PROVENGE® (sipuleucel-T)

Think more about special occasions.
Think less about cancer.

PROVENGE is a personalized immunotherapy that activates the immune system to help fight advanced prostate cancer and has been proven to help certain men live longer.

INDICATION
PROVENGE® (sipuleucel-T) is a prescription medicine used to treat certain men with advanced prostate cancer.

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
What is PROVENGE?

PROVENGE is the first FDA-approved personalized immunotherapy that is clinically proven to extend life for certain men with metastatic castration-resistant prostate cancer (mCRPC). Men are diagnosed with mCRPC when their cancer has spread (metastasized) from the prostate to other areas of the body and the cancer becomes resistant to androgen deprivation therapy (ADT), also known as hormone therapy.

PROVENGE is personal

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 attack your prostate cancer cells.

SINCE FDA APPROVAL, IN 2010

NEARLY

40,000 men

have received PROVENGE

IMPORTANT SAFETY INFORMATION, CONT

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
How PROVENGE works

PROVENGE works to boost your immune system’s ability to target and attack prostate cancer cells immediately, with effects that last over time.

Is PROVENGE right for me?

PROVENGE immunotherapy is indicated for men with mCRPC who:

- Are castrate resistant
  - Have disease progression on hormone therapy
  - Have testosterone levels that are less than or equal to 50 ng/dL
- Have been diagnosed with metastatic disease, meaning the cancer has spread from the prostate to other areas of the body, such as bones or lymph nodes
- Are not taking drugs for cancer-related pain

Ask your doctor about the benefits of receiving PROVENGE
What to expect with PROVENGE

The IMPACT study showed greater overall survival (OS) in men who received PROVENGE

The IMPACT study compared men who received PROVENGE to men who did not receive PROVENGE. It was a randomized, placebo-controlled study of 512 men with mCRPC.

A further analysis of the IMPACT study suggests that men with a lower baseline prostate-specific antigen (PSA) level who receive PROVENGE may live longer

Median Overall Survival

In all 4 groups of the exploratory analysis, men who received PROVENGE saw improved median OS when compared with men who did not receive PROVENGE (control)

PROVENGE and 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 treatment with PROVENGE is not to lower PSA level, it is to extend life.

IMPORTANT SAFETY INFORMATION, CONT

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
In PROCEED, men who started PROVENGE when their PSA was lower lived longer

The PROCEED registry was a real-world study in which there was no control group. It evaluated the safety and, secondarily, the survival of nearly 2000 men who received PROVENGE. These men may have received other cancer therapies in addition to PROVENGE, as prescribed by their doctor.

**In a Subanalysis of the PROCEED Registry**

**Median Overall Survival**

~4 years

For men with a baseline PSA level of ≤5.27 ng/mL

Improvement to Median Overall Survival:

- ≤5.27: 47.7 months
- >5.27–≤15.08: 33.2 months
- >15.08–≤46: 27.2 months
- >46: 18.4 months

This subgroup analysis of the PROCEED registry was exploratory and results need careful interpretation.
The most common side effects of PROVENG E were generally mild to moderate and were well tolerated.

Most infusion-related side effects were resolved within 1 or 2 days.

PROVENG E infusion can cause serious reactions.

There are potential risks associated with PROVENG E:

- In controlled clinical trials, 71.2% of men treated with PROVENG E developed an acute infusion reaction.
  - The most common adverse events ≥20% were chills, fever, and fatigue. In 95.1% of men 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 PROVENG E due to adverse events.

IMPORTANT SAFETY INFORMATION, CONT

PROVENG E 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 on deep breathing.
- Have signs of infection such as a fever over 100°F, redness or pain at the infusion or collection sites.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
PROVENGE treatment can be completed in about a month

The PROVENGE treatment process includes 3 personalized cycles using your own immune cells, activating them to empower your immune system. This process can be completed in 6 appointments over the course of about a month.

It’s important to keep all of your scheduled appointments in order to prevent delays in your treatment.

PROVENGE treatment process

**Step 1: Cell collection**

What to expect:
Treatment begins at your local blood center with leukapheresis, a 2- to 4-hour cell collection process in which your blood is passed through a machine that extracts a small amount of your immune cells, along with some platelets and red blood cells. The remainder of the blood is returned to your body.

You may experience chills, fatigue, or slight tingling in your hands and feet while the cells are being collected.

Prior to beginning treatment, a vein assessment will be conducted to determine whether an additional procedure is required to complete the cell collection process.

**Step 2: PROVENGE infusion**

What to expect:
The infusion of PROVENGE will take place at your healthcare provider’s office or infusion center. The process takes about 1 hour, followed by 30 minutes of post-infusion monitoring.
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Ask your doctor today about PROVENGE.

Support for you
There are many resources for men with advanced prostate cancer. You can find support organizations, locate urologists or oncologists, and connect with other men who have advanced prostate cancer by visiting the RESOURCES page of provenge.com

Coverage for PROVENGE
PROVENGE is covered by Medicare and most private insurance plans. For men receiving PROVENGE, 90% of Medicare fee-for-service members have a supplement and are expected to have minimal to no out-of-pocket costs; 85% of out-of-pocket costs are less than $50.

Travel assistance programs may be available to those who qualify.
Visit the COVERAGE & SUPPORT page of provenge.com to learn more.

IMPORTANT SAFETY INFORMATION, CONT
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 1-800-FDA-1088.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.