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Cabazitaxel Injection

pronounced as (ka baz i tax' el)

IMPORTANT WARNING:

Cabazitaxel injection may cause a serious or life-threatening decrease in the number of white blood cells (a type of blood cell that is needed to fight infection) in your blood. This increases the risk that you will develop a serious infection. Tell your doctor if you are 65 years of age or older, if you have or have ever had a low number of white blood cells along with a fever, if you have been treated with radiation therapy, and if you are unable to eat a healthy diet. Your doctor will order laboratory tests to check the number of white blood cells in your blood before and during your treatment. If you have a low number of white blood cells, your doctor may decrease your dose or stop or delay your treatment. Your doctor may also prescribe a medication to help prevent life-threatening complications if your white blood cells decrease. If you experience any of the following symptoms, call your doctor immediately: sore throat, fever (a temperature greater than 100.4°F), chills, muscle aches, cough, burning on urination, or other signs of infection.

Cabazitaxel injection may cause severe or life-threatening allergic reactions, especially when you receive your first two infusions of cabazitaxel injection. Your doctor will give you medications to prevent an allergic reaction at least 30 minutes before you receive cabazitaxel injection. You should receive your infusion in a medical facility where you can be treated quickly if you have a reaction. Tell your doctor if you are allergic to cabazitaxel injection or polysorbate 80 (an ingredient found in some foods and medications). Ask your doctor if you are not sure if a food or medication you are allergic to contains polysorbate 80. If you experience an allergic reaction to cabazitaxel injection, it may begin within a few minutes after your infusion starts, and you may experience the following symptoms: rash, reddening of the skin, itching, dizziness, faintness, or tightening of the throat. Tell your doctor or nurse right away if you experience any of these symptoms.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to check your body's response to cabazitaxel injection.

Talk to your doctor about the risks of taking cabazitaxel injection.

Why is this medication prescribed?

Cabazitaxel injection is used along with prednisone to treat prostate cancer (cancer of a male reproductive organ) that has already been treated with other medications. Cabazitaxel injection is in a class of medications called microtubule inhibitors. It works by slowing or stopping the growth of cancer cells.

How should this medicine be used?

Cabazitaxel injection comes as a liquid to be given intravenously (into a vein) over 1 hour by a doctor or nurse in a medical facility. It is usually given once every 3 weeks.

You will need to take prednisone every day during your treatment with cabazitaxel injection. It is important that you take prednisone exactly as prescribed by your doctor. Tell your doctor if you have missed doses or have not taken prednisone as prescribed.

Your doctor may need to stop or delay your treatment or decrease your dose if you experience certain severe side effects. Be sure to tell your doctor how you are feeling during your treatment.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before receiving cabazitaxel injection,

- tell your doctor and pharmacist if you are allergic to cabazitaxel injection, any other medications, polysorbate 80, or any of the other ingredients in cabazitaxel injection. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin); antifungals such as ketoconazole (Nizoral), itraconazole (Sporanox), and voriconazole (Vfend); antiplatelet medications; aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Advil, Motrin) and naproxen (Aleve, Naprosyn); clarithromycin (Biaxin); certain medications for human immunodeficiency virus (HIV) such as atazanavir (Reyataz), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); certain medications for seizures such as carbamazepine (Carbatrol, Equetro, Tegretol), phenytoin (Dilantin), and phenobarbital; nefazodone; rifabutin (Mycobutin), rifapentine (Priftin); rifampin (Rimactin, in Rifamate, in Rifater); steroid medication; and telithromycin (Ketek). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with cabazitaxel injection, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have or have ever had liver disease. Your doctor may probably tell you not to receive cabazitaxel injection.
- tell your doctor if you have or have ever had kidney disease or anemia (a lower than normal number of red blood cells).

- you should know that cabazitaxel injection is usually used in men with prostate cancer. If used by pregnant women, cabazitaxel injection can cause harm to the fetus. Women who are or may become pregnant or are breast-feeding should not receive cabazitaxel injection. If you receive cabazitaxel injection while you are pregnant, call your doctor. You should use birth control to prevent pregnancy during your treatment with cabazitaxel injection.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are receiving cabazitaxel injection.

What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medication.

What side effects can this medication cause?

Cabazitaxel injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- heartburn
- change in ability to taste food
- loss of appetite
- weight loss
- swelling of the inside of the mouth
- headache
- joint or back pain
- numbness, burning, or tingling in the hands, arms, feet, or legs
- hair loss

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- nausea
- diarrhea
- vomiting
- stomach pain
- constipation
- swelling of the face, arms, hands, feet, ankles, or lower legs
- decreased urination
- blood in the urine
- blood in stool
- changes in stool color
- dry mouth, dark urine, decreased sweating, dry skin, and other signs of dehydration

- irregular heartbeat
- shortness of breath
- pale skin
- tiredness or weakness
- unusual bruising or bleeding

Cabazitaxel injection may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- sore throat, cough, fever, chills, muscle aches, burning on urination, or other signs of infection
- unusual bruising or bleeding
- pale skin
- shortness of breath
- excessive tiredness or weakness
- nausea
- vomiting
- diarrhea

What other information should I know?

Ask your pharmacist any questions you have about cabazitaxel injection.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Jevtana[®]

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