

**VANCOUVER HOSPITAL & HEALTH SCIENCES CENTRE
CSU PHARMACEUTICAL SCIENCES
NON-FORMULARY DRUG DATA SHEET**

DRUG NAME

Bortezomib

ALTERNATE NAMES

Velcade™

MANUFACTURER

Ortho Biotech

STRENGTH

3.5mg vial as powder for reconstitution

DOSAGE FORM

Injection

INDICATIONS

- Bortezomib, a reversible inhibitor of the 26S proteasome in mammalian cells, is a neoplastic agent used in the treatment of refractory multiple myeloma.

DOSAGE AND ADMINISTRATION

- 1.3mg/m² IV bolus injection given over 3 to 5 seconds.
- Give twice weekly for two weeks (days 1,4,8 and 11) followed by a 10-day rest period (days 12-21) to complete one 3-week cycle. A total of 8 cycles may be administered. At least 72 hours should elapse between consecutive doses.
- Dose reductions to 1 mg/m² or 0.7 mg/m² may be required depending upon the severity of adverse events.
- Dose preparation: add 3.5 mL of PFNS to 3.5 mg vial for a final concentration of 1 mg/mL. Final solution should appear clear, colourless and free from particles or foreign matter. Dispense dose in syringe. Reconstituted solution stable for 8 hours in the vial or syringe - store at room temperature, protected from light.

POTENTIAL ADVERSE EFFECTS*

- *Major toxicities* include peripheral neuropathy (burning sensation, increased or decreased sensitivity to sensory stimuli, numbness, tingling, discomfort, neuropathic pain), cardiovascular effects (cardiogenic shock, CHF, cardiac arrest, cardiopulmonary arrest), hypotension, dyspnea, respiratory insufficiency, respiratory failure, GI effects (nausea, diarrhea, constipation vomiting), thrombocytopenia, neutropenia, anemia, fever, tumor lysis syndrome.
- *Most common* include painful sensations or numbness and tingling in hands or feet (may not resolve after discontinuation), nausea, diarrhea, decreased appetite, constipation, vomiting, fever, thrombocytopenia, and anemia, fatigue, malaise, weakness, psychiatric disorders, cough.
- *Less common* include deterioration in kidney and liver function, hepatitis, decreased serum Na⁺ or K⁺, severe bleeding, tumor lysis syndrome.
- *Rare include* allergic reactions (fever, severe skin rash, joint swelling, pain), anaphylactic shock, death.
- *Other adverse effects* include headache, insomnia, bone/joint/muscle pain, limb pain, fluid retention, shortness of breath, dizziness, rash, dehydration, UTI, cough, anxiety, back pain, flu-like symptoms (fever, chills, muscle cramps), dyspepsia, hypotension, rigors, herpes zoster, infection, itchiness, blurred vision, pneumonia.

SPECIAL PRECAUTIONS

- Cytotoxic precautions apply during handling, administration, and disposal.
- Nonvesicant.
- Evaluate patients for possible toxicities BEFORE each dose is given. Adjust doses in those who develop severe peripheral neuropathy or other adverse grade 3 non-hematologic or grade 4 hematologic effects.
- Administer through a central line or peripheral line. Follow with a standard saline flush.
- Do not mix with any other drugs or IV solutions.
- Bortezomib is metabolized by and may inhibit CYP-450 isoenzymes.
- Store un-reconstituted vials at room temperature and protected from light.

REPORT ANY ADVERSE DRUG REACTIONS TO CSU PHARMACEUTICAL SCIENCES