



# Notice to Readers: Updated Information Regarding Antiretroviral Agents Used as HIV Postexposure Prophylaxis for Occupational HIV Exposures

In 1996, the U.S. Public Health Service first recommended using antiretrovirals as postexposure prophylaxis (PEP) after occupational exposure to human immunodeficiency virus (HIV) ([1](#)). Since the updated HIV PEP recommendations in 2005 ([2](#)), two important changes to antiretroviral use have occurred that affect the management of occupational exposures.

First, Kaletra<sup>®</sup> (Abbott Laboratories, Abbott Park, Illinois), a combination protease inhibitor, is no longer available in its original formulation: capsules containing 133 mg of lopinavir and 33 mg of ritonavir. Although the recommended daily prescribed amount of Kaletra ingredients is unchanged, the dosing regimen has changed as a result of the new Kaletra formulation. The previous dosing regimen for the capsule formulation was three capsules twice daily. Kaletra is now manufactured only in tablet form, with each tablet containing 200 mg of lopinavir and 50 mg of ritonavir. To achieve the same recommended daily prescribed amount of the tablet formulation, two tablets of 200 mg of lopinavir and 50 mg of ritonavir should be taken twice daily. Health-care providers should not prescribe three tablets twice a day of the new Kaletra formulation; that dose would be the equivalent of 1,200 mg of lopinavir and 300 mg of ritonavir daily, a higher dose than the recommended 800 mg of lopinavir and 200 mg of ritonavir daily.

Second, on September 10, 2007, Pfizer, Inc. issued a letter\* warning health-care providers about the use of Viracept<sup>®</sup> (nelfinavir) (Pfizer, Inc., New York, New York), another protease inhibitor, because the Viracept manufactured in Europe contained high levels of ethyl methane mesylate (EMS). EMS is a byproduct of the manufacturing process and a known animal carcinogen, mutagen, and teratogen. The level at which EMS might become carcinogenic or teratogenic in humans is not known. The warning in the letter applies to pregnant women and states that information about the ability of EMS to cross the placenta or to enter breast milk is currently unknown. A review of data from the Antiretroviral Pregnancy Registry, which collects data on approximately 6,000 HIV-infected pregnant

women, indicated that, during January 1989--January 2007, no statistically significant difference was observed in the prevalence of birth defects among the infants of women who used Viracept compared with those whose mothers used other antiretroviral therapies (3). Nonetheless, the Food and Drug Administration (FDA) recommends that pregnant women limit their exposure to EMS during pregnancy. Until further notice, pregnant women who need to begin antiretroviral therapy or HIV PEP should not be offered regimens containing Viracept. As a precautionary measure, pregnant women currently receiving Viracept should be switched to an alternative antiretroviral therapy while Pfizer and FDA work to implement a long-term EMS specification for Viracept. Specific recommendations for use of antiretroviral agents in pregnant HIV-1--infected patients are indicated in the U.S. Department of Health and Human Services guidelines (4) and can be consulted to determine an alternative treatment option.

Because nearly 80% of U.S. health-care personnel are female (5) and many of these women are of child-bearing age, this updated information about Viracept might be relevant to the choice of drugs included in an HIV PEP regimen taken by female health-care personnel. Additional information and guidance regarding management of specific exposures are available from the National Clinicians' Post-Exposure Prophylaxis Hotline by telephone (888-448-4911) or online (<http://www.ucsf.edu/hivcntr>).

## References

1. [CDC. Update: provisional Public Health Service recommendations for chemoprophylaxis after occupational exposure to HIV. MMWR 1996; 45:468--72.](#)
2. [CDC. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. MMWR 2005;54\(No. RR-9\):1--17.](#)
3. Antiretroviral Pregnancy Registry Steering Committee. Antiretroviral Pregnancy Registry international interim report for 1 January 1989 through 31 January 2007. Wilmington, NC: Registry Coordinating Center; 2007. Available at <http://www.apregistry.com>.
4. US Department of Health and Human Services, Panel on Clinical Practices for Treatment of HIV Infection. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents---December 1, 2007. Available at <http://aidsinfo.nih.gov/contentfiles/adultandadolescentgl.pdf>.
5. US Department of Labor, Bureau of Labor Statistics. Employed persons by detailed industry and sex, 2006 annual average. Available at <http://www.bls.gov/cps/wlf-table14-2007.pdf>.

\* Available at [http://www.viracept.com/pdf/viracept\\_hcpletter\\_9\\_10\\_07.pdf](http://www.viracept.com/pdf/viracept_hcpletter_9_10_07.pdf).

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