

Sipuleucel-T (Provenge)

About This Therapy

Sipuleucel-T is used to treat cancer. It is made using your own immune cells. Your immune cells will be collected via leukapheresis, a procedure that circulates your blood through a machine and removes some of your immune cells. Your collected immune cells are then mixed with a protein to activate them and make them ready for your infusion. Sipuleucel-T contains your activated immune cells and is given to you through the vein (IV).

Possible Side Effects

- Headache
- Fever
- Chills
- Tiredness
- Nausea
- Back pain
- Joint pain/ache

Note: Each of the side effects above was reported in 15% or greater of patients treated with sipuleucel-T. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- While you are getting this therapy in your vein (IV), you may have a reaction to the infusion. Sometimes you may be given medicine to stop or lessen these side effects. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, low blood pressure, passing out, rash, itching, chest tightness, or chest pain. These reactions may happen after your infusion. **If this happens, call 911 for emergency care.**
- Blood clots and events such as stroke and heart attack. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Infusion reactions may occur after your infusion. **If this happens, call 911 for emergency care.**
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.

Food and Medicine Interactions

- There are no known interactions of sipuleucel-T with food.
- This therapy may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness that interferes with your daily activities
- Feeling dizzy and/or lightheaded
- Headache that does not go away
- Wheezing and/or trouble breathing
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or



sudden, bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**

- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Signs of infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **If this happens, call 911 for emergency care.**
- Your leg and/or arm is swollen, red, warm and/or painful
- Pain that does not go away, or is not relieved by prescribed medicines
- If you think you may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** It is not known if this therapy may harm an unborn child. Sipuleucel-T is not indicated for use in women.
- **Breastfeeding warning:** It is not known if this therapy passes into breast milk. Sipuleucel-T is not indicated for use in women.
- **Fertility warning:** Fertility studies have not been done with this medicine. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm banking.

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