April 2014

IMPORTANT PRESCRIBING INFORMATION

SANOFI

Avoiding preparation errors with JEVTANA® (cabazitaxel) Injection that may cause an overdose

Dear Healthcare Provider,

Sanofi-aventis U.S. ("Sanofi") has recently been informed of cases of reconstitution errors with JEVTANA (cabazitaxel) Injection that led to overdoses, with actual doses delivered that were 15% to 20% higher than the prescribed dose. JEVTANA Injection single-use vial requires **two** dilutions prior to administration. In the reported cases, the errors in the administered doses occurred due to inappropriate reconstitution in the first dilution step. The entire contents of the diluent vial (5.7 mL) were **not** transferred to the JEVTANA Injection vial, which led to overdoses in patients treated with JEVTANA. Anticipated complications of overdose may include exacerbation of adverse reactions such as bone marrow suppression and gastrointestinal disorders. Please refer to section ***10 Overdose*** of the JEVTANA Prescribing Information.

Sanofi is reminding you of the appropriate preparation instructions for JEVTANA. JEVTANA Injection single-use vial requires **two** dilutions prior to administration. Both the JEVTANA Injection and the diluent vials contain an overfill to compensate for liquid loss during preparation. Using the **entire contents** of the accompanying diluent, including overfill, during the first dilution step, ensures there is an initial diluted solution containing 10 mg/mL JEVTANA. The initial diluted JEVTANA solution requires a second (final) dilution before administration.

Sanofi has updated the JEVTANA Prescribing Information to emphasize the importance of using the **entire contents** of the diluent container in the first step and the need for **two** dilutions of JEVTANA prior to administration. Refer to section ***2.5 Instructions for Preparation*** of the JEVTANA Prescribing Information for this update. *Please read this entire section carefully before mixing and diluting JEVTANA.*

Where an automated software system is used to prepare JEVTANA, the system must be programmed to allow withdrawal of the entire contents of the diluent vial (5.7 mL) when it is added to the JEVTANA Injection vial. This will ensure a concentration of 10 mg/mL in the initial diluted JEVTANA solution.

JEVTANA (cabazitaxel) Injection 60 mg/1.5 mL is supplied as a kit consisting of the following:

- JEVTANA Injection 60 mg/1.5 mL: contains 60 mg cabazitaxel in 1.5 mL polysorbate 80.
- Diluent for JEVTANA Injection: contains approximately 5.7 mL of 13% (w/w) ethanol in water for injection.

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

Please refer to the enclosed Prescribing Information for complete safety information before prescribing JEVTANA.

Reporting adverse events

Healthcare professionals should report adverse events associated with JEVTANA use to Sanofi at 1-800-633-1610, option 2.

Alternatively, report this information to the FDA's MedWatch reporting system by phone (1-800-FDA-1088), facsimile (1-800-FDA-0178), online (www.fda.gov/medwatch/report.htm), or mail using the MedWatch form FDA 3500, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787.

For additional information, call Sanofi Medical Information Services department at 1-800-633-1610, option 1.

Sincerely,

Charles Hugh-Jones, MD
US Chief Medical Officer
sanofi-aventis U.S.

Please see the enclosed full Prescribing Information, including BOXED **WARNING**.

This letter was prepared with the guidance of FDA.

Reference: 1) JEVTANA® (cabazitaxel) Injection [package insert]. Bridgewater, NJ: sanofi-aventis U.S., LLC; March 2014.

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