

IMPORTANT NEW PRESCRIBING INFORMATION
Re: Updated VIRAMUNE® (nevirapine) Package Insert

Boehringer Ingelheim
Pharmaceuticals, Inc

Dear Investigator,

Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) is writing to inform you that labeling changes for VIRAMUNE®, a non-nucleoside reverse transcriptase inhibitor indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents, have recently been submitted to the FDA.

February 11, 2005

The nevirapine label has been revised several times over the last two years to include more information on risk factors associated with liver toxicity when taking chronic nevirapine therapy. The Indications and Usage section of the VIRAMUNE® package insert now recommends against initiating nevirapine in females with CD4+ cell counts > 250 cell/mm³ or in males with CD4+ cell counts > 400 cell/mm³ unless the benefit outweighs the risk. The new text within the package insert is:

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Ridgefield, CT 06877-0368
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- Based on serious and life-threatening hepatotoxicity observed in controlled and uncontrolled studies, VIRAMUNE® should not be initiated in adult females with CD4+ cell counts greater than 250 cells/mm³ or in adult males with CD4+ cell counts greater than 400 cells/mm³ unless the benefit outweighs the risk

Please consider this new information in the context of the clinical trial(s) you are currently conducting using VIRAMUNE. A copy of the newly revised package insert is enclosed with this letter for your review.

Sincerely,



Peter J. Piliero, MD
Senior Associate Director
Clinical & Scientific Affairs

Enclosure: Package Insert