

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 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

Fusion Inhibitor/Binding Inhibitor

T-20 (Enfurvitide)/Fuzeon

Roche Laboratories Inc, /Trimeris, Inc.

The following side effects have been associated with the use of T-20:

- **Injection site reactions:** Almost all people have skin reactions at the site where T-20 is injected. Reactions may include: itching, swelling, redness, pain or tenderness, hardened skin, bumps. Most reactions are mild. Occasionally they may be severe or rarely associated with infections or collection of thick liquid (abscess) at the injection site.
- **Lung infection (pneumonia).** You should contact your healthcare provider right away if you have a cough, fever, or trouble breathing.
- **Serious allergic reactions.** Symptoms may include: trouble breathing, fever, nausea, vomiting, chills, shakes, skin rash, blood in your urine, swelling in your feet, dizziness, severe muscle weakness starting in your feet and quickly moving to your upper body (Guillain-Barre Syndrome). Contact your healthcare provider right away if you get any of these allergic reaction symptoms and do not take any more T-20. T-20 should not be restarted if your doctor thinks that you had an allergic reaction that was related to T-20.

Other side effects of T-20 may include:

- Numbness and tingling of the hands and feet
- Difficulty sleeping
- Depression, or anxiety
- Decreased appetite
- Sinus infections and other infections in other places, including the skin (herpes) and the blood (sepsis)
- Swollen glands (Lymphadenopathy)
- Muscle pain
- Constipation
- Pancreatitis (swelling of the pancreas). If you develop pancreatitis, you may have one or more of the following: stomach pain, nausea, and vomiting.
- Abnormal blood tests including: increases in eosinophils (a special type of white blood cell), which sometimes can be a sign of an allergic reaction, increases in liver functions, which could mean you have liver damage and in rare cases may lead to liver failure.
- If people without HIV infection mistakenly inject themselves with T-20, they may have a false-positive HIV antibody test by the ELISA assay.

Injection risk when using needle-free system “Biojector”:

- Shooting nerve pain and tingling lasting up to 6 months from injecting close to large nerves or near joints, and bruising and/or collection of blood under the skin have been reported
- If you are taking any blood thinners, or have hemophilia or any other bleeding disorder, you may be at higher risk of bruising or bleeding after using the needle-free system “Biojector.”