

**NOTES FOR DAIDS Medical Officers/Informed Consent 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 Coadministration 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.**

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**The information stated below which includes the 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 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, 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

## **Non-Nucleoside Reverse Transcriptase Inhibitor**

### **Rilpivirine (RPV, Edurant®)**

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

- Depression or mood changes. Be sure to contact your health care provider immediately if you are feeling sad or hopeless, feeling anxious or restless, or have thoughts of hurting yourself (suicide) or have tried to hurt yourself.

Additional side effects include:

- Liver problems can happen in people who take rilpivirine. People who have abnormal liver tests before starting rilpivirine and people with liver diseases, like Hepatitis B or C, have an increased risk of worsening liver disease. 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.
- Headache
- Trouble sleeping
- Rash