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Care During Chemotherapy and Beyond

Provenge

Generic Name: Sipuleucel-T

Sipuleucel-T is the generic name for the trade name drug Provenge®. In some cases, health care professionals may use the trade name Provenge® when referring to the generic drug name Sipuleucel-T.

Drug Type:

Provenge is an autologous cellular immunotherapy. This means that it is a drug made by a person's own blood cells and is meant to be used only for the person whose blood cells were used to create it. Provenge works by stimulating the man's own immune system to fight his prostate cancer. (For more detail, see "How Provenge Works", below)

What Provenge Is Used For:

Provenge is indicated for the treatment of metastatic prostate cancer in men whose disease had progressed following hormonal treatment who have either no or very minimal symptoms related to the prostate cancer.

How Provenge Is Given:

Provenge is given in 3 doses with 1-2 weeks in between each dose. Each individual dose is comprised of ≥ 50 million activated cells. Each patient has these cells taken from him during a process called leukapheresis. The cells are then sent to a processing plant to be treated with the vaccine. The treated cells are then sent back to the physician's office to be re-infused (an IV is placed and the cells administered, like a blood transfusion) to the donating man.

Prior to each Provenge infusion pre-medications are given to decrease the chance of having a reaction to the infusion. Each infusion takes about 60 minutes and you will be monitored for about 30 minutes afterwards. This process is repeated 3 times over about a 1 month time frame (once every 1-2 weeks). Your doctor and the drug manufacturer will determine your exact leukapheresis and infusion schedules.

Side Effects:

Important things to remember about the side effects of Provenge:

- Most people will not experience all of the Provenge side effects listed.

- Provenge side effects are often predictable in terms of their onset, duration, and severity.
- Provenge side effects will improve or completely resolve after therapy is complete.
- Provenge side effects may be quite manageable. There are many options to minimize or prevent the side effects of Provenge.

The following side effects are common (occurring in greater than 30%) for patients taking Provenge:

- Infusion Reaction - usually occurs at the time of infusion or within 1 day of infusion. It is a group of symptoms including, but were not limited to, fever, chills, shortness of breath, bronchospasm, nausea, vomiting, fatigue, hypertension, and an increased heart rate. In clinical trials, these symptoms were serious in about 3.5% of patients getting sipuleucel-T
- Chills
- Fatigue
- Fever
- Loss of appetite
- Back pain

These are less common (occurring in 10-29%) side effects for patients receiving Provenge:

- Nausea
- Headache
- Citrate Toxicity: Citrate is the substance used in blood products to prevent clotting of the infusing blood, this is broken down by the liver. Giving blood products quickly may cause your calcium and magnesium levels to decrease because the citrate binds calcium and magnesium. This can cause the blood's ability to clot to be impaired. Infusing blood products slowly allows citrate to be metabolized, and decreases this risk.
- Vomiting
- Anemia(low red blood cell counts)
- Dizziness
- Pain
- Myalgia (muscle pain)
- Weakness
- Flu-like Syndrome: Usually occurs within the 2 days following the Provenge infusion.

Not all side effects are listed above. Side effects that are very rare -- occurring in less than about 10 percent of patients -- are not listed here. But you should always inform your health care provider if you experience any unusual symptoms.

When to contact your doctor or health care provider:

Contact your health care provider immediately, day or night, if you should experience any of the following symptoms:

- Fever of 100.4° F (38° C) or higher
- Breathing problems
- Severe headache

- Signs of a cerebrovascular event (stroke) such as one-sided weakness, confusion, slurred speech, and/or facial droop.

The following symptoms require medical attention, but are not necessarily an emergency. Contact your health care provider within 24 hours of noticing any of the following:

- Nausea (interferes with ability to eat and unrelieved with prescribed medication)
- Severe chills
- Dizziness
- Unusually high blood pressure
- Vomiting (more than 4-5 episodes in 24 hours)
- Significant muscle aches
- Any symptoms of irregular heartbeat (such as chest pain, shortness of breath, palpitations)

Always inform your health care provider if you experience any unusual symptoms.

Precautions:

- Before starting Provenge, make sure you tell your doctor about *any* other medications you are taking (including prescription, over-the-counter, vitamins, herbal remedies, etc.).
- Provenge is designed to stimulate the immune system. Use of immunosuppressive agents, such as steroids like prednisone / hydrocortisone / dexamethasone with Provenge, may alter the effectiveness and/or safety of sipuleucel-T. Therefore, if you are on an immunosuppressive medication, you should be carefully evaluated to determine whether it is medically appropriate to reduce or discontinue those agents prior to treatment with Provenge. Make sure to tell your doctor if you are taking any kind of immunosuppressive agent.
- Because of the risk of acute infusion reactions, patients with cardiac and/or pulmonary conditions should be closely monitored while getting treatment with Provenge.
- Provenge is intended solely for autologous use (meaning using the patient's own blood cells for making the drug for treatment).
- Reproductive, fertility, and mutagenicity (genetic mutations) studies were not done on Provenge; so it is unknown if it is safe to father a child while getting this treatment. Therefore, it is recommended that men, whose partners are able to bear children, use contraception and do not conceive a child (get pregnant) while taking Provenge. Barrier methods of contraception, such as condoms, are recommended.

Self-Care Tips:

- Each infusion of Provenge is preceded by a leukapheresis procedure 3 days before the vaccine infusion. It is critical that you follow the given appointment schedule and arrive at each appointment on time, as there are expiration times for each vaccine product made, which cannot be adjusted, changed, or exceeded. If you are unable to receive the prepared Provenge infusion, you will need to undergo the entire leukapheresis procedure again.
- Follow the preparation instructions for the leukapheresis procedures. (See leukapheresis section below).

- Prior to your first leukapheresis procedure, you will be assessed to determine if you have adequate 'venous access' (meaning will your veins support intravenous catheters) to support both the leukapheresis procedure and the Provenge infusions. If there is concern that the veins in your arms will not support the leukapheresis procedure and the Provenge infusions, you may need a central venous catheter placed. If a central line is necessary, you will be instructed how to care for the line, will have arrangements made to have it flushed regularly to keep it from developing a clot that would close it off, and will also be instructed on the signs to look for indicating that it may have become infected.
- Get plenty of rest.
- Maintain good nutrition.
- It is important to report signs and symptoms of acute infusion reactions such as fever, chills, fatigue, breathing problems, dizziness, high blood pressure, nausea, vomiting, headache, or muscle aches.

If you experience symptoms or side effects, be sure to discuss them with your health care team. They can prescribe medications and/or offer other suggestions that are effective in managing such problems.

Monitoring and Testing:

You will be checked regularly by your doctor while you are taking Provenge, to monitor side effects. Periodic blood work will be obtained to monitor your complete blood count (CBC) to make sure it is safe for you to undergo the leukapheresis procedure. Your doctor may also order blood work to monitor the function of other organs (such as your kidneys and liver).

Leukapheresis:

In order to make Provenge, which is tailor made for each patient, a particular type of white blood cell needs to be taken from the patient and sent to the vaccine manufacturing plant. The process of taking these white blood cells from a person is called *leukapheresis* [loo-KA-fer-ee-ses].

Leukapheresis involves having an intravenous catheter (IV) placed in each arm (unless you have an appropriately sized central line catheter). Blood is taken out of one of the IVs, filtered through a machine that pulls out the necessary white blood cells, and the rest of the blood is then given back to you through the second IV. This process takes about 3-4 hours and is done 3 days prior to the infusion of Provenge. When preparing to go for your leukapheresis procedure, it is important to remember the following helpful tips:

- Stay well hydrated in the few days before each procedure
- On the day of leukapheresis, avoid caffeinated beverages
- On the day of leukapheresis, eat a calcium-rich breakfast
- Wear loose-fitting clothing, especially clothing with sleeves that can be raised above the elbow (if you don't have a central venous catheter).
- You will not be able to get up and move around during the procedure. So, for example, if you need to void, it will be in a portable urinal, so wear pants that are easy to maneuver.

- The immune cells collected during the leukapheresis procedure are sent to a manufacturing facility to be manufactured into Provenge.
- Provenge is then shipped to the physician's office/infusion center for infusion into the patient, 3 days later.

How Provenge Works:

Immunotherapy is the use of the immune system to reject and/or fight cancer. The immune system can be stimulated to attack the cancer cells. This can be either through immunization of the patient (with a vaccine, such as Provenge), during which a patient's own immune system is trained to recognize tumor cells as targets to be destroyed, or through the administration of therapeutic antibodies (in drug form), which directly destroy cancer cells.

The immune system acts through a number of different ways. Most of these ways identify the abnormal cells by their "antigen" which is a specific marker or code, present on the surface of these cells. Autologous cellular immunotherapy involves taking a patient's own blood cells, pulling out specific immune cells, and 'loading' those cells with a vaccine. These 'loaded' cells are re-infused into the patient. The loaded cells then activate certain types of immune cells, causing those cells to multiply, recognize and target abnormal cancer cells by identifying their unique antigens.

Provenge is an autologous immunotherapy that activates a man's immune cells to multiply and attack prostate cancer cells by way of activating certain immune cells with a vaccine that triggers immune cells to identify prostate cancer cells by an antigen that is highly specific to prostate cancer. By targeting this antigen, these loaded cells are primed to identify and attack prostate cancer cells.

The specific mechanism by which Provenge works remains unknown. What is known is that the vaccine appears to improve the survival in some men who receive it, however, it does not result in a decrease in PSA and does not replace the need for other treatment for your prostate cancer.

Note: We strongly encourage you to talk with your health care professional about your specific medical condition and treatments. The information contained in this website is meant to be helpful and educational, but is not a substitute for medical advice.

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