



STEP Electronic Treatment Ezine

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The Seattle Treatment Education Project's (STEP) EZINE is an electronic treatment resource distributed bi-monthly to people living with HIV/AIDS, people affected by HIV/AIDS, case managers, front-line workers, physicians, other public health and allied health professionals. STEP's contact information is: Seattle Treatment Education Project, 1123 East John Street, Seattle, WA 98102, (206) 329-4857 or 1-877-597-STEP (WA, OR, AK, HA, ID, MT)

SUSTIVA (EFAVIRENZ) IN NEW FORMULATION

The Food and Drug Administration approved on February 1, 2002, a new formulation of *Sustiva* (efavirenz). *Sustiva* is a once-daily non-nucleoside reverse transcriptase inhibitor (NNRTI) used in combination treatment for HIV. The new formulation will provide physicians with the option to prescribe one 600-mg *Sustiva* tablet once daily instead of three 200-mg capsules once daily (as *Sustiva* has been used since it was approved in September 1998). The manufacturer indicates that the 600-mg tablet is approximately the same size as one *Sustiva* 200-mg capsule.

Bristol-Myers Squibb Virology believes that the new tablet formulation of *Sustiva* will help reduce the number of pills people living with HIV have to take. The 600-mg tablet formulation will be available in late February. Bristol-Myers Squibb Virology will continue to manufacture the 200-mg capsules for those who still wish to take *Sustiva* as three capsules once-daily as part of their combination regimen.

Including the changes in the drug formulation, Bristol Myers Squibb Virology included new statements in the package insert to be reflective of the NNRTI. The changes in the package insert reflect drug interactions, adverse event information, and precautions.

Note: *Sustiva* should still not be taken with Hismanal® (astemizole), Propulsid® (cisapride), Versed® (midazolam), Halcion® (triazolam) or ergot derivatives. *Sustiva* drug interaction information includes the following medications and herbs: St. John's wort, lorazepam, methadone, cetirizine and rifabutin.

To review the revised label insert:

<http://www.fda.gov/cder/foi/label/2002/21360lbl.pdf>

GARLIC AND SAQUINAVIR INTERACTIONS

A recently published research article shows that garlic supplementation reduces the plasma level of saquinavir, a protease inhibitor. This is important research as it sheds more light on the interaction between pharmaceuticals and natural supplements. However, it is equally important to put this research into context and consider its limitations.

Let's begin with the findings of this garlic/saquinavir study. This study found that the blood levels of saquinavir were reduced by 51% with garlic supplementation (equivalent to two raw 4-gram cloves a day) in nine healthy, HIV-negative participants. The researchers believe that allicin, a compound released by garlic, may be responsible for the interaction.

Next, saquinavir is an antiretroviral that has poor bioavailability and is not likely to be used clinically as a sole protease inhibitor. It is necessary to combine it with another protease inhibitor (ritonavir) to boost saquinavir to therapeutic levels. Therefore, the methods used in this study are not representative of what happens clinically. In other words it's not clear how garlic would affect saquinavir levels in a highly active antiretroviral therapy (HAART) regimen when combined with ritonavir.

Since saquinavir is metabolized in a similar fashion as other protease inhibitors and some non-nucleoside reverse transcriptase inhibitors, there is concern that garlic may affect the levels of these HAART medications as well. It is not clear whether the effect of garlic on saquinavir is due to changes of the bioavailability (absorption of saquinavir in the stomach), or metabolism (removal of saquinavir from the blood by the liver). Therefore, more research is needed to determine if the other protease inhibitors and non-nucleoside drugs would be similarly affected by garlic.

Another issue to consider with garlic is that it is a foodstuff. Some people eat large doses of garlic on a regular basis. Most people use it as a seasoning and consume it at levels well below those that may interact with saquinavir. However, caution should be taken to avoid large amounts of fresh, raw garlic, especially as whole cloves, since they may release high levels of allicin. Allicin is the compound believed to interact with saquinavir and other protease inhibitors. Cooked garlic should be considered safer, since it does not release allicin.

Finally, let us consider how the general media has displayed this research. Headlines have read, "Garlic pills may block AIDS drugs". The media can distort what research findings are. It is important to consider all the information offered as well as the context. It is helpful to ask questions to clarify what the findings are and to determine the limitations of any research.

The discussions regarding this research come to the same conclusion: more research is needed to understand the interaction between garlic and HIV medications. It is also agreed that caution should be used when taking supplemental garlic with HIV antiretrovirals. The Bastyr Research Institute is currently conducting an NIH-funded study in close collaboration with the University of Washington to measure the effects of garlic on the cholesterol levels of people on antiretrovirals. To address the concerns that the garlic/saquinavir study raises, the Bastyr study will closely monitor viral loads of the participants. In addition, anyone on saquinavir as a sole protease inhibitor is not eligible for participation in the study. If you have questions regarding this clinical study, call 425/602-3171 or www.bastyr.edu/research/recruit/.

U.S. HEALTH AND HUMAN SERVICES (HHS) BUDGET FOR HIV/AIDS UNVEILED

The Department of Health and Human Services (HHS) released President Bush's budget plan for fiscal year 2003, which includes a total of \$12.9 billion dollars to fight HIV and AIDS. This is an increase of \$906 million, or 8 percent, over the current year's budget. Although under the 2003 budget plan there is an overall increase in funding, there is no increase for Ryan White Funding (for HIV/AIDS Care Services). It stays the same as last year. However, there was a 40 percent increase in the budget for ADAP (HIV prescription drug assistance for states). The specifics of the budget include:

- **Scientific research for vaccines and treatment:** The HHS budget allocates \$2.8 billion to the National Institutes of Health (NIH) for research on HIV and AIDS, which is a 10 percent increase above the current year's funding level. Included in the NIH budget is a 24 percent increase for AIDS vaccine research.
- **Prevention (stopping the spread of HIV/AIDS):** The HHS budget includes \$939 million for the Centers for Disease Control and Prevention (CDC), allocated for prevention, which is about the same amount as last year. With those resources, CDC will focus on “supporting HIV prevention programs in the United States, including efforts to reducing the number of people at high risk for acquiring or transmitting the virus; increasing HIV testing efforts; linking infected individuals with appropriate care and treatment; and strengthening the nation's ability to monitor the epidemic and respond effectively”. In addition, CDC will dedicate 15 percent of the budget to promote prevention strategies and programs internationally, including expanded efforts in Africa, Latin America and Asia.
- **Care (improving efforts to care for those living with HIV/AIDS):** The HHS budget will allocate \$1.9 billion, the same as the current year, to fund Ryan White treatment programs, which would continue to provide care and services to an estimated 500,000 Americans living with HIV/AIDS. About \$639 million of this funding would be available for the AIDS Drug Assistance Program, which provides medications to about 85,000 people.
- **Addressing HIV/AIDS among minorities:** The HHS budget would allocate \$410 million for efforts targeted specifically at reducing the disproportionate impact of HIV/AIDS on racial and ethnic minorities.

For more information on the HHS budget:

<http://www.hhs.gov/>

CORRECTION AND ADDITIONS FROM EZINE #31

Due to the overwhelming response for more information on what was reported in the last EZINE, we have inserted additional information that may be of assistance to those who are interested in more information on the various topics listed in EZINE #31.

CORRECTION from HIV Viral Load Response to Antiretroviral Therapy Based on CD4 Cell Count and Viral Load:

Paragraph #2 should have read: “People were analyzed according to baseline CD4 cell count (below 200, 200 to 349, and 350 or more), and baseline viral load (below 10,000, 10,000 to 99,999, 100,000 or more). The authors analyzed the number of people who achieved a viral load **BELOW** 500 after initiating therapy, and the number who had viral rebound to more than 500. There were no significant differences observed in the number of people achieving a viral load below 500, or in the number who had viral rebound based on the starting CD4 cell count or viral load. There were no differences observed based on gender. The only difference noted was that in the high viral load group, 100,000 or more, it took longer to achieve viral suppression. Overall, 85% of people achieved viral suppression. The death rate was higher in the people who started ART with a CD4 cell count below 200, but was not different in the other two groups, 200 to 349, and 350 or more.”

ADDITIONS to CDC Revises Guidelines for HIV Counseling, Testing, and Referral and Recommendations for HIV Screening of Pregnant Women:

A noted colleague has asked that we mention that the CDC report indicates that “HIV testing should become routine for pregnant women with their awareness and ability to “opt-out” of testing if desired”.

In response to the many requests to give reference to the “**Revised Guidelines for HIV Counseling, Testing and Referral and Revised Recommendations for HIV Screening of Pregnant Women**”, we have included the web address so that people can download from the Centers for Disease Control and Prevention Website in PDF and HTML formats. The web hyperlink (HTML) is as follows: [Revised Recommendations for HIV Screening of Pregnant Women](#) and the PDF format is: <http://www.cdc.gov/mmwr/PDF/rr/rr5019.pdf>

ACKNOWLEDGEMENTS

- Please note that this is not a complete list of all HIV-related treatment information. STEP strives to provide the very latest in HIV treatment information, research and drug development information. The most current research directions and antiretroviral drug data are provided throughout the Ezine publications. You will find highlight reports as well as extensive follow-up reports from many of the AIDS research and science conferences on the Ezine. In addition, all STEP quarterly treatment journals are available on our Web site at <http://www.thebody.com/step/steppage.html> or by calling our Talkline at 1-877-597-STEP. STEP works hard to give unbiased treatment information to all interested parties. If you have comments, questions, suggestions or grievances, please contact adimikam@stepproject.org or ezine@stepproject.org.

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