Patient Case Study

BASED ON A REAL PATIENT CASE

JEVTANA® (cabazitaxel) injection

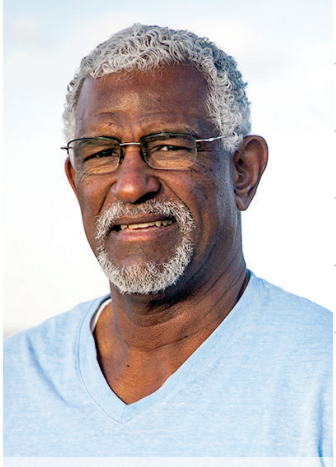


*Image is not of an actual patient

Patient:	Carl
PMHx:	Erectile dysfunction, hypertension, history of DVT
Medications:	none
Allergies:	NKDA
Surgical Hx:	none
FMHx:	father died of prostate cancer (PCa) at age 80, 2 brothers with PCA, no other significant cancer maternal/paternal grandparents, mother, aunts/uncles/other siblings. BRCA1 positive.

CASE SUMMARY

Patient with rapidly progressing metastatic castration-resistant prostate cancer.

INDICATION

JEVTANA is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) previously treated with a docetaxel-containing treatment regimen.

IMPORTANT SAFETY INFORMATION

WARNING: NEUTROPENIA AND HYPERSENSITIVITY

Neutropenia: Neutropenic deaths have been reported. Monitor for neutropenia with frequent blood cell counts. JEVTANA is contraindicated in patients with neutrophil counts of ≤1,500 cells/mm^3. Primary prophylaxis with G-CSF is recommended in patients with high-risk clinical features. Consider primary prophylaxis with G-CSF in all patients receiving a dose of 25 mg/m^2.

Severe hypersensitivity: Severe hypersensitivity reactions can occur and may include generalized rash/erythema, hypotension and bronchospasm. Severe hypersensitivity reactions require immediate discontinuation of the JEVTANA infusion and administration of appropriate therapy. Patients should receive premedication. JEVTANA is contraindicated in patients who have a history of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING.

Patient Case Study, cont'd

JEVTANA® (cabazitaxel) injection

History of Present Illness

Carl is a 66 y/o black male who presented with elevated PSA after a routine screening in 2013. He has PMHx of erectile dysfunction, hypertension, and a history of DVT. During the evaluation, his PSA was 8.2 ng/mL and a DRE revealed an enlarged hard prostate. Transrectal biopsy – Gleason 4+4=8. pT2N0M0. His bone scan and CT A/P were negative.

Initial Management

- Patient underwent a radical prostatectomy but was lost to follow-up. 5 years later in 2018, his PSA was 17.3 ng/mL and his scans were negative. Leuprolide was initiated and his PSA initially declined.
- After 12 months, his disease progressed. A bone scan revealed 2 rib lesions and 2 spine lesions. A CT scan revealed extensive abdominal and pelvic adenopathy. His PSA increased to 30.4 ng/mL. He had progressed to mCRPC.

Subsequent Management

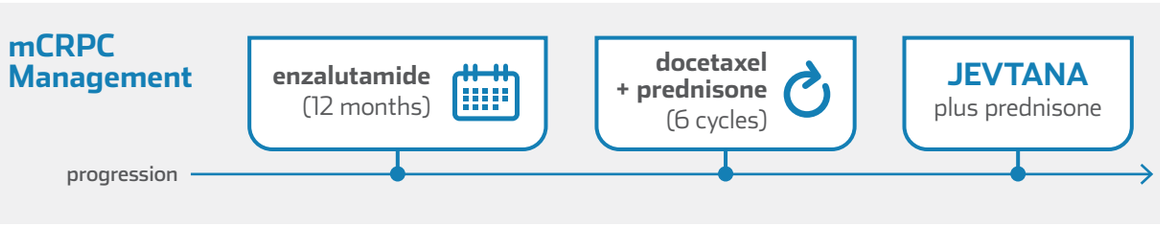
- ADT continued and patient was started on enzalutamide. He had a PSA nadir of 5.05 ng/mL and saw a decrease of abdominal and pelvic adenopathy. He experienced Grade 1 fatigue and arthralgia.
- At 12 months, his PSA increased in 10.0 ng/mL and bone scan showed radiographic progression with new lesions at lumbar spine, pelvis, and bilateral femoral. Enzalutamide was discontinued.

Subsequent Management

- ADT was still continued and patient was started on docetaxel 75 mg/m^2 Q3W and prednisone 10 mg daily. He had a PSA nadir of 7.13 ng/mL and saw a decrease of lesions in skull, ribs, sternum, spine, and femur. He experienced diarrhea, nausea, neutropenia, fatigue, and alopecia. Docetaxel was discontinued after 6 cycles due to cumulative toxicities.
- After discontinuance of docetaxel + prednisone, patient continued ADT only. 5 months after discontinuance, PSA increased to 30.0 ng/mL and radiographic progression was documented.

Treatment Goals and Plans

- Begin treatment with JEVTANA 20 mg/m^2 Q3W and prednisone. ADT is maintained throughout mCRPC treatment.



NKDA=no known drug allergies; DVT=deep vein thrombosis, DRE=digital rectal exam; pT2N0M0=pathologic tumor >20mm but <50mm in greatest dimension with no regional lymph node mets; CT A/P=computerized tomography scan of abdomen and pelvis; ADT=androgen deprivation therapy; Q3W=every 3 weeks

IMPORTANT SAFETY INFORMATION – cont'd

CONTRAINDICATIONS

JEVTANA is contraindicated in patients with neutrophil counts of ≤1,500/mm^3, patients with a history of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80, and patients with severe hepatic impairment (total bilirubin >3x upper limit of normal (ULN)).

WARNINGS AND PRECAUTIONS

Bone Marrow Suppression (BMS): BMS manifested as neutropenia, anemia, thrombocytopenia and/or pancytopenia may occur. Neutropenic deaths have been reported. Monitor blood counts frequently to determine if initiation of G-CSF and/or dosage modification is needed. Monitoring of complete blood counts is essential on a weekly basis during cycle 1 and before each treatment cycle thereafter so that the dose can be adjusted, if needed. Caution is recommended in patients with hemoglobin <10 g/dl.

Increased Toxicities in Elderly Patients: Patients ≥65 years of age were more likely to experience fatal outcomes not related to disease progression and certain adverse reactions, including neutropenia and febrile neutropenia. Monitor closely.

Hypersensitivity Reactions: Severe hypersensitivity reactions can occur. Premedicate all patients with antihistamines, corticosteroids and H_2 antagonists prior to JEVTANA. Observe patients closely, especially during the first and second infusions. Discontinue JEVTANA immediately if severe hypersensitivity occurs and treat as indicated.

Gastrointestinal (GI) Adverse Reactions: Nausea, vomiting, and severe diarrhea may occur. Death related to diarrhea and electrolyte imbalance occurred in the randomized clinical trials and mortality related to diarrhea has been reported. Intensive measures may be required for severe diarrhea and electrolyte imbalance. Rehydrate and treat with antiemetics and antidiarrheals as needed. If experiencing grade ≥3 diarrhea, dosage should be modified.

GI hemorrhage and perforation, ileus, enterocolitis, neutropenic enterocolitis, including fatal outcome, have been reported. Risk may be increased with neutropenia, age, steroid use, concomitant use of NSAIDs, antiplatelet therapy or anticoagulants, and prior history of pelvic radiotherapy, adhesions, ulceration and GI bleeding. Abdominal pain and tenderness, fever, persistent constipation, diarrhea, with or without neutropenia, may be early manifestations of serious GI toxicity and should be evaluated and treated promptly. JEVTANA treatment delay or discontinuation may be necessary.

Renal Failure: Cases, including those with fatal outcomes, have been reported. Identify cause and manage aggressively.

Urinary Disorders including Cystitis: Cystitis, radiation cystitis, and hematuria, including that requiring hospitalization, has been reported with JEVTANA in patients who previously received pelvic radiation. Cystitis from radiation recall may occur late in treatment with JEVTANA. Monitor patients who previously received pelvic radiation for signs and symptoms of cystitis while on JEVTANA. Interrupt or discontinue JEVTANA in patients experiencing severe hemorrhagic cystitis. Medical and/or surgical supportive treatment may be required to treat severe hemorrhagic cystitis.

Respiratory Disorders: Interstitial pneumonia/pneumonitis, interstitial lung disease and acute respiratory distress syndrome have been reported and may be associated with fatal outcome. Patients with underlying lung disease may be at higher risk for these events. Acute respiratory distress syndrome may occur in the setting of infection. Interrupt JEVTANA if new or worsening pulmonary symptoms develop. Closely monitor, promptly investigate, and appropriately treat patients receiving JEVTANA. Consider discontinuation. The benefit of resuming JEVTANA treatment must be carefully evaluated.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING.

IMPORTANT SAFETY INFORMATION – cont'd

WARNINGS AND PRECAUTIONS, cont'd

Use in Patients with Hepatic Impairment: JEVTANA dose should be reduced for patients with mild (total bilirubin >1 to ≤1.5 x ULN or AST >1.5 x ULN) and moderate (total bilirubin >1.5 to ≤3.0 x ULN and any AST) hepatic impairment, based on tolerability data in these patients. Administer JEVTANA 20 mg/m^2 for mild hepatic impairment. Administer JEVTANA 15 mg/m^2 for moderate hepatic impairment. Monitor closely.

Embryo-Fetal Toxicity: JEVTANA can cause fetal harm and loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the last dose of JEVTANA.

ADVERSE REACTIONS (ARs)

The most common all grades adverse reactions and laboratory abnormalities (≥10%) with JEVTANA 20 mg/m^2 or 25 mg/m^2 are neutropenia, anemia, diarrhea, nausea, fatigue, asthenia, vomiting, hematuria, constipation, decreased appetite, back pain, and abdominal pain.

DRUG INTERACTIONS

Avoid coadministration of JEVTANA with strong CYP3A inhibitors. If patients require coadministration of a strong CYP3A inhibitor, consider a 25% JEVTANA dose reduction.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** The safety and efficacy of JEVTANA have not been established in females. There are no human data on the use of JEVTANA in pregnant women to inform the drug-associated risk.
- **Lactation:** The safety and efficacy of JEVTANA have not been established in females. There is no information available on the presence of JEVTANA in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production.
- **Females and Males of Reproductive Potential:** Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the last dose of JEVTANA.

Please see full Prescribing Information, including Boxed WARNING.

sanofi

JEVTANA® (cabazitaxel) injection

MAT-US-2406668-v1.0-07/2024