

# NEVIRAPINE (VIRAMUNE)



## THE SIMPLE FACTS PROJECT

**Side effects:** The major side effect of nevirapine is a rash, which happened to 22% of people in studies. 6% of people in studies had a severe rash. 6.7% of people had to stop taking nevirapine because of this problem. If nevirapine causes a severe rash and you have to stop treatment, the company that makes the drug recommends that you DO NOT try the drug again. Other side effects can be elevated liver function tests, fever and muscle soreness.

**Avoiding the rash:** There may be ways to reduce the chance of getting a rash from nevirapine. One recent study gave antihistamines (e.g. Benadryl) during the first two weeks of nevirapine treatment, and no-one in this study got a rash. Another study gave people 40-50mg of the drug prednisone daily during the first two weeks of nevirapine treatment, and only one person out of 83 developed a rash which was mild and went away on its own.

Boehringer Ingelheim/Roxanne, the manufacturers of nevirapine, have set up a patient assistance program for people needing assistance accessing the drug. Call **(800) 274-8651** for more information.

The Simple Facts Project is a program of the AIDS Treatment Data Network (The Network). This information does not intend to promote or endorse any specific treatment for any health related condition.

Nevirapine (trade name Viramune) is one of a class of drugs called non-nucleoside reverse transcriptase inhibitors (NNRTIs). Reverse transcriptase is a part of HIV required to infect cells in the body and make more virus. NNRTIs stop the reverse transcriptase from working properly. The recommended dosage of nevirapine is 200 mg once a day for the first two weeks, and then 200 mg *twice* a day thereafter. Nevirapine is also available as a liquid suspension for children.

Nevirapine has been approved for use in combination with other anti-HIV drugs, including protease inhibitors. New Public Health Service HIV treatment guidelines recommend combinations of three or four anti-HIV drugs as first treatment for HIV:

- Two nucleoside analogs (AZT+3TC, d4T+3TC, d4T+ddl, AZT+ddl, or AZT+ddC) with one of the following: Crixivan, Fortovase, Norvir, Sustiva, Viracept or Norvir and Fortovase combined.
- If one of the above combinations cannot be used, an alternative is two nucleoside analogs (same combinations as listed above) with Viramune or Rescriptor.

The guidelines also say that nevirapine may be useful as part of a second-line combination if a standard combination stops working.

**Trial results:** In a trial known as the INCAS study, nevirapine was combined with ddl (Videx) and AZT (Retrovir). This three-drug combination reduced viral load (the amount of HIV in the blood) very effectively. After a year, just over half the people taking the triple combination had a viral load of less than 20 copies. T4 cell counts increased by an average of 140 cells. No one in the study had taken anti-HIV drugs before. Smaller studies have been done of nevirapine combined with other anti-HIV drugs, including d4T (Zerit) and 3TC (EpiVir), AZT and 3TC, d4T and ddl. All of these combinations seem promising as potential first-line HIV treatments.

Nevirapine has also been studied with protease inhibitors. A recent trial of nevirapine, d4T and nelfinavir (Viracept) reported that the combination appears safe and effective over the short term. This study is ongoing. Nevirapine combined with indinavir (Crixivan) has been shown to have a strong anti-HIV effect, but the dose of Crixivan may need to be increased to 1,000mg every 8 hours due to a drug interaction (see below).

Nevirapine has also been studied in people whose first-line combination has failed them. The best results reported so far have been with a combination of nevirapine and two protease inhibitors: ritonavir (Norvir) and saquinavir (Fortovase). Another second-line combination that has shown promise is nevirapine, 3TC and Crixivan.

**Resistance:** HIV seems to get resistant to the effects of nevirapine very quickly unless the drug is used as part of an effective anti-HIV drug combination. If a person becomes resistant to nevirapine, they may also be resistant to other NNRTI drugs such as delavirdine (Rescriptor) and efavirenz (Sustiva). This is called cross-resistance.

**Drug interactions:** Nevirapine is processed in the body by the liver, as are many other drugs. Nevirapine can affect the liver and cause other drugs to be processed too quickly. When a drug goes through the liver too quickly, there may not be enough of the drug left in the system to work properly. With the protease inhibitor Crixivan, it may be necessary to increase the dose to offset the effect of nevirapine. Other protease inhibitors can be given at standard doses with nevirapine. Nevirapine greatly reduces the levels of methadone in the body, which can lead to symptoms of withdrawal. In one recent nevirapine study, the methadone dose had to be increased to 150mg a day or more in order to avoid withdrawal.

The antibiotic drugs rifabutin and rifampin can lower nevirapine levels. People taking these drugs with nevirapine should be closely monitored for interactions. In studies, taking nevirapine with the antifungal drug fluconazole (Diflucan) increased the chance of getting a rash. For updated information on drug interactions, there is a medical information contact at the manufacturer that can be reached by calling **(800) 542-6257**.

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