PROVENGE® (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.  

**INDICATION**

PROVENGE® (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

**IMPORTANT SAFETY INFORMATION**

**Acute Infusion Reactions:** Acute infusion reactions (reported within 1 day of infusion) may occur and include nausea, vomiting, fatigue, fever, rigor or chills, respiratory events (dyspnea, hypoxia, and bronchospasm), syncope, hypotension, hypertension, and tachycardia.

**Thromboembolic Events:** Thromboembolic events, including deep vein thrombosis, pulmonary embolism, peripheral artery thrombosis, stroke, and transient ischemic attacks, may occur. Thromboembolic events may occur as early as 3 days following the last dose of PROVENGE. The clinical significance and causal relationship are uncertain. Most patients had multiple risk factors for these events.

**Vascular Disorders:** Cerebrovascular events (hemorrhagic/ischemic strokes and transient ischemic attacks) and cardiovascular disorders, including myocardial infarctions, have been reported following infusion of PROVENGE. The clinical significance and causal relationship are uncertain. Most patients had multiple risk factors for these events.

**Adverse Reactions:** The most common adverse reactions reported with PROVENGE include grade 1-2 diarrhea, rigors, chills, myalgia, arthralgia, fever, hypotension, and hypertension. Severe adverse events, including death, have also been reported.

**Handling Precautions:** Prolonged (12 hours or longer) exposure of PROVENGE to temperatures below 2°C or above 38°C can result in a decrease in viability and function. PROVENGE should be used with caution in patients with risk factors for these events.

**Concomitant Chemotherapy or Immunosuppressive Therapy:** Chemotherapy or immunosuppressive agents (such as systemic corticosteroids) given concurrently with the leukapheresis procedure may alter the efficacy and/or safety of PROVENGE. Concurrent use of immune-suppressive agents may alter the efficacy and/or safety of PROVENGE.

**Discontinuation:** Discontinue PROVENGE if a patient develops a severe infusion reaction.

**For Healthcare Providers**

**FOR HEALTHCARE PROVIDERS**

**FOR PROVENGE TREATMENT**

Please see additional Important Safety Information on reverse side.
IDENTIFYING ELIGIBLE mCRPC PATIENTS FOR PROVENGE TREATMENT

FOR HEALTHCARE PROVIDERS

MORE PATIENTS THAN YOU MAY REALIZE
Routine scans may uncover metastatic castrate-resistant prostate cancer (mCRPC) early

- Over 30% of men thought to have non-metastatic CRPC were found to have metastatic disease when screened via imaging.
- Most men with CRPC will eventually develop metastatic disease.

Most CRPC patients fit in the PROVENGE window at the time of metastatic diagnosis

At the time of metastatic diagnosis

{87%}
of CRPC patients may be eligible for PROVENGE

INDICATION
PROVENGE® (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer.

IMPORTANT SAFETY INFORMATION

Acute Infusion Reactions:

Acute infusion reactions (reported within 1 day of infusion) may occur and include nausea, vomiting, fatigue, fever, rigor or chills, respiratory events (dyspnea, hypoxia, and bronchospasm), syncope, hypotension, hypertension, and tachycardia.

Thromboembolic Events:

Thromboembolic events, including deep venous thrombosis and pulmonary embolism, can occur following infusion of PROVENGE. The clinical significance and causal relationship are uncertain. Most patients had multiple risk factors for these events.

Please see accompanying full Prescribing Information.

Vascular Disorders:

Cerebrovascular events (hemorrhagic/ischemic strokes and transient ischemic attacks) and cardiovascular disorders (myocardial infarctions) have been reported following infusion of PROVENGE. The clinical significance and causal relationship are uncertain. Most patients had multiple risk factors for these events.

Handling Precautions:

PROVENGE is not tested for transmissible infectious diseases.

Concomitant Chemotherapy or Immunosuppressive Therapy:

Chemotherapy or immunosuppressive agents (such as systemic corticosteroids) given concurrently with the leukapheresis procedure in PROVENGE has not been studied. Concurrent use of immune-suppressive agents may alter the efficacy and/or safety of PROVENGE.

Adverse Reactions:

The most common adverse reactions reported in clinical trials (≥ 15% of patients receiving PROVENGE) were chills, fatigue, fever, back pain, nausea, joint ache, and headache.

www.PROVENGEHCP.com

Does your practice have patients like these?

If your patient:

✓ Has confirmed metastatic disease

✓ Has testosterone <50 ng/dL

✓ Progressed on ADT

✓ Is asymptomatic and does not require narcotics for cancer pain

✓ Is now castrate resistant

✓ Received ADT for 24 months following biological recurrence

✓ Prior radical prostatectomy

✓ Prior radiation therapy for prostate cancer

•  A recent scan revealed 3 metastatic lesions

•  Is asymptomatic and does not require narcotics for cancer pain

•  Recently diagnosed with metastatic disease

•  Is now castrate resistant

•  Received ADT for 24 months following biological recurrence

•  Prior radical prostatectomy

•  Prior radiation therapy for prostate cancer

•  63-year-old bus driver

•  72-year-old retired engineer

Patents:

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REFERENCES:


PROVENGE® (sipuleucel-T)

PATIENT INFORMATION

This leaflet is designed to help you understand treatment with PROVENGE® (pronounced proh-VEN-gee). It will help you 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 healthcare professional about your medical condition or your treatment. If you have any questions, speak with your doctor.

What is PROVENGE®?

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 will 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 rescheduled. Your doctor will work with you to schedule a new appointment at the cell collection center. You may also get a new infusion appointment.

(Continued on Other Side)
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 your body, dizziness, difficulty speaking. 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, 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.

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

What are the possible or reasonably likely side effects of PROVENGE?

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

If you would like more information about PROVENGE, talk with your doctor. You can also call toll-free 1-877-336-3763 or visit www.PROVENGE.com.