

Sipuleucel-T (Provenge®)

Pronounced: SI-pu-LOO-sel tee

Classification: Autologous Cellular Immunotherapy

About Sipuleucel-T (Provenge®)

Sipuleucel-T is an example of immunotherapy, which is a type of therapy that is designed to stimulate the body's immune system to attack the cancer cells. Sipuleucel-T is tailor-made specifically for each patient, created from his body's own immune cells. Immune cells are first collected from the patient and exposed to a protein that "teaches" the immune cells to target the cancer cells. These immune cells are then given back to the patient to help treat the cancer.

How to Take Sipuleucel-T

Sipuleucel-T is given by intravenous (IV, into a vein) infusion. Prior to each dose, you may be given medications, including acetaminophen and an antihistamine (such as diphenhydramine), to decrease the risk of an infusion reaction.

A few days prior to each dose, the patient must undergo collection of their immune cells, which will be used to make that dose. This is done by leukapheresis, a procedure that is similar to dialysis or platelet donation. The immune cells are sent to a processing facility, where they are combined with an immune cell activator called granulocyte-macrophage colony-stimulating factor (GM-CSF), and then returned to the cancer center for infusion.

Possible Side Effects of Sipuleucel-T

There are a number of things you can do to manage the side effects of sipuleucel-T. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common side or effects:

Immune System Reactions

Sipuleucel-T stimulates the immune system, much like a flu virus would, and expected side effects are related to this stimulation. Often called "flu-like symptoms", these include chills, fever, fatigue, achy joints and muscles, and headache. Talk to your healthcare team about using acetaminophen or ibuprofen to manage these symptoms. They typically last only a few days after the infusion.

Infusion-Related Side Effects

The infusion can cause a reaction. Symptoms of an infusion reaction include: fever, chills, low blood pressure, racing heart, shortness of breath, flushing, swelling of the throat or face, abdominal or back pain, nausea, and vomiting. You will receive Tylenol and diphenhydramine prior to the infusion to help prevent these reactions. Some patients will also receive a steroid before the infusion to prevent a reaction. Most patients can resume the infusion at a slower rate. It is possible to have a reaction up to one day after the infusion, so be sure to notify your healthcare provider if you experience any symptoms.

Fatigue

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Less common, but important side effects can include:

- Blood Clots, Heart Attack, and Stroke: Sipuleucel-T can increase the risk of blood clots, heart attack, and stroke. Symptoms can include: swelling, redness or pain in an extremity, chest pain or pressure, pain in your arm, back, neck or jaw, shortness of breath, numbness or weakness on one side of the body, trouble talking, confusion, or mental status changes. If you experience any of these symptoms, you should contact your oncology care team immediately or go to an emergency room.
- Leukapheresis (Cell Collection) Side Effects: Your immune cells are collected using a process called leukapheresis. Your blood is run through a machine, which removes the immune cells needed to make the medication, and then the blood is returned to you. The process can cause numbness or tingling felt around the lips, which is usually resolved by taking some calcium tablets (like Tums). Patients may also feel tired after the collection. In some cases, enough cells to make the medication cannot be collected with one leukapheresis session and an additional session is required. If it is difficult to place a peripheral IV in a patient, a central line catheter may be placed for the weeks of the collections. Talk with your healthcare team about side effects related to the catheter if this is an option for you. You should monitor the collection and infusion sites for redness, warmth, and pain, which can be signs of infection. Call your provider for a fever of 100.4° F/38°C or greater.

Reproductive Concerns

It has not been studied if exposure of an unborn child to this medication could cause birth defects, so you should not father a child while on this medication. Effective birth control is necessary during treatment. Even if you believe you are not producing sperm, you could still be fertile.

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