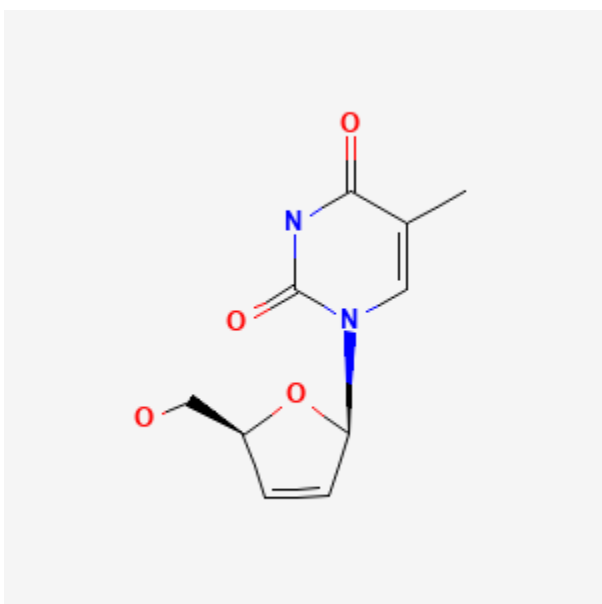




Stavudine

Revised: February 15, 2024.

CASRN: 3056-17-5



Drug Levels and Effects

Summary of Use during Lactation

Stavudine is not a recommended agent during breastfeeding.[1,2] 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.[3,4]

Disclaimer: Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

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Drug Levels

Maternal Levels. One study measured stavudine in breastmilk samples from nursing mothers who had been randomized to receive the drug as part of a clinical trial to evaluate maternal to child transmission of HIV infection. The dosages, dosage regimens and time of breastmilk sample collection times were not reported. The stavudine milk to plasma ratio was found to be 1.73 in 2 patients.[5]

Fifty-two mothers who were taking stavudine either 30 mg (<60 kg) or 40 mg (>60 kg) twice daily had milk samples analyzed for stavudine. Exact timing of the previous dose was not available. Stavudine was detectable in 44 samples of whole milk and 45 samples of skim milk. The median stavudine concentrations were 151 mcg/L in whole milk and 190 mcg/L in skim milk. The average infant intake of stavudine via breastmilk was estimated to be 22.7 mcg/kg daily.[6]

Twenty-eight mothers who were receiving stavudine 30 mg twice daily as part of a combination antiretroviral regimen provided a total of 93 milk samples at birth, 1 month, 3 months and/or 6 months postpartum. Milk samples were collected at a median of 4.5 hours (range 3.5 to 6 hours) after the previous dose. The median breastmilk stavudine concentration was 105 mcg/L (range 34 to 117 mcg/L).[7]

Infant Levels. Fifty-two infants whose mothers who were taking stavudine either 30 mg (<60 kg) or 40 mg (>60 kg) twice daily had blood samples analyzed for stavudine. Exact timing of the mothers' previous dose was not available. Stavudine was undetectable (<5 mcg/L) in all but 7 of the infants with an estimated stavudine intake from milk of 22.7 mcg/kg daily. In the 7 infants who had detectable serum concentrations, all had serum concentrations less than 10 mcg/L and their median serum concentration was 5% (range 1 to 15%) of their mothers' serum concentration.[5]

Breastfed infants of 28 mothers who were receiving stavudine 30 mg twice daily as part of a combination antiretroviral regimen had a total of 30 blood samples analyzed at 1 month, 3 months and/or 6 months postpartum. Samples were collected at a median of 4.5 hours (range 3.5 to 6 hours) after the previous maternal dose and a median of 30 minutes (range 20 to 60 minutes) after the previous nursing. The infants' stavudine plasma concentrations ranged from 0 to 2.5 mcg/L, which was a median of 4% (range 0 to 8%) of the maternal serum concentration.[7]

Effects in Breastfed Infants

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

Effects on Lactation and Breastmilk

Gynecomastia has been reported among men receiving highly active antiretroviral therapy. Gynecomastia is unilateral initially, but progresses to bilateral in about half of cases. No alterations in serum prolactin were noted and spontaneous resolution usually occurred within one year, even with continuation of the regimen.[8-10] Some case reports and in vitro studies have suggested that protease inhibitors might cause hyperprolactinemia and galactorrhea in some male patients,[11,12] although this has been disputed.[13] One case series found an incidence of gynecomastia of 2.4 cases per person annually among men receiving highly active antiretroviral therapy; 70% of the affected patients were taking stavudine. Gynecomastia was unilateral initially, but progressed to bilateral in 53% of cases. No alterations in serum prolactin were noted and spontaneous resolution usually occurred within one year, even with continuation of the regimen.[8] The relevance of these findings to nursing mothers is not known. The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Alternate Drugs to Consider

Lamivudine, Nelfinavir, Nevirapine, Zidovudine

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Substance Identification

Substance Name

Stavudine

CAS Registry Number

3056-17-5

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents

Antiviral Agents

Anti-HIV Agents

Anti-Retroviral Agents

Reverse Transcriptase Inhibitors