



Cabazitaxel (Jevtana)

Drug type

- A taxane derivative, which is a microtubule inhibitor

Indications

- In combination with prednisone, treatment of hormone-refractory metastatic prostate cancer in patients previously treated with a docetaxel-containing treatment regimen.

Mechanism of action

- Binds to tubulin and promotes its assembly into microtubules, simultaneously inhibiting disassembly
- This leads to microtubule stabilization, resulting in the inhibition of mitotic and interphase cellular functions.
- Unlike the other taxanes, cabazitaxel has poor affinity for the multidrug resistance proteins, thereby conferring activity in resistant tumors

Dosage and administration

- Based on calculation of body surface area (BSA)
 - 25 mg/m² administered as a 1-hour IV infusion, using a filter, every 3 weeks
 - In combination with oral prednisone 10 mg daily throughout treatment
 - Premedication is recommended to reduce risk and/or severity of hypersensitivity
 - Antihistamine (dexchlorpheniramine 5 mg, diphenhydramine [Benadryl, generics] 25 mg, or equivalent antihistamine)
 - Corticosteroid (dexamethasone 8 mg or equivalent corticosteroid)
 - H₂ antagonist (ranitidine [Zantac, generics] 50 mg or equivalent H₂ antagonist)
 - Oral or IV antiemetic prophylaxis as needed is recommended.

Pregnancy and lactation

- Pregnancy category: D
- Lactation
 - Cabazitaxel or cabazitaxel metabolites are excreted in maternal milk of lactating rats.
 - Unknown whether excreted in human milk

Cautions

- Neutropenia
 - Neutropenic deaths have been reported.
 - Obtain frequent blood counts to monitor for neutropenia
 - Should not be administered to patients with neutrophils $\leq 1,500/\text{mm}^3$
- Hypersensitivity reactions
 - Severe hypersensitivity can occur
 - Do not use in patients with a history of hypersensitivity to cabazitaxel or polysorbate 80
 - Symptoms may include generalized rash/erythema, hypotension, and bronchospasm
 - Discontinue immediately if severe reactions occur and administer appropriate therapy
 - Premedicate all patients prior to initiating infusion
- GI symptoms
 - Nausea, vomiting, severe diarrhea may occur
 - Death related to diarrhea and electrolyte imbalance occurred in randomized clinical trial
 - May require intensive measures for severe diarrhea and electrolyte imbalance
- Renal failure
 - Reported in a randomized clinical trial, including

four cases that resulted in fatal outcome.

- Hepatic impairment
 - Should not be given to patients with hepatic impairment
 - Cabazitaxel is extensively metabolized in the liver. Hepatic impairment likely to increase cabazitaxel concentrations
- Elderly patients
 - Patients 65 years and older are more likely to experience certain adverse reactions, including neutropenia and febrile neutropenia.

Drug interactions

- No formal clinical drug-drug interaction trials have been conducted
- Prednisone or prednisolone administered 10 mg daily did not affect pharmacokinetics of cabazitaxel
- CYP3A4 inhibitors
 - Concomitant administration of strong CYP3A inhibitors (eg, ketoconazole [Nizoral, generics], itraconazole [Sporanox, Onmel, generic], clarithromycin [Biaxin, generics], atazanavir [Reyataz], indinavir [Crixivan], nefazodone, nelfinavir [Viracept], ritonavir [Norvir], saquinavir [Invirase], telithromycin [Ketek], voriconazole [Vfend, generics]) expected to increase cabazitaxel concentrations
 - Avoid coadministration with strong CYP3A inhibitors
 - Exercise caution with concomitant use of moderate CYP3A inhibitors
- CYP3A4 inducers
 - Concomitant administration of strong CYP3A inducers (eg, phenytoin [Dilantin, generics], carbamazepine, rifampin [Rifadin, generics], rifabutin [Mycobutin], rifapentine [Priftin], phenobarbital) expected to decrease cabazitaxel concentrations
 - Avoid coadministration with strong CYP3A inducers
 - In addition, patients should refrain from taking St. John's Wort.

Food interactions

- Patients should avoid drinking grapefruit juice, which can increase effects/levels of cabazitaxel

What to tell your patient

- Your doctor has prescribed this anticancer medicine that is used with the corticosteroid medicine, prednisone. It is used to treat people with prostate cancer that has

progressed after treatment with other anticancer medicines, including docetaxel.

- You cannot have this medication 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 nurse or doctor if you are not sure.
- Tell your nurse or doctor if
 - You have had allergic reactions in the past.
 - You have kidney or liver problems.
 - You are older than 65 years.
 - You have any other medical conditions.
- Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.
 - Cabazitaxel can interact with many other medicines. Do not take any new medicines without asking your doctor first.

How cabazitaxel is administered

- Cabazitaxel will be given to you by an intravenous (IV) infusion.
- Your treatment will take approximately 1 hour.
- Cabazitaxel is usually given every 3 weeks.
- Your doctor will also prescribe prednisone for you to take by mouth every day during your treatment with cabazitaxel.

This medication may cause serious side effects including

- Low white blood cell count (WBC)
 - 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 doctor will take blood regularly to check your white blood cell count during your treatment.
 - Tell your nurse or doctor right away if you have any of these symptoms of infection while receiving cabazitaxel
 - Fever—take your temperature often during treatment
 - Burning on urination
 - Muscle aches
 - Diarrhea
- Severe allergic reactions.
 - May occur within a few minutes after your infusion starts, especially during the first and second infusions

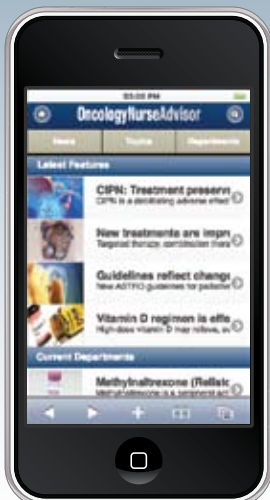
- Your doctor should prescribe medicines before each infusion to help prevent severe allergic reactions.
- Tell your nurse or doctor right away if you have any of these symptoms of a severe allergic reaction during or soon after an infusion
 - Skin redness
 - Feeling dizzy or faint
 - Rash or itching
 - Breathing problems
 - Chest or throat tightness
 - Swelling of face
- Gastrointestinal symptoms
 - Severe vomiting and diarrhea with this medication can lead to loss of too much body fluid (dehydration), or too much of your body salts (electrolytes)
 - Tell your nurse or doctor if you have vomiting or diarrhea
- Kidney failure
 - Kidney failure may occur because of severe infection, dehydration, and other reasons
 - Tell your nurse or doctor if you develop
 - Swelling of your face or body
 - Decrease in the amount of urine

Side effects

- Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects.
- Common side effect of this medication include

- Low red blood cell count (RBC), also known as anemia
 - Your nurse or doctor will regularly check your red blood cell count
 - Symptoms of anemia include shortness of breath and tiredness
- Low blood platelet count. Tell your nurse or doctor if you have any unusual bruising or bleeding.
- Tell your nurse or doctor if you have any of the following
 - Back pain
 - Blood in the urine
 - Change in your sense of taste
 - Constipation
 - Cough
 - Decreased appetite
 - Fever
 - Hair loss
 - Joint pain
 - Nausea
 - Numbness, tingling, burning, or decreased sensation in your hands or feet
 - Shortness of breath
 - Stomach (abdominal) pain
 - Tiredness
 - Weakness

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