



## Jevtana<sup>®</sup> (cabazitaxel) – New warning

- On January 9, 2018, the FDA approved a new warning to the [Jevtana \(cabazitaxel\)](#) drug label regarding the risk of urinary disorders including cystitis.
- Jevtana is indicated in combination with [prednisone](#) for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a [docetaxel](#)-containing treatment regimen.
- Cystitis, radiation cystitis, and hematuria, including that requiring hospitalization, have been reported with Jevtana in patients who previously received pelvic radiation.
  - In the Proselica trial, cystitis and radiation cystitis were reported in 1.2% and 1.5% of patients who received prior radiation, respectively.
  - Hematuria was reported in 19.4% of patients who received prior radiation and in 14.4% of patients who did not receive prior radiation.
  - Cystitis from radiation recall may occur late in treatment with Jevtana. Patients who previously received pelvic radiation should be monitored for signs and symptoms of cystitis while on Jevtana.
  - Jevtana should be interrupted or discontinued in patients experiencing severe hemorrhagic cystitis. Medical and/or surgical supportive treatment may be required to treat severe hemorrhagic cystitis.



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