

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

Efavirenz (EFV, SUSTIVA®)

Bristol-Myers Squibb

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

- A small number of people may experience the following serious psychiatric problems:
- Depression, which may be severe
- Suicidal thoughts or attempts (rarely)
- Aggressive behavior
- Psychosis-like symptoms, such as abnormal thinking, paranoia, and delusions

People with a history of psychiatric problems may be at greater risk for these serious psychiatric problems.

Side effects associated with the central nervous system may include the following:

- Dizziness
- Trouble sleeping
- Abnormal dreams
- Drowsiness
- Confusion
- Difficulty concentrating
- Hallucinations

- A feeling of strangeness and losing touch with reality
- An exaggerated feeling of well-being
- Agitation or anxiety

If alcohol or mind- or mood-altering drugs are used with efavirenz, it is possible that the central nervous system side effects could become worse.

Serious liver problems and worsening liver disease can occur. These problems can be life-threatening. People with these conditions may have abnormal liver function blood tests. If you are developing liver problems, you may have one or more of the following: yellowing of the skin or whites of your eyes, dark urine, pain on the right side of your stomach, loss of appetite, upset stomach or vomiting, pale colored stools, itchy skin.

- Additional side effects include:
- Rash, which in rare cases may be severe
- Upset stomach
- Loose or watery stools
- Headache
- Abnormal increases in the amount of triglycerides and cholesterol in the blood
- Abnormal increases in pancreatic enzyme levels in the blood and or inflammation of the pancreases (pancreatitis), which may result in stomach pain, nausea, and /or vomiting

Efavirenz and Pregnancy:

The use of this drug during pregnancy and especially early pregnancy should be avoided. Efavirenz may cause fetal harm when taken during the first three months of pregnancy. Serious birth defects, including those of the central nervous system, have been seen in the offspring of animals and women on Efavirenz.

A false-positive urine-screening test for marijuana has been seen with one particular test brand and has not been seen when using other screening tests or with tests used to confirm results for marijuana.