

DAIDS Core Risk List (side effects/risks of study drug) Template for DAIDS Informed Consent Form

DAIDS Core Risk List (side effects/risks of study drug) for Dolutegravir (DTG)

The DAIDS core Risk Lists provides the DAIDS Medical Officer with a list of recommended risks (side effects) that will be used in the DAIDS Sample Informed Consent (SIC) Form. The list draws on all relevant sources of risk information. The risk list is usually reviewed by the protocol team with guidance from the DAIDS Medical Officer before it is included in the DAIDS Sample Informed Consent (SIC) Form.

The following are not usually addressed in the DAIDS core Risk List and should be included in the DAIDS SIC form as per the applicable DAIDS SOPs and if applicable for the specific study: Virologic Failure, Development of Resistance , Pregnancy risks related to ARV agents and study product interactions with other agents.

The risks of side effects from the study drug listed below apply to the risk section of the DAIDS SIC Form. These side effects/risks should be addressed in the risk section of the DAIDS SIC Form.

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. It is very important that you tell your study doctor of any changes in your medical condition while taking part in the study. At any time during the study, if you believe you are experiencing any of these side effects, you have the right to ask questions on possible and /or known risks.

There is a risk of serious and/or life-threatening side effects when non-study medications are taken with the study drugs. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study and you must ask approval for taking any new medication while you are on the study.

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

Integrase Inhibitor

Dolutegravir, (DTG, Tivicay®)

Dolutegravir can cause serious, life-threatening side effects. These include allergic (hypersensitivity) reactions and liver problems.

- Allergic reaction which may cause a rash. You may develop a rash with any of the following signs or symptoms:
 - Fever
 - General ill feeling
 - Extreme tiredness
 - Muscle or joint aches
 - Blisters or sores in your mouth
 - Blisters or peeling skin
 - Redness or swelling of your eyes
 - Swelling of your mouth, face, lips, or tongue
 - Trouble breathing
- Liver problems which may cause:
 - Yellowing of your skin or whites of your eyes (jaundice)
 - Dark or tea-colored urine
 - Pale-colored bowel movements
 - Nausea or vomiting
 - Loss of appetite
 - Pain, aching, or tenderness on your right side below your ribs
 - Changes in liver test results, more common in people with hepatitis B or C

People with pre-existing history of depression or other mental health illness may be at greater risk for suicidal thoughts, or attempts, which may lead to death. If your mental health illness worsens, or if you develop suicidal thoughts, call your healthcare provider right away.

Additional side effects include:

- Trouble sleeping
- Abnormal dreams
- Tiredness
- Headache
- Anxiety (fear, worry)
- Muscle and joint aches
- Dizziness
- Nausea/Vomiting

- Flatulence (gas in the abdomen)

Dolutegravir and Pregnancy:

Early results from a large study in Botswana of pregnant women showed a possible increased risk of certain types of serious birth defects involving the brain, and spinal cord in babies born to women who received dolutegravir for HIV treatment at the time of becoming pregnant or early in their pregnancy. No cases of babies born with these types of birth defects have been reported among women who started dolutegravir later in pregnancy.