FREQUENTLY ASKED QUESTIONS ABOUT PROVENGE®

(sipuleucel-T)

How do I know if my cancer has spread beyond the prostate?

Regular monitoring is recommended by nationally recognized medical organizations to determine if the cancer has spread beyond the prostate.

What is PROVENGE?

PROVENGE is the first and only FDA-approved, personalized immunotherapy for advanced prostate cancer (metastatic castration-resistant prostate cancer, or mCRPC). PROVENGE is made from your own cells. By activating immune cells already in your body, PROVENGE personalizes the fight against your advanced prostate cancer. PROVENGE is clinically proven to extend life in certain men with advanced prostate cancer.

When should I consider PROVENGE?

Several leading nationally recognized medical organizations recommend sipuleucel-T (PROVENGE) as initial therapy for certain men with metastatic castration-resistant prostate cancer (mCRPC). This includes the American Urological Association (AUA), the National Comprehensive Cancer Network® (NCCN®), and the Society for Immunotherapy of Cancer (SITC). Sipuleucel-T (PROVENGE) may be used before or after certain other therapies for advanced prostate cancer, or mCRPC. So even if you have already received treatment for advanced prostate cancer, you may benefit from sipuleucel-T (PROVENGE).[a]

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This information reflects general guidelines only and is not intended as a substitute for clinical judgment.

FREQUENTLY ASKED QUESTIONS

What are the benefits of PROVENGE® (sipuleucel) for me?

The PROCEED Registry showed median overall survival of approximately 4 years in men who were treated with PROVENGE when their prostate-specific antigen (PSA) levels were less than or equal to 5.27 ng/mL. The median is not the average but the middle of a set of numbers.

The PROCEED Registry evaluated side effects and secondarily survival following treatment with PROVENGE in a medical-practice setting where all patients received PROVENGE and there was no untreated group. Patients may have received other cancer treatments as prescribed by their physician. Scientists used the survival data to identify groups of patients who may live longer after treatment with PROVENGE. Exploratory analyses like these are limited in their ability to reliably predict treatment effects and individual results may vary.

In the IMPACT trial, median survival was 13 months longer for men with a low PSA level (less than or equal to 22.1 ng/mL) treated with PROVENGE compared with men who did not receive treatment with PROVENGE. The median is not the midpoint but the middle of a series of numbers. In all 4 groups of the exploratory analysis, men who received PROVENGE saw improved median overall survival when compared to men who did not receive PROVENGE (control).[b]

What side effects can occur with PROVENGE?

The most common side effects of PROVENGE are generally mild to moderate and are well tolerated.

There are potential risks associated with PROVENGE:

- In controlled clinical trials, 71.2% of men treated with PROVENGE developed an acute infusion reaction

— The most common events ≥20% were chills, fever, and fatigue. In 95.1% of patients reporting acute infusion reactions, the reactions were mild or moderate. Fevers and chills generally resolved within 2 days (71.9% and 89%, respectively)

- 1.5% of men discontinued their treatment with PROVENGE due to side effects

The most common side effects of treatment with PROVENGE include:

- Chills
- Fatigue
- Fever
- Back pain
- Nausea
- Joint ache
- Headache

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, nausea, 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, decreased vision in one eye, or difficulty speaking. Any of these may be signs of a stroke.

[b] Analysis was exploratory and individual results may vary.

FREQUENTLY ASKED QUESTIONS

- You develop symptoms of thrombosis which may include: pain and/or swelling of an arm or leg with warmth over the affected area, discoloration 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.

These are not all the possible side effects of PROVENGE® (sipuleucel) treatment. For more information, talk with your doctor. Please see Important Safety Information.

Is PROVENGE different from other therapies?

As a personalized immunotherapy, PROVENGE works differently from other cancer treatments, such as chemotherapy or hormone therapy.

- PROVENGE is personalized because it's made from your own immune cells. It empowers your immune system's ability to recognize and remember prostate cancer cells
- Similar to a vaccine, PROVENGE boosts your immune system's ability to target and attack prostate cancer cells immediately, with effects that last over time

How does PROVENGE affect PSA level?

PROVENGE works differently from other cancer treatments, such as chemotherapy or hormone therapy. Unlike these treatments, PROVENGE may not lower your PSA level. The goal of PROVENGE treatment is not to lower PSA level, it is to extend life.

What kind of testing should I be getting to help manage my prostate cancer?

Measuring prostate-specific antigen (PSA) level and imaging (for example, bone scans) are 2 ways your doctor may watch for changes in your prostate cancer. These tests do not necessarily reflect how well a treatment works in advanced prostate cancer; they are part of standard monitoring for prostate cancer progression. In fact, PSA testing and imaging have led to early detection of metastases and to opportunities for treatment with the potential for improved outcomes. If you are receiving hormone therapy, talk to your doctor about regular monitoring to identify disease progression.

As a caregiver, how can I help?

If you are a caregiver for someone with advanced prostate cancer, you understand the physical and emotional toll this disease takes on your loved one. Many men living with advanced prostate cancer don't feel comfortable asking for help, but just knowing you are there can mean so much to him.

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PROVENGE®
(sipuleucel-T)

INDICATION

PROVENGE® (sipuleucel-T) is a prescription medicine used to treat certain men with advanced prostate cancer. PROVENGE is an established cellular immunotherapy and is customized to each individual by using his own immune cells.

IMPORTANT SAFETY INFORMATION

Before receiving PROVENGE®, tell your doctor about any medical conditions, including heart or lung problems, or if you have had a stroke.

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

The most common side effects of PROVENGE include chills, fatigue, fever, back pain, nausea, joint ache, and headache. These are not all the possible side effects of PROVENGE treatment.

PROVENGE is made from your own immune cells, which are collected during a process called leukapheresis. The cells are processed, returned, and then infused back into the patient through an IV (intravenous) infusion about 3 days later. This process is completed in 3 cycles, about 2 weeks apart. Each infusion takes approximately 1 hour and requires 30 minutes of post-infusion monitoring.

PROVENGE infusion can cause serious reactions. Tell your doctor right away if you:

- Have signs of a heart attack or lung problems, such as trouble breathing, chest pains, racing or irregular heartbeats, high or low blood pressure, dizziness, fainting, nausea, or vomiting
- Have signs of a stroke, such as numbness or weakness on one side of the body, decreased vision in one eye, or difficulty speaking
- Develop symptoms of thrombosis which may include: pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, shortness of breath, chest pain that worsens or deep breathing
- Have signs of infection such as a fever over 100°F, redness or pain at the infusion or collection sites

Tell your doctor about any side effect(s) that concerns you or does not go away. For more information, talk with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 800-FDA-1088.

To report an adverse event, please email our Pharmacovigilance department at drugsafety@dendreon.com, or fax adverse event details to 833-464-0123. Please provide details pertaining to the adverse event and provide contact information so that our Pharmacovigilance team may contact you with any questions.

To report a product complaint, email our Quality department at CQAcomplaints@dendreon.com. Please provide details pertaining to the quality issue and provide contact information so that our Quality team may contact you with any questions.

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