

NOTES FOR DAIDS Medical Officers/ Consent Form Authors:

Be sure to address the Virologic Failure and Development of Resistance in the risk section of the DAIDS Sample Informed Consent Form, if appropriate. This topic is not addressed in this core risk list below.

Be sure to address the Coadministraton with Other Products in the risk section of the DAIDS Sample Informed Consent Form, if appropriate. DAIDS has template language to assist you if needed. This topic is not addressed in this core risk list below.

According to federal guidelines, language in Informed Consent Forms should be suitable for the general public, meaning language at the 8th grade level or lower. Some of the Lay Language used in the DAIDS risk lists (drug profiles) is taken from the following: National Comprehensive Cancer Network (NCCN) Informed Consent Language Database-Lay Glossary

INSTRUCTIONS: The above notes are NOT to be included in the DAIDS SAMPLE INFORMED CONSENT FORM.

The information stated below which includes the possible side effects/risks of the study agent (s) are to be included in the risk section of the DAIDS Sample Informed Consent Form

DAIDS Sample Informed Consent Form Core Risk List:

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 additional study drug side effects please ask the medical staff at your site.

Use of Combination Antiretroviral Drugs

In some people with advanced HIV infection, symptoms from other infections or certain diseases may occur soon after starting combination anti-HIV treatment but can also occur later. Some of these symptoms may be life threatening. If you start having new symptoms, or notice that existing symptoms are getting worse after starting your antiretroviral therapy, tell your healthcare provider right away.

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

Nucleotide 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.

Tenofovir Disoproxil Fumarate (Tenofovir DF, TDF, VIREAD®)

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

- Upset stomach, vomiting, gas, loose or watery stools
- Generalized weakness
- Dizziness
- Depression
- Headache
- Abdominal pain
- Worsening or new kidney damage or failure
- Liver problems. If you are developing liver problems, you may have one or more of the following symptoms:
 - 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.
- Shortness of breath
- Rash
- Allergic reaction: symptoms may include fever, rash, upset stomach, vomiting, loose or watery stools, abdominal pain, achiness, shortness of breath, a general feeling of illness or a potentially serious swelling of the face, lips, and/or tongue.
- Bone pain and bone changes such as thinning and softening which may increase the risk of breakage
- Muscle pain and muscle weakness
- Sleeping problems

NOTE: If you have hepatitis B virus (HBV) infection and take tenofovir DF and then stop using it, you may have worsening of your HBV infection. Tell your health care provider about any new or unusual symptoms after you stop taking tenofovir DF.