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Bictegravir

Revised: February 15, 2024.

CASRN: 1611493-60-7

Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that maternal bictegravir 50 mg once daily produce low levels in milk and infant serum. Until more data become available, an alternate drug may be preferred, especially while nursing a newborn or preterm infant. 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. Three mothers taking bictegravir 50 mg once daily provided milk samples at a median of 8.5 hours after a dose. The median drug concentration in milk was 57 mcg/L, which resulted in an estimated infant dosage of 10 mcg/kg daily.[3]

Infant Levels. An infant was breastfed by a mother taking bictegravir 50 mg once daily, although the extent of breastfeeding was not sated. The infant's serum concentrations taken 19 hours after maternal drug intake at 1 month of age was 103 mcg/L.[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.

Alternate Drugs to Consider

Raltegravir

References

- 1. Department of Health and Human Services. Recommendations for the use of antiretroviral drugs during pregnancy and interventions to reduce perinatal HIV transmission in the United States. Infant feeding for individuals with HIV in the United States. 2023. Available at: https://clinicalinfohivgov/en/guidelines/perinatal/infant-feeding-individuals-hiv-united-states?view=full
- 2. World Health Organization. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. 2021. Available at: https://www.who.int/publications/i/item/9789240031593
- 3. Aebi-Popp K, Kahlert CR, Crisinel PA, et al. Transfer of antiretroviral drugs into breastmilk: A prospective study from the Swiss Mother and Child HIV Cohort Study. J Antimicrob Chemother 2022;77:3436-42. PubMed PMID: 36177836.
- 4. García-Benayas T, Blanco F, Martin-Carbonero L, et al. Gynecomastia in HIV-infected patients receiving antiretroviral therapy. AIDS Res Hum Retroviruses 2003;19:739-41. PubMed PMID: 14585204.
- 5. Pantanowitz L, Evans D, Gross PD, Dezube BJ. HIV-related gynecomastia. Breast J 2003;9:131-2. PubMed PMID: 12603389.
- 6. Evans DL, Pantanowitz L, Dezube BJ, Aboulafia DM. Breast enlargement in 13 men who were seropositive for human immunodeficiency virus. Clin Infect Dis 2002;35:1113-9. PubMed PMID: 12384846.
- 7. Hutchinson J, Murphy M, Harries R, Skinner CJ. Galactorrhoea and hyperprolactinaemia associated with protease-inhibitors. Lancet 2000;356:1003-4. PubMed PMID: 11041407.
- 8. Orlando G, Brunetti L, Vacca M. Ritonavir and saquinavir directly stimulate anterior pituitary prolactin secretion, in vitro. Int J Immunopathol Pharmacol 2002;15:65-8. PubMed PMID: 12593790.
- 9. Montero A, Bottasso OA, Luraghi MR, et al. Galactorrhoea, hyperprolactinaemia, and protease inhibitors. Lancet 2001;357:473-5. PubMed PMID: 11273087.

Bictegravir

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Substance Identification

Substance Name

Bictegravir

CAS Registry Number

1611493-60-7

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents

Antiviral Agents

Anti-HIV Agents

Anti-Retroviral Agents

HIV Integrase Inhibitors