



Florida/Caribbean AIDS Education and Training Center

HIV CareLink

A Newsletter for HIV/AIDS Primary Care Providers

ABOUT US

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

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Updated Adult/Adolescent Department of Health and Human Services (DHHS) Antiretroviral Guidelines Released October 14, 2011

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The DHHS released updated *Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents* on October 14, 2011. Developed by the DHHS Panel, a working group of the Office of AIDS Research Advisory Council, it provides an update to the Guidelines version from January 10, 2011. This edition of HIV CareLink summarizes the most relevant changes to the Guidelines. The reader is encouraged to access the complete version of the Guidelines available online at: <http://aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx>. Most of the changes have been on the **What to Start: Initial Combination Regimens for the Antiretroviral-Naïve Patients** section, and there are updated tables for the drug interactions, drug characteristics, and recommendations for patients with renal and hepatic insufficiency.

Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Based Regimens

- Rilpivirine is now an *alternative* NNRTI option for initiation of therapy in treatment-naïve patients.
- Nevirapine-based regimens, including the extended release version, are now considered *acceptable* options for treatment-naïve patients (maintaining restrictions regarding pre-treatment CD4 count in males and females to reduce potential for hepatic complications).

Protease Inhibitor (PI)-Based Regimens

- Abacavir/lamivudine + ritonavir-boosted darunavir is now upgraded to an *alternative regimen* (BIII) from *may be acceptable but more definitive data needed* (CIII) in prior guidelines since new data have emerged.
- Combinations using unboosted fosamprenavir have been removed as PI options in treatment-naïve patients due to inferior potency compared to other PI-based regimens and the risk of selecting darunavir-resistant mutations on failing these regimens.

Raltegravir-Based Regimens

- Raltegravir + abacavir/lamivudine combination has been reclassified as an *alternative regimen* (BIII) from *acceptable* (CIII) since more data are now available.

Dual-Nucleoside Reverse Transcriptase Inhibitor (NRTI) Options as Regimen Components

- Zidovudine/lamivudine has been reclassified to an *acceptable* option from *alternative* since it has more toxicities compared to

tenofovir/emtricitabine and abacavir/lamivudine and requires twice daily dosing. Zidovudine/lamivudine is still the preferred dual-NRTI for pregnant women in the prevention of perinatal transmission of HIV.

- Didanosine + lamivudine combination has been removed as an initial therapy option due to greater toxicity when compared to the other available dual-NRTI options.

Rilpivirine Drug interactions

- The reader should consider reviewing the [HIV CareLink from June 22, 2011](#), regarding the approval of rilpivirine (RPV) for a more extensive review in this drug.
- Drugs that should not be used with RPV include St. John's wort, other NNRTIs, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifamycins (i.e. rifampin, rifabutin, and rifapentine).
- The use of proton pump inhibitors with RPV is contraindicated.
- H2-receptor antagonists should be given at least 12 hours before or at least 4 hours after RPV.
- Antacids should be given at least 2 hours before or at least 4 hours after RPV since RPV levels are expected to decrease when given simultaneously.
- Fluconazole, itraconazole, posaconazole, and voriconazole may increase the levels of RPV but no dosage adjustment is necessary. Monitor for break-through fungal infections as RPV may decrease azole levels (based on data with ketoconazole, no data with other azoles).

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Rilpivirine Drug interactions (Continued)

- Clarithromycin may increase the levels of RPV and an alternative agent (i.e. azithromycin) should be considered for MAC prophylaxis and treatment.
- Atorvastatin may be used with RPV without any dosage adjustment (no data with other statins, RPV expected to decrease levels of lovastatin and simvastatin).
- R-Methadone AUC levels decrease by 16% when used with RPV; no dosage adjustment is necessary but monitor for withdrawal symptoms.
- Sildenafil use does not require dosage adjustment (no data with other erectile dysfunction agents).

Interactions Between ARV and Rilpivirine (RPV)

- Use standard dose of RPV if combined with boosted and unboosted atazanavir, boosted darunavir, unboosted fosamprenavir, and lopinavir/ritonavir.
- Do not combine with other NNRTIs.
- There are no data on the use of RPV in combination with raltegravir or maraviroc.

Characteristics of the Recently Approved Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

- Viramune XR™ 400-mg once daily tablet has similar elimination, serum half-life, and adverse events as nevirapine 200-mg tablet. Dose escalation lead in still required. See [HIV CareLink from April 25, 2011](#) for information about Viramune XR™.
- Rilpivirine 25-mg tablet is taken once daily with a meal. It is a CYP3A4 substrate and its serum half-life is 50 hours. Adverse events include rash, depression, insomnia, and headache. It is also available as Complera™ (RPV 25mg + TDF 300 mg + FTC 200 mg). See page 4 of the [HIV CareLink from August 25, 2011](#), for information about Complera™.

Recommendations in Patients with Renal or Hepatic Insufficiency

- Viramune XR™ has no dosage adjustment in renal insufficiency; there is limited data in hemodialysis patients. No dosage adjustment in Child-Pugh Class A but contraindicated in Class B or C.
- Rilpivirine does not require adjustment in renal insufficiency; it may be used on Child-Pugh Class A or B; there are no recommendations for Class C.
- The fixed combination of RPV + TDF + FTC (Complera™) is not recommended if CrCl < 50 mL/min (see dosing recommendations for individual agents).

References:

1. Updated Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents – October 14, 2011. Available at <http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf> Accessed October 18, 2011



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