Jevtana® (cabazitaxel) – New Warning

- On September 12, 2016, the FDA approved a new update to the *Warnings and Precautions* section of the Jevtana (cabazitaxel) drug label regarding the risk of interstitial pneumonia/pneumonitis, interstitial lung disease and acute respiratory distress syndrome.
    - Similar information was added to the *Adverse Reaction* sections.
- Jevtana is a microtubule inhibitor indicated in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.
- 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.
- Jevtana should be interrupted or discontinued if new or worsening pulmonary symptoms develop. Patients receiving Jevtana therapy should be closely monitored, promptly investigated, and appropriately treated. The benefit of resuming Jevtana treatment must be carefully evaluated.
- Other warnings and precautions of Jevtana include bone marrow suppression, gastrointestinal adverse reactions, renal failure, use in elderly patients, use in patients with hepatic impairment, and embryo-fetal toxicity.
- Jevtana carries a boxed warning for neutropenia and hypersensitivity.