JEVTANA (cabazitaxel) injection

Prostate Cancer Treatment

Many options may be considered

Treatment varies from person to person.
Age, overall health, stage and grade of tumor, and PSA levels all factor into a prostate cancer treatment plan. For a man with advanced prostate cancer, many strategies may be used to treat the cancer.All treatment options can cause side effects, some life-threatening. All treatment options and risks should be discussed with your healthcare team.

This Web page provides information on the most common ways of treating prostate cancer. Work with your healthcare provider and the other members of your healthcare team to create the treatment plan that's right for you.

Learn more about a specific treatment:

Surgery
Radiation
Cellular immunotherapy
Hormone therapy
Chemotherapy

Surgery

Surgery is a common treatment for early-stage cancer.
When a cancer is confined to the actual prostate gland, or localized (it is stage I or II and has a low Gleason score), surgery is often recommended. It may also be recommended for younger men who are in good health.

One common type of prostate cancer surgery is called a radical prostatectomy. During a radical prostatectomy, a surgeon removes the entire prostate gland and sometimes the nearby lymph nodes, along with the seminal vesicles and other surrounding tissues. "Nerve-sparing" radical prostatectomies leave intact the nerves to the penis that control erections.

Another type of prostate cancer surgery is cryosurgery.
Cryosurgery, also called cryotherapy, is a relatively new technique which uses very cold gasses to freeze and destroy the prostate. Cryosurgery also often comes with side effects, such as incontinence and impotence.

Radiation

Radiation therapy uses X-rays to kill cancer cells.
Using high-energy X-rays, emitted either by a machine or by implanted radioactive "seeds," radiation therapy kills cancer cells in the prostate. Radiation therapy sometimes serves as an alternative to surgery, or it may be used after surgery to kill any remaining cancer cells.

The types of radiation therapy are external beam radiation and brachytherapy ("seed" implantation).

Cellular immunotherapy

Cellular immunotherapy is used to treat advanced prostate cancer that is no longer responding to hormone therapy. It is thought to work by helping the body's own immune system identify and attack prostate cancer cells.

One example of cellular immunotherapy is obtained by a patient's immune cells from the blood, and then using a machine in a process known as leukapheresis.

To enhance their response against the cancer, the immune cells are then exposed to a protein that is found in most prostate cancers, linked to an immune-stimulating substance. After this process, the patient's own cells are returned to the patient to treat the prostate cancer.

This treatment is given as a series of 3 infusions into a vein, with about 2 weeks between each infusion.

For advanced prostate cancers, treatments that target the whole body are used.
Hormone therapy may slow the advance of a tumor by shrinking it. Hormone therapy may be given before surgery or radiation therapy. And sometimes hormone therapy is used after surgery or radiation therapy to prevent prostate cancer from coming back.

Because hormones are found throughout the body, hormone therapy can fight cancers that have spread beyond the prostate gland. Hormone therapy cannot cure prostate cancer, but, for some men, it can stop the disease from getting worse.

Hormone therapy targets testosterone.
Hormone therapy targets prostate cancer by cutting off the male hormones (called androgens), which make prostate cancer grow. The main androgen is testosterone, produced in the testes. Testosterone is usually the target of hormone therapy.

To reduce the amount of testosterone in the body, the testicles can be removed surgically (this is called orchiectomy or castration), or medications can be used.

Hormone drugs can cut off the supply of testosterone.
Here are some of the types of hormone drugs used to treat prostate cancer:

- Luteinizing hormone-releasing hormone (LHRH) analogs. These medicines lower the amount of androgens that the testicles produce. LHRH analogs are the most common drugs used for lowering the levels of testosterone in the body
- Female hormones (estrogens). These block the release of testosterone.
- Antiandrogens. These block the activity of androgens

Chemotherapy

As a cancer spreads, chemotherapy is another treatment option.
Chemotherapy, or "chemo," is a systemic treatment, meaning it can fight cancer throughout the body. Chemotherapy may be given orally (through the mouth) or by infusion (using an IV).

Chemotherapy is often used to treat advanced prostate cancer if hormone therapy is no longer working. Chemo may shrink a tumor and can affect cancer at different sites in the body.

Chemotherapy may be used as a form of palliative therapy to try to relieve symptoms caused by the cancer, such as pain, or problems with breathing and swallowing.

The multidisciplinary team

Each man fighting prostate cancer is going to have a different experience.
So it's important that you talk to your whole healthcare team, or multidisciplinary team-meaning a group of healthcare providers with different specialties. This team can include:

- Your primary physician
- A urologist, or doctor who specializes in diseases of the urinary system and male reproductive system
- An oncologist, or a doctor who specializes in treating people with cancer
- A surgeon, or a doctor who performs operations
- A radiologist, or a doctor who specializes in the diagnosis and treatment of medical conditions through use of medical imaging techniques.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about JEVTANA (cabazitaxel)?
JEVTANA may cause serious side effects, including:

Low white blood cells can cause you to get serious infections, and may lead to death. People who are 65 years or older may be more likely to have these problems. Your healthcare provider (HCP):

- will do blood tests regularly to check your white blood cell counts during your treatment with JEVTANA.
- may lower your dose of JEVTANA, change how often you receive it, or stop JEVTANA until your HCP decides that you have enough white blood cells.
- may prescribe a medicine for you called G-CSF, to help prevent complications if your white blood cell count is too low.

Tell your HCP right away if you have any of these symptoms of infection during treatment with JEVTANA: fever (take your temperature often during treatment with JEVTANA), cough, burning on urination, or muscle aches.
Also, tell your HCP if you have any diarrhea during the time that your white blood cell count is low. Your HCP may prescribe treatment for you as needed.
Severe allergic reactions can happen within a few minutes after your infusion of JEVTANA starts, especially during the first and second infusions. Your HCP should prescribe medicines before each infusion to help prevent severe allergic reactions.

Tell your HCP or nurse right away if you have any of these symptoms of a severe allergic reaction during or soon after an infusion of JEVTANA: rash or itching, skin redness, feeling dizzy or faint, breathing problems, chest or throat tightness, or swelling of face.

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

Vomiting and diarrhea can happen when you receive JEVTANA. Severe vomiting and diarrhea with JEVTANA 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 JEVTANA. Your HCP will prescribe medicines to prevent or treat vomiting and diarrhea, as needed with JEVTANA.

Tell your HCP if: you have vomiting or diarrhea, or if your symptoms get worse or do not get better.

JEVTANA 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 HCP if you get any of these symptoms: severe stomach-area (abdomen) pain, constipation, fever, blood in your stool, or changes in the color of your stool.

Tell your HCP if you develop these signs or symptoms: swelling of your face or body, or decrease in the amount of urine that your body makes each day.

Lung or breathing problems may happen with JEVTANA and may lead to death. People who have lung disease before receiving JEVTANA may have a higher risk for developing lung or breathing problems with JEVTANA treatment. Your HCP will check you for this problem and treat you if needed.

Tell your HCP right away if you develop any new or worsening symptoms, including: trouble breathing, shortness of breath, chest pain cough or fever.

Who should not receive JEVTANA Injection?

Do not receive JEVTANA if: your white blood cell (neutrophil count) is too low, you have had a severe allergic reaction to cabazitaxel or other medicines that contain polysorbate 80 (ask your HCP if you are not sure), or you have severe liver problems.

What should I tell my HCP before receiving JEVTANA?

Before receiving JEVTANA, tell your HCP if you: had allergic reactions in the past, have kidney or liver problems, have lung problems, are age 65 or older, have any other medical conditions, or are female and

- are pregnant or plan to become pregnant. JEVTANA can harm your unborn baby. Talk to your HCP about the best way for you to prevent pregnancy while you are receiving JEVTANA.
- are breastfeeding or plan to breastfeed. It is not known if JEVTANA passes into your breast milk. You and your HCP should decide if you will take JEVTANA or breastfeed. You should not do both.

Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. JEVTANA can interact with many other medicines. Do not take any new medicines without asking your HCP first. Your HCP will tell you if it is safe to take the new medicine with JEVTANA.

What are the possible side effects of JEVTANA?

Common side effects of JEVTANA include:

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

Tell your HCP 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 HCP or pharmacist.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

See Full Prescribing Information.