

Risk List for Informed Consent

General Disclaimer

The drugs used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with these drugs. These lists include the more serious or common side effects with a known, or possible relationship. If you have questions concerning the additional study drug side effects, please ask the medical staff at your site.

Use of Combination Antiretroviral Drugs

Immune Reconstitution Syndrome: In some people with advanced HIV infection, signs and symptoms of inflammation from other infections may occur soon after anti-HIV treatment is started.

The use of potent antiretroviral drug combinations may be associated with an abnormal placement of body fat and wasting. Some of the body changes include:

Increase in fat around the waist and stomach area
Increase in fat on the back of the neck
Thinning of the face, legs and arms
Breast enlargement

Non-Nucleoside Reverse Transcriptase Inhibitor

Nevirapine (NVP, Viramune®)

Boehringer Ingelheim Pharmaceuticals, Inc.

The following serious side effects have been associated with the use of nevirapine:

Severe liver damage that can result in death may occur and is often associated with a rash. Being female or having a higher CD4 cell count, regardless of gender, increases the risk of developing liver damage.

Women with CD4 cell counts greater than 250, including pregnant women receiving chronic nevirapine therapy, are at greatest risk for developing liver damage. Men with CD4 cell counts greater than 400 are also at increased risk. However, these reactions can happen at any CD4 count in both men and women. People who have abnormal liver function tests before starting nevirapine and people with active Hepatitis B or C infection are also at higher risk for liver damage.

If you are developing liver damage, you may have one or more of the following:

- Tiredness
- General feeling of illness or flu-like feeling
- Loss of appetite

- Nausea
- Pale stools
- Dark urine
- Yellowing of the skin or whites of your eyes
- Liver tenderness or abnormal liver function tests

Hypersensitivity reactions (“allergic reaction”) may occur. These reactions are rarely fatal. The symptoms that you may notice are rash, fever, tiredness, muscle or joint aches, flu-like feeling, blisters, mouth sores, facial swelling, red eyes and irritation of the eyes, general feeling of discomfort, and/or liver damage described above, kidney problems, and/or changes in white blood cell levels.

Muscle break down causing muscle aches or pain has been observed in some people experiencing skin and/or liver reactions associated with nevirapine.

Rash is the most common side effect associated with nevirapine. Rash occurs more often in women. Most rashes occur early during treatment. The rash may be severe and rarely may cause death. One of the risk factors for developing serious skin reactions includes failure to take nevirapine properly during the first 14 days of treatment.

The risk of people developing any of the serious side effects listed above is greatest during the first few months of treatment, but these side effects also can occur later. If you develop any of the side effects listed above, no matter how long you have been receiving nevirapine, you must contact your health care provider right away and before you take your next dose. Your health care provider will instruct you on what to do next. If you and your doctor then decide to stop your treatment because of liver damage, hypersensitivity or severe skin reactions, you should never take nevirapine again.

In addition to the serious side effects listed above, additional side effects include:

- Fever
- Headache
- Upset stomach (nausea, vomiting)