

Risk Lists 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

Nucleoside Analogue

Lactic acidosis (elevated lactic acid levels in the blood) and severe hepatomegaly (enlarged liver) with steatosis (fatty liver) that may result in liver failure, other complications or death have been reported with the use of antiretroviral nucleoside analogues alone or in combination. The liver complications and death have been seen more often in women on these drug regimens. Some nonspecific symptoms that might indicate lactic acidosis include: unexplained weight loss, stomach discomfort, nausea, vomiting, fatigue, cramps, muscle pain, weakness, dizziness and shortness of breath.

Abacavir Sulfate (ABC, ZIAGEN®)

GlaxoSmithKline

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

People taking abacavir may have a serious allergic reaction that involves several organs of the body. This reaction can be severe or may rarely cause death. Your risk of this allergic reaction is much higher if you have a certain type of gene called HLA-B*5701. Your doctor can determine if you have this by doing a blood test. If you have tested positive for this blood test before, do not take abacavir and let your doctor know right away. If you have two or more of the following while taking abacavir, stop taking the abacavir and call your doctor right away:

- Fever
- Rash
- Upset stomach, vomiting, loose or watery stools, abdominal pain
- General feeling of illness, extreme tiredness, achiness
- Shortness of breath, cough, sore throat.

This serious allergic reaction is also seen in children and the side effects are similar to those seen in adults. In addition to the side effects listed for adults, children may experience one or more of the following: weakness or sluggishness, poor appetite, difficulty breathing.

This serious reaction usually appears within the first six weeks after starting this drug but can occur at any time during treatment. This reaction can be severe and can lead to death especially if abacavir is not stopped. IF YOU STOP ABACAVIR BECAUSE OF AN ALLERGIC REACTION, YOU SHOULD NEVER TAKE ABACAVIR OR ANY OTHER ABACAVIR-CONTAINING MEDICINE AGAIN.

A more severe or fatal allergic-type reaction can occur within hours if abacavir is restarted in patients who have interrupted abacavir therapy for any reason. If you interrupt abacavir, immediately contact the medical staff at the site before re-starting abacavir. Your doctor may want to test your blood for HLA-B*5701. If your doctor decides to restart abacavir, you may need to be monitored more closely in the clinic or in the hospital.

IF YOU THINK YOU MIGHT BE DEVELOPING A REACTION TO ABACAVIR, DO NOT TAKE ANY MORE DOSES AND CONTACT THE DOCTOR AT THE SITE IMMEDIATELY.

Other than a serious allergic reaction, additional side effects may include:

- Upset stomach
- Vomiting
- Vague overall feeling of discomfort
- Feeling tired
- Decrease in appetite
- Loose or watery stools
- Pancreatitis (inflammation of the pancreas), with one or more of the following: stomach pain, nausea or vomiting
- Headache

Note: It is unclear if abacavir may be associated with heart disease. If you have risk factors for heart disease tell your doctor.