Dosing and Administration

Dosing schedule[1]

For patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen:

JEVTANA® 25 mg/m^2 as a 1-hour IV infusion every 3 weeks + oral predisone 10 mg daily throughout treatment

Dose modifications[1]

Toxicity	Dose modification
Prolonged grade ≥3 neutropenia[a] (>1 week) despite appropriate medication including G-CSF	Delay treatment un il neutrophil count is >1,500 cells/mm^3, hen reduce dosage of JEVTANA® to 20 mg/m^2. Use G-CSF for secondary prophylaxis.
Febrile neutropenia or neutropenic infec ion	Delay treatment un il improvement or resolu ion, and until neutrophil count is >1,500 cells/mm^3, hen reduce dosage of JEVTANA to 20 mg/m^2. Use G-CSF for secondary prophylaxis.
Grade ≥3 diarrhea or persisting diarrhea despite appropriate medication, fluid and electrolyte replacement	Delay treatment un il improvement or resolu ion, hen reduce dosage of JEVTANA® to 20 mg/m^2.
Grade 2 peripheral neuropathy	Delay treatment un il improvement or resolu ion, hen reduce dosage of JEVTANA to 20 mg/m^2.
Grade ≥3 peripheral neuropa hy	Discontinue JEVTANA.

[a] Absolute neutrophil count <1 0 x 10^9/L.

G-CSF=granulocyte colony-stimulating factor.

Discontinue JEVTANA® treatment if a patient continues to experience any of these reactions at 20 mg/m^2

Dose reductions were reported in 12% of JEVTANA®-treated patients and 4% of mitoxantrone-treated patients

Dose delays were reported in 28% of JEVTANA®-treated patients and 15% of mitoxantrone-treated patients

Important Safety Information for JEVTANA®[1]

Patients should be observed closely for hypersensitivity reactions, especially during the first and second infusions

Severe hypersensitivity can occur and may include generalized rash/erythema, hypotension and bronchospasm. Discontinue JEVTANA® immediately if severe reactions occur and administer appropriate therapy

Contraindicated if history of severe hypersensitivity reactions to JEVTANA® or to drugs formulated with polysorbate 80

Nausea, vomiting and severe diarrhea, at times, may occur. Death related to diarrhea and electrolyte imbalance occurred in the randomized clinical trial. Intensive measures may be required for severe diarrhea and electrolyte imbalance

Women of childbearing potential should be advised to avoid becoming pregnant during treatment with JEVTANA®

Important Safety Information for JEVTANA® (cabazitaxel) Injection

WARNING: NEUTROPENIA AND HYPERSENSITIVITY

- **Neutropenic deaths have been reported. In order to monitor the occurrence of neutropenia, frequent blood cell counts should be performed on all patients receiving JEVTANA®. JEVTANA® should not be given to patients with neutrophil counts of ≤1,500 cells/mm^3**
- **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® must not be given to patients who have a history of severe hypersensitivity reactions to JEVTANA® or to other drugs formulated with polysorbate 80**

Continue »

JEVTANA® is a microtubule inhibitor indicated in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer (mHRPC) previously treated with a docetaxel-containing treatment regimen.

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CONTRAINDICATIONS

- JEVTANA® should not be used in patients with neutrophil counts of ≤1,500/mm^3
- JEVTANA® is contraindicated in patients who have a history of severe hypersensitivity reactions to JEVTANA® or to other drugs formulated with polysorbate 80

WARNINGS AND PRECAUTIONS

- Neutropenic deaths have been reported
  - 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
  - Monitor blood counts frequently to determine if initiation of G-CSF and/or dosage modification is needed
  - Primary prophylaxis with G-CSF should be considered in patients with high-risk clinical features
- Severe hypersensitivity reactions can occur
  - Premedicate with antihistamines, corticosteroids and H_2 antagonists
  - Patients should be observed closely for hypersensitivity reactions, especially during the first and second infusions
  - Discontinue infusion immediately if hypersensitivity is observed and treat as indicated
- Mortality related to diarrhea has been reported
  - Rehydrate and treat with anti-emetics and anti-diarrheals as needed
  - If experiencing grade ≥3 diarrhea, dosage should be modified
- Nausea, vomiting and severe diarrhea, at times, may occur. Death related to diarrhea and electrolyte imbalance occurred in the randomized clinical trial. Intensive measures may be required for severe diarrhea and electrolyte imbalance
- Gastrointestinal (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, anti-platelet therapy or anti-coagulants, 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, including cases with fatal outcomes, has been reported. Identify cause and manage aggressively
- 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
- Patients with impaired hepatic function were excluded from the randomized clinical trial
  - Hepatic impairment is likely to increase the JEVTANA® concentrations
  - JEVTANA® should not be given to patients with hepatic impairment
- JEVTANA® can cause fetal harm when administered to a pregnant woman
  - There are no adequate and well-controlled studies in pregnant women using JEVTANA®
  - Women of childbearing potential should be advised to avoid becoming pregnant during treatment with JEVTANA®

ADVERSE REACTIONS

- Deaths due to causes other than disease progression within 30 days of last study drug dose were reported in 18 (5%) JEVTANA® treated patients. The most common

- The most common (≥10%) grade 1-4 adverse reactions were anemia, leukopenia, neutropenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, dysgeusia, cough, arthralgia, and alopecia
- The most common (≥5%) grade 3-4 adverse reactions in patients who received JEVTANA® were neutropenia, leukopenia, anemia, febrile neutropenia, diarrhea, fatigue, and asthenia

Please see full prescribing information including boxed **WARNING**.

Reference

1. JEVTANA® Prescribing Information. Bridgewater, NJ: sanofi-aventis U.S. LLC; November 2014.