

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

Protease Inhibitors

The use of protease inhibitors may be associated with the following:

- *Increases in the amount of triglycerides and/or cholesterol in the blood*
- *Development of diabetes or the worsening of high blood sugar*

There have been reports of increased bleeding in HIV-infected persons with hemophilia who were treated with protease inhibitors. It is not known if protease inhibitors were the cause of these bleeding episodes.

Lopinavir/Ritonavir (LPV/r, KALETRA™)

Abbott Laboratories

The following serious side effects are associated with the use of lopinavir/ritonavir:

- Abnormal heart rhythm and electrocardiogram (EKG) changes. These changes can lead to serious heart problems. Your risk for these problems may be higher if you:
 - Already have a history of abnormal heart rhythm or other types of heart disease
 - Take other medicines that can affect your heart rhythm while you take lopinavir/ritonavir

If you develop abnormal heart rhythm you may experience lightheadedness, fainting spells or an abnormal heart beat.

- Pancreatitis (inflammation of the pancreas), which may cause death. If you develop pancreatitis, you may have one or more of the following: Stomach pain, nausea, vomiting or abnormal pancreatic function blood tests
- Large increases in triglycerides and cholesterol in the blood
- Liver problems and worsening liver disease, which may result in death. 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.
- Rash, which could blister, and may be severe or life-threatening. Contact your Healthcare Provider if you develop a rash

Additional side effects may include:

- Abnormal bowel movements (stools), including loose or watery stools, upset stomach and stomach pain
- Feeling weak and tired
- Headache