 0.5, 1, 2, 4, 8 and 12 hours after the dose. The median peak breastmilk concentration from dried breastmilk spots was 843 mcg/L (IQR 702 to 1132 mcg/L) at a median of 4 hours after the dose (IQR 2 to 8 hours).[8]

Twenty-nine mothers taking emtricitabine 200 mg once daily provided milk samples at a median of 15.5 hours after a dose. The median drug concentration in milk was 803 mcg/L, which resulted in an estimated infant dosage of 120 mcg/kg daily and a relative infant dose of 4.02% of the maternal weight-adjusted dosage.[9]

Infant Levels. Fifty HIV-negative women who were nursing their infants were given pre-exposure prophylaxis daily with the combination of tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg by directly observed therapy for 10 days. A single infant blood sample was obtained after the mother's 7th dose. Of 49 infant blood samples collected, 47 had detectable concentrations of emtricitabine, with a median plasma concentration of 13.2 mcg/L. Infants under 13 weeks of age had a statistically significant lower plasma concentration than those who were 13 weeks of age or older, 16.6 mcg/L and 10.5 mcg/L, respectively.[6]

Emtricitabine 300 mg daily was given to 6 HIV-positive nursing mothers. One breastfed infant had a detectable emtricitabine serum level of 17.5 mcg/L.[7]

Sixteen Nigerian women took emtricitabine 200 mg once daily as part of a combination therapy for HIV. Their exclusively breastfed infants were fed on demand and had blood samples taken at 2 and 8 hours after the dose. Dried blood spots were analyzed and only 3 samples contained quantifiable (>16.6 mcg/L) blood levels of 17.5, 18.8, and 19.4 mcg/L.[8]

Eleven infants were breastfed by mothers taking _, although the extent of breastfeeding was not sated. Infant serum concentrations taken 2 to 20 hours after maternal drug intake at 1 month of age ranged from 0 to 49 mcg/L.[9]

Effects in Breastfed Infants

In a study of 50 infants breastfed by HIV-negative women who were given pre-exposure prophylaxis daily with the combination of tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg by directly observed therapy for 10 days, 2 infants reportedly had diarrhea lasting 2 to 3 days. No other side effects were reported.[6]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Hepatitis B) Lamivudine, Tenofovir

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Substance Identification

Substance Name

Emtricitabine

CAS Registry Number

143491-57-0

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents

Antiviral Agents

Anti-HIV Agents

Anti-Retroviral Agents

Reverse Transcriptase Inhibitors