

Velcade (bortezomib): Starting Dose Adjustments for Patients with Hepatic Impairment

Audience: Hematology, Oncology healthcare professionals

Takeda Oncology and FDA notified healthcare professionals about revisions to the Prescribing Information for Velcade, section 2.5, pertaining to patients with hepatic impairment at the start of Velcade therapy. The changes also include new safety information on dose adjustment for patients with moderate to severe hepatic impairment in label Section 5.11, stating: "Bortezomib is metabolized by liver enzymes. Bortezomib exposure is increased in patients with moderate or severe hepatic impairment; these patients should be treated with VELCADE at reduced starting doses and closely monitored for toxicities."

Velcade is indicated for the treatment of patients with multiple myeloma. Velcade also is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.

Read the complete MedWatch 2010 Safety Summary, including a link to the Dear Healthcare Professional letter and revised Prescribing Information, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm198424.htm>