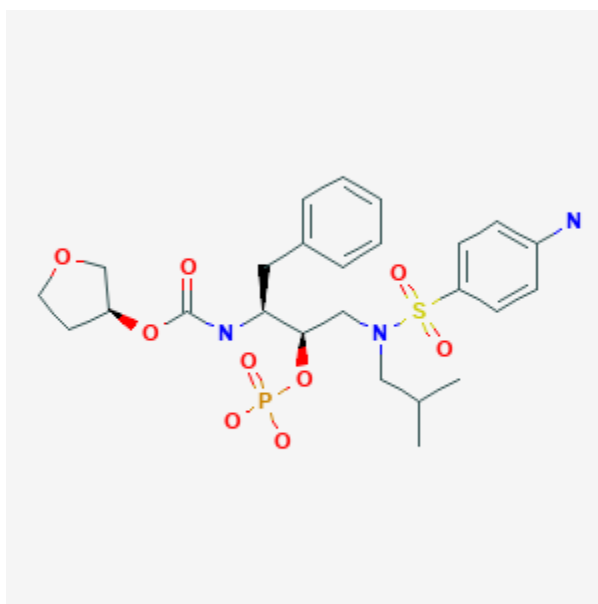




Fosamprenavir

Revised: October 31, 2018.

CASRN: 226700-79-4



Drug Levels and Effects

Summary of Use during Lactation

In the United States and other developed countries, HIV-infected mothers should generally not breastfeed their infants. No published information is available on the use of fosamprenavir during breastfeeding. In countries in which no acceptable, feasible, sustainable and safe replacement feeding is available, World Health Organization guidelines recommend that all women with an HIV infection who are pregnant or breastfeeding should be maintained on antiretroviral therapy for at least the duration of risk for mother-to-child transmission. Mothers should exclusively breastfeed their infants for the first 6 months of life; breastfeeding with complementary feeding should continue through at least 12 months of life up to 24 months of life.[1] The first choice regimen for nursing mothers is tenofovir, efavirenz and either lamivudine or emtricitabine. If these drugs are unavailable, alternative regimens include: 1) zidovudine, lamivudine and efavirenz; 2) zidovudine, lamivudine and

nevirapine; or 3) tenofovir, nevirapine and either lamivudine or emtricitabine. Exclusively breastfed infants should also receive 6 weeks of prophylaxis with nevirapine.[2][3]

Drug Levels

Maternal Levels. Relevant published information was not found as of the revision date. *Infant Levels.* Relevant published information was not found as of the revision date.

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][5][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

1. Anon. Guideline: Updates on HIV and infant feeding: The duration of breastfeeding, and support from health services to improve feeding practices among mothers living with HIV. Geneva: World Health Organization. 2016. PubMed PMID: 27583316.
2. World Health Organization. HIV and infant feeding: update. 2007. Available at: http://whqlibdoc.who.int/publications/2007/9789241595964_eng.pdf
3. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: World Health Organization. 2013. Available at: <http://www.who.int/hiv/pub/guidelines/arv2013/en/>
4. Garcia-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, Aboulaflia 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. Galactorrhea 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. Galactorrhea, hyperprolactinaemia, and protease inhibitors. *Lancet*. 2001;357:473-4; author reply 475. PubMed PMID: 11273087.

Substance Identification

Substance Name

Fosamprenavir

CAS Registry Number

226700-79-4

Drug Class

Breast Feeding

Lactation

Anti-Infective Agents

Anti-HIV Agents

Antiviral Agents

Anti-Retroviral Agents

HIV Protease Inhibitors