

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

Entry Inhibitor- CCR5 co-receptor antagonist

Maraviroc (MVC, Selzentry®)

Pfizer, Inc

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

Liver problems (liver toxicity) have occurred in people who took maraviroc. An allergic reaction may happen before liver problems occur. Stop taking maraviroc and call your Health Care Provider right away if you get any of the following signs or symptoms: rash on your body (allergic reaction), yellowing of the skin or whites of your eyes, dark urine, vomiting, stomach pain, or elevated liver related function tests. People who are co-infected with hepatitis B or C might be at higher risk of having liver problems.

Heart problems, including heart attack

Low blood pressure when standing up, which can cause dizziness or fainting. People who have serious kidney problems may be at increased risk.

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

- Colds
- Cough

- Fever
- Rash
- Dizziness
- Diarrhea
- Swelling of parts of the body
- Flu and flu-like symptoms
- Muscle aches, spasms and pain
- Stomach pain and bloating
- Sleeping problems
- Runny, congested nose
- Problems with urination
- Low amounts of white blood cell counts (neutropenia)

Note: Because of how the drug works in your body, there is a possible increased risk for getting other infections or cancer, although there is no evidence from the clinical trials of an increase in serious infections or cancer.

Maraviroc contains soy lecithin. If you have a medical history of allergy to soy (soya or soybeans) or peanuts, you may develop an allergic reaction to maraviroc. Before starting maraviroc, you should inform your health care provider if you are allergic to soy or peanuts.