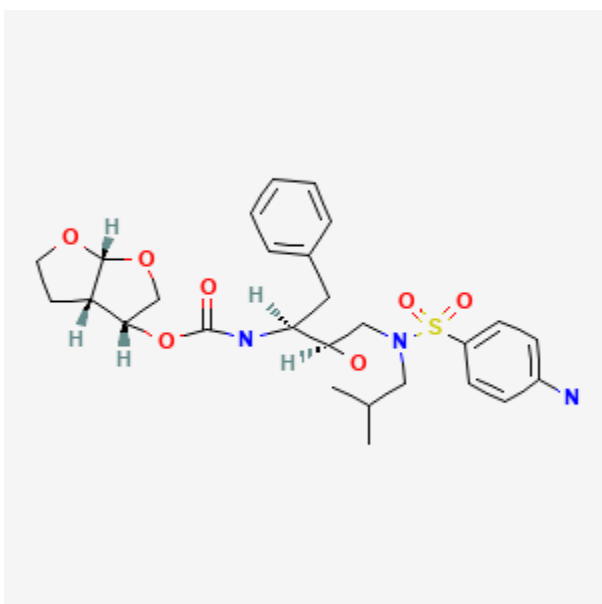




Darunavir

Revised: February 15, 2024.

CASRN: 618109-00-5



Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that maternal doses of darunavir up to 800 mg daily with ritonavir produce low to unmeasurable levels in milk and would not be expected to cause any adverse effects in breastfed infants. The combination of darunavir and cobicistat is expected to produce similar results. 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]

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. Four mothers taking darunavir 800 mg plus ritonavir 100 mg once daily provided milk samples at a median of 15.4 hours after a dose. The median drug concentration in milk was 316 mcg/L, which resulted in an estimated infant dosage of 50 mcg/kg daily and a relative infant dose of 0.12% of the maternal weight-adjusted dosage.[3]

Infant Levels. An infant was breastfed by a mother taking darunavir 800 mg plus ritonavir 100 mg once daily, although the extent of breastfeeding was not stated. The infant's serum concentrations taken 16 hours after maternal drug intake at 1 month of age was undetectable.[3]

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.[4-6] Some case reports and in vitro studies have suggested that protease inhibitors might cause hyperprolactinemia and galactorrhea in some male patients,[7,8] although this has been disputed.[9] 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.

References

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Substance Identification

Substance Name

Darunavir

CAS Registry Number

618109-00-5

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents

Antiviral Agents

Anti-HIV Agents

Anti-Retroviral Agents

HIV Protease Inhibitors