Sipuleucel-T (Provenge®)

About This Drug

Sipuleucel-T is used to treat cancer. It is given in 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. Not all possible side effects are included above.*

Warnings and Precautions

- While you are getting this drug in your vein (IV), you may have a reaction to the drug. Sometimes you may be given medication 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, 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.
- Low blood pressure and passing out

*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 plenty of fluids (a minimum of eight glasses per day is recommended).
• To help with nausea, 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 or stop 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 Drug Interactions

• There are no known interactions of sipuleucel-t with food.
• This drug 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 100.5 F (38 C) or higher
• Chills
• Fatigue that interferes with your daily activities
• Feeling dizzy 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
• Signs of infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain.
• Your leg or arm is swollen, red, warm and/or painful
• If you think you may be pregnant

Reproduction Warnings

• **Pregnancy warning:** It is not known if this drug may harm an unborn child. Sipuleucel-t is not indicated for use in women.

• **Breastfeeding warning:** It is not known if this drug passes into breast milk. Sipuleucel-t is not indicated for use in women.

• **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm banking.

Revised May 2018