Viramune (nevirapine)

Viramune is supplied in 200 mg tablets that are white, oval and biconvex. One side is embossed with "54 193," with a single-line bisect separating them. The opposite side has a single-line bisect. Other dose formulations of Viramune are available. Dosing may vary.

Also known as: NVP, BI-RG-587

Background and description. Viramune is a non-nucleoside reverse transcriptase inhibitor (NNRTI), manufactured by Boehringer Ingelheim Pharmaceuticals, Inc. and distributed by Roxanne Laboratories, Inc. Viramune was granted accelerated approval for use in combination with nucleoside reverse transcriptase inhibitors (NRTIs) by the US Food & Drug Administration (FDA) in June 1996.

Dose. Viramune is supplied in tablet and oral suspension. The dose for the tablet formulation is 200 mg (1 tablet) for the first 14 days; followed by 200 mg (1 tablet) twice a day.

Food restrictions. Viramune may be taken with or without food.

Storage. Viramune should be stored at 59° to 86°F.

Patient assistance. The patient assistance program can be reached at 800.274.8651.

Side effects and toxicity. The most common and potentially serious side effect of Viramune is rash. If a rash develops, it usually does so within 6 weeks of starting the drug. If rash develops within the first 2 weeks of therapy, the dose of Viramune should not be increased until the rash resolves. A patient experiencing a severe rash or a rash accompanied by fever, blistering, oral lesions, conjunctivitis, swelling, muscle or joint aches or general malaise should immediately stop taking Viramune. Such symptoms may indicate a life-threatening condition called Stevens-Johnson syndrome.

Liver damage is another serious potential side effect of Viramune. Cases of hepatotoxicity, including cases resulting in death, have been reported with the use of Viramune. Patients experiencing moderate or severe liver function test abnormalities should interrupt therapy until liver function tests return to normal. If the abnormalities return after restarting Viramune, the drug should be permanently discontinued. In particular, women with T cell counts greater than 250 are at an increased risk (12 fold) of hepatotoxicity; males with T cell counts greater than 400 are at a 3-fold increased risk of hepatoxicity. The greatest risk is within the first 6 months of treatment (often seen with rash), but close monitoring by a doctor should continue for the first 18 weeks of treatment. Some liver damage could progress even after the drug is stopped.

Drug interactions. Viramune lowers the levels of Rifadin and Rimactane (generically known as rifampin) but there is insufficient data to recommend a dose adjustment. Also, combining Viramune and Mycobutin (rifabutin) results in lower levels of both drugs. Some experts recommend increasing the dose of Mycobutin to 450 mg. The manufacturer recommends that any of these drugs only be used in combination with Viramune "if clearly indicated and with careful monitoring." Caution should be used with Voriconazole (VFEND) when given with Viramune.

Nizoral (ketaconazole) should not be co-administered with Viramune. Since Viramune decreases the level of oral contraceptives when the two are co-administered, an additional or alternative method of birth control should be used. Also, St. John's Wort (*Hypericum perforatum*) is likely to decrease Viramune levels in the body and therefore should be avoided when taking Viramune. Also, methadone levels may need to be adjusted in patients taking Viramune.

Viramune should not be combined with the hard-gel protease inhibitor Invirase. Viramune decreases the levels of Crixivan and increasing the dose of Crixivan to 1000 mg every 8 hours is recommended. There are no data regarding the interaction between Agenerase and Viramune. A dose increase in Kaletra (to 4 capsules twice a day) is recommended for protease-inhibitor-experienced patients, but not for protease-inhibitor-naïve patients, when combining Kaletra with Viramune.

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Additional info:

Resistance and cross-resistance. Resistance to Viramune is associated with mutations at positions 103 and 181. Mutations at positions 106, 108, 188, and 190 can also occur. Mutations at positions 103 and 181 lead to broad cross-resistance to all approved NNRTIs.

Clinical data. The pivotal trial for Viramune was ACTG 241, which enrolled patients with over 6 months of prior NRTI experience. Patients were randomized to receive Viramune/Retrovir/Videx or Retrovir/Videx. At 4 weeks the mean reduction in the 3-drug arm was 1.0 log versus 0.5 log in the 2-drug arm. By 48 weeks viral loads had returned to baseline with the viral load in the 3-drug arm being 0.25 log less than in the 2-drug arm.

BI Trial 1046 or INCAS studied Viramune in antiretroviral-naïve patients comparing the following regimens: Viramune/Retrovir/Videx compared to Viramune/Retrovir or Retrovir/Videx. At week 52 there was a significant difference in the number of patients with viral loads below 400 copies/mL among the arms. In the triple-therapy arm 51% of the patients had viral loads below 400 copies/mL compared to less than 6% in the other 2 arms. The mean CD4 T cell count increase from baseline was 139 cells/

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