PROVENGE®
(sipuleucel-T)

PATIENT INFORMATION

This leaflet is designed to help you understand treatment with PROVENGE (pronounced PRO-ven-ge). We encourage you to understand your treatment, the better you will be able to participate in your care. This leaflet does not take the place of talking with your doctor or health professional about your medical condition or your treatment. If you have any questions, speak with your doctor.

What is PROVEN GE? PROVENGE is a prescription medicine that is used to treat certain patients with advanced prostate cancer. PROVENGE is made from your own immune cells.

What should I tell my doctor before getting PROVENGE? Tell your doctor about all your medical problems, including:
- heart problems
- lung problems
- history of stroke

Tell your doctor about all the medicines you take, including prescription and nonprescription drugs, vitamins, and dietary supplements.

How will I get PROVENGE? Since PROVENGE is made from your own immune cells, your cells will be collected approximately 3 days before each scheduled infusion of PROVENGE. You may go to a cell collection center for this collection. The collection is called “leukapheresis” (pronounced loo-kuh-fuh-REE-sis). Your collected cells are sent to a manufacturing center where they are mixed with a protein to make them ready for your infusion.

You will get PROVENGE in 3 intravenous infusions (put into your veins), about 2 weeks apart. Each infusion takes about 60 minutes. Following each infusion, you will be monitored for at least 30 minutes.

Your doctor will give you a schedule for your cell collection and infusion appointments. It is very important that you arrive on time for your appointments. If you miss an appointment and cannot be infused, your PROVENGE dose will be wasted. Your doctor will work with you to schedule a new appointment at the cell collection center. You may also get a new infusion appointment.

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The most common side effects of PROVENGE include:
- chills
- nausea
- fatigue
- joint ache
- fever
- headache
- back pain

PROVENGE infusion can cause serious reactions. Tell your doctor right away if:
- you have breathing problems, chest pains, racing heart or irregular heartbeats, high or low blood pressure, dizziness, fainting, nausia, or vomiting after getting PROVENGE. Any of these may be signs of heart or lung problems.
- you develop numbness or weakness on one side of the body, difficulty speaking or difficulty breathing. Any of these may be signs of a stroke.
- you develop symptoms of thrombosis which may include: pain and/or swelling of an arm or leg with warmth over the affected area, disoloration of an arm or leg, unexplained shortness of breath, chest pain that worsens on deep breathing.
- you get a fever over 100°F, or redness or pain at the infusion or collection sites. Any of these may be signs of infection.

Tell your doctor about any side effect that concerns you or PROVENGE treatment. For more information, talk with your doctor.

What are the ingredients in PROVENGE? The active components of PROVENGE are your own immune cells mixed with the active core component, which is made in a laboratory to produce an immune response to prostate cancer. The product is suspended in an infusion solution called Lactated Ringer's Injection, USP, an inactive ingredient.