



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Jevtana is in the taxane class and acts by binding to tubulin and promoting its assembly into microtubules while inhibiting disassembly. This causes the stabilization of microtubules which in turn inhibits mitotic and interphase cellular functions. The drug is administered as a one hour intravenous infusion every three weeks in combination with 10 mg oral prednisone taken daily throughout the Jevtana treatment. Other potential strategies for treatment in the setting of post-docetaxel progression of prostate cancer include ixabepilone, mitoxantrone/prednisone, platinum agents, immunotherapies, and molecularly targeted agents (1-2).

Regulatory Status

FDA-approved indication: Jevtana is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen (1).

Jevtana carries a boxed warning for severe hypersensitivity and neutropenia. Obtain frequent blood counts to monitor for neutropenia. Do not give Jevtana if neutrophil counts are $\leq 1,500$ cells/mm³. Severe hypersensitivity reactions can occur and may include generalized rash/erythema, hypotension, and bronchospasm. To reduce the risk and/or severity of hypersensitivity of the infusion, the patient must be premedicated at least 30 minutes prior to each dose of Jevtana with an antihistamine, corticosteroid, and a H₂ antagonist. Antiemetic prophylaxis is recommended and can be given if needed. Jevtana is contraindicated if there is a history of severe hypersensitivity reactions to cabazitaxel or polysorbate 80. Jevtana should not be given to patients with severe hepatic impairment (total bilirubin $> 3 \times$ Upper Limit of Normal (ULN)) (1).

The safety and effectiveness of Jevtana have not been established in pediatric patients (1).

Summary

Jevtana is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen. There are several potential patient safety concerns with treatment. Jevtana can cause serious side effects such as dangerously low neutrophil counts, severe allergic reactions, and kidney failure. Frequent and routine blood tests need to be monitored during treatment (1).



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JEVTANA
(cabazitaxel)

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Jevtana while maintaining optimal therapeutic outcomes.

References

1. Jevtana [package insert]. Bridgewater, NJ: Sanofi-Aventis US LLC; July 2023.
2. NCCN Drugs & Biologics Compendium® Cabazitaxel 2024. National Comprehensive Cancer Network, Inc. Accessed on May 14, 2024.