



What Is Prostate Cancer?

Cancer and the prostate

What is the prostate?

The prostate is a small, walnut-shaped gland, or organ used to produce a substance. Found at the base of a man's urethra, the prostate adds a nutrient-rich fluid to semen.

The male hormone testosterone is what spurs the prostate to grow, and in older men it is sometimes enlarged. This condition is called benign prostatic hyperplasia, or BPH, and it is not usually a life-threatening problem.

Cancerous cells in the prostate are the result of a series of genetic mutations, or changes in the cells' DNA (their genetic blueprints). These mutated cells may form a solid growth called a tumor, and the tumor may spread from the prostate to other areas of the body, such as the bones, the blood, the lymph nodes, or other organs. A cancer that has spread to other organs is called advanced, or metastatic.

Because the prostate surrounds the urethra and is below the bladder, it is usually examined by a urologist, or doctor who specializes in problems with the urinary system.



Prostate cancer risk

Prostate cancer is relatively common.

Other than skin cancer, prostate cancer is the most common cancer among men in the United States. It's estimated that, in the US, more than 2 million men have had the disease. And 1 in 7 men will be diagnosed with prostate cancer during their lifetime.

The causes of prostate cancer are not known.

But some of the risks associated with it are. Here are the major ones:

- Genes (family history). Genes are DNA instructions that tell the body how to make the proteins it needs. You get your genes from your parents. Over time, genes can change, or mutate, and certain mutations can make cells grow uncontrollably, leading to cancer. Only 5% to 10% of cancers are thought to have a genetic component that strongly affects risk. But prostate cancer does tend to be more common in men whose close family members have had this condition. If you have prostate cancer, your immediate family members may want to be screened early and regularly
- Age. Approximately 60% of all cancers of the prostate are found in men aged 65 and older
- Race. Prostate cancer develops more often in African-American men than in Caucasian men, and, unfortunately, African-American men are more than twice as likely to die of this disease
- Geography. For reasons not well understood, prostate cancer rates are higher in North America and Europe, and lower in Asia, Africa, and South America

Symptoms of advanced prostate cancer

As prostate cancer spreads, it can cause more and more symptoms.

At first, many men with prostate cancer report surprisingly few or even no symptoms. For a long time, they may not know that they have the disease.

But when the cancer spreads outside the prostate and nearby lymph nodes (becomes metastatic), it is usually accompanied by symptoms.

These can include:

- Trouble urinating
- Blood in the urine
- Numbness in the feet or legs
- Loss of bladder or bowel control
- Back pain



IMPORTANT SAFETY INFORMATION FOR JEV TANA® (CABAZITAXEL) INJECTION

WARNING

JEV TANA may cause serious side effects, including low white blood cells. Low white blood cells can cause you to get serious infections, and may lead to death. The earliest sign of infection may be fever, so tell your healthcare provider right away if you have a fever. People who are 65 years or older may be more likely to have these problems. JEV TANA should not be given to patients with low white blood cell counts. Your healthcare provider:

- Will do blood tests regularly to check your white blood cell counts during your treatment with JEV TANA
- May lower your dose of JEV TANA, change how often you receive it, or stop JEV TANA until you have enough white blood cells
- May prescribe a medicine for you to help prevent complications if your white blood cell count is too low

JEV TANA can also cause severe allergic reactions. Severe allergic reactions can happen within a few minutes after your infusion of JEV TANA starts, especially during the first and second infusions. Your healthcare provider should prescribe medicines before each infusion to help prevent severe allergic reactions.

- Symptoms of severe allergic reactions may include rash or itching, skin redness, feeling dizzy or faint, breathing problems, chest or throat tightness, swelling of face. Tell your healthcare provider right away if you have any of these symptoms. Your healthcare provider will stop your JEV TANA treatment right away and treat your allergic reaction.

You should not take JEV TANA if you have had a severe allergic reaction to JEV TANA or other medicines that contain polysorbate 80. Ask your healthcare provider if you are not sure.

Severe stomach and intestine (gastrointestinal) problems. JEV TANA can cause severe stomach and intestine problems, which may lead to death. You may need to go to the hospital for treatment.

Vomiting and diarrhea can happen when you take JEV TANA. Severe vomiting and diarrhea with JEV TANA can lead to loss of too much body fluid (dehydration), or too much of your body salts (electrolytes). Death has happened from having severe diarrhea and losing too much body fluid or body salts with JEV TANA. Your healthcare provider will prescribe medicines to prevent or treat vomiting and diarrhea, as needed with JEV TANA.

Tell your healthcare provider if:

- you have vomiting or diarrhea
- your symptoms get worse or do not get better

JEV TANA can cause a leak in the stomach or intestine, intestinal blockage, infection, and bleeding in the stomach or intestine. This can lead to death.

Tell your healthcare provider if you have any of these symptoms:

- severe stomach-area (abdomen) pain
- constipation
- fever
- blood in your stool or changes in the color of your stool

Kidney failure.

Kidney failure may happen with JEV TANA, because of severe infection, loss of too much body fluid (dehydration), and other reasons, which may lead to death. Your healthcare provider will check you for this problem and treat you if needed.

Tell your healthcare provider if you develop these signs or symptoms:

- swelling of your face or body
- decrease in the amount of urine that your body makes each day

Do not receive JEV TANA if you have severe liver problems.

Before receiving JEV TANA, tell your healthcare provider if you:

- had allergic reactions in the past
- have kidney or liver problems
- are age 65 or older as these patients:
 - may be more likely to experience certain adverse reactions, including low white blood cell count with or without fever, tiredness, weakness, fever, dizziness, urinary tract infection and dehydration
- have any other medical conditions
- if you are female and:
 - are pregnant or plan to become pregnant as JEV TANA can harm your unborn baby
 - are breastfeeding or plan to breastfeed

Serious side effects of JEV TANA include low white blood cell counts that could lead to serious or life-threatening infections, severe allergic reactions, severe stomach and intestine (gastrointestinal) problems (severe vomiting and diarrhea, a leak in the stomach or intestine, intestinal blockage, infection, and bleeding in the stomach or intestine) that could lead to death and kidney failure.

Common side effects of JEV TANA include:

- Low blood platelet count. Low platelet count is common with JEVTANA, but can sometimes also be serious. Tell your healthcare provider if you have any unusual bruising or bleeding.
- Fever
- tiredness
- nausea
- constipation
- weakness
- blood in the urine - Tell your healthcare provider or nurse if you see blood in your urine.
- back pain
- numbness, tingling, burning or decreased sensation in your hands or feet
- shortness of breath
- stomach (abdominal) pain
- change in your sense of taste
- cough
- joint pain
- hair loss
- decreased appetite

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of JEVTANA. For more information, ask your healthcare provider or pharmacist. You may report side effects to FDA at 1-800-FDA-1088.

Remember, your healthcare provider is the single best source of information regarding your health. Please consult your healthcare provider if you have any questions about your health or your medicine.

For more information, go to www.sanofi.us or call 1-800-633-1610.

[See Full Prescribing Information including Boxed WARNING.](#)