

HIV CareLink

A Newsletter for HIV/AIDS
Primary Care Providers

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NEW SAFETY INFORMATION FOR PREGNANT WOMEN AND PEDIATRIC PATIENTS CONCERNING VIRACEPT® (NELFINAVIR)

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On September 10, 2007, Pfizer released a "Dear Healthcare Professional" letter to inform healthcare professionals of the presence of unacceptable levels of ethyl methanesulfonate (EMS), a process-related impurity in the protease inhibitor Viracept®, and to provide new guidelines for the prescribing of Viracept® in pregnant women and pediatric populations.

EMS is a potential human carcinogen. It has known teratogenic, mutagenic and carcinogenic properties based on animal studies; however no data in human populations exists.

While the high levels of EMS were only in Viracept® manufactured by Roche-Ltd and marketed in the European Union, the FDA is not ruling out the possibility of EMS being found in Viracept® marketed in the United States as well.

The FDA and Pfizer have agreed upon new specifications to limit the amount of EMS in Pfizer-manufactured Viracept® marketed in the United States. **However, until this situation is resolved, the FDA and Pfizer are issuing the following new prescribing guidelines:**

- Pregnant women who need to begin antiretroviral therapy **should not be offered regimens containing Viracept®** until further notice.
- Pregnant women currently receiving Viracept® **should be switched to an alternative antiretroviral**, as a precautionary measure, while Pfizer and the FDA work to implement the long term EMS specification for Viracept®.
- For pregnant women with no alternative treatment options, the FDA and Pfizer agree that the risk-benefit ratio remains favorable for the continued use of Viracept®.
- Pediatric patients who need to begin HIV treatment **should not start regimens containing Viracept®** until further notice.

- Pediatric patients who are stable on an antiretroviral regimen containing Viracept®, should continue using Viracept®.
- For all other patients (i.e. non-pregnant, non-pediatric) there is currently no change in the recommended use of Viracept®.

A copy of the "Dear Healthcare Professional" letter issued by Pfizer can be found online at:
http://www.fda.gov/medwatch/safety/2007/VIRACEPT_T_HCPLetter_9_10_07.pdf

A copy of the DHHS Perinatal Panel Notice can be found online at:
<http://aidsinfo.nih.gov/contentfiles/PeriNFVNotice.pdf>

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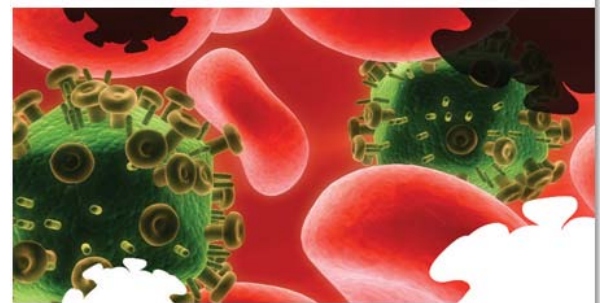
ABOUT US

The Florida/Caribbean AIDS Education and Training Center provides HIV education, consultation, and resource materials to health care providers in Florida, Puerto Rico and the US Virgin Islands.

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07 FLORIDA HIV/AIDS TREATMENT UPDATE SYMPOSIA

Saturday, September 22nd in Tampa - Quorum Hotel
Saturday, November 17th in Hollywood - Westin Diplomat
Saturday, December 8th in Jacksonville - Omni Hotel



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