BORTETOR

For the use of an Oncologist or a Hospital or a Cancer Institute

Abbreviated Prescribing information for BORTETOR (Lyophilized) (Bortezomib 2mg for injection) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Bortezomib for injection is an antineoplastic agent available for Intravenous injection (bolus) use only. Bortezomib is a reversible inhibitor of the chymotrypsin-like activity of the 26S proteasome in mammalian cells.

INDICATIONS: Bortezomib for bolus I.V. injection is indicated for the treatment of patients with multiple myeloma and for the treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy.

DOSAGE AND ADMINISTRATION: The recommended starting dose of bortezomib is 1.3 mg/m^2 administered either as a 3 to 5 second bolus intravenous injection. Retreatment for multiple myeloma: May retreat starting at the last tolerated dose.Hepatic Impairment: Use a lower starting dose for patients with moderate or severe hepatic impairment.Dose must be individualized to prevent overdose.

CONTRAINDICATIONS: Patients with hypersensitivity (not including local reactions) to bortezomib, boron, or mannitol, including anaphylactic reactions.Contraindicated for intrathecal administration.

WARNINGS AND PRECAUTIONS: Embryo-fetal risk, peripheral neuropathy, hypotension, cardiac disorders, pulmonary disorders, posterior reversible encephalopathy syndrome, gastrointestinal adverse events, thrombocytopenia or neutropenia, tumor lysis syndrome, hepatic toxicity, renal impairment and diabetes.

DRUG INTERACTIONS: Interacts with ketoconazole, melphalan-prednisone, omeprazole, inhibitors or inducers of cytochrome P450 3A4 when used concomitantly.

ADVERSE REACTIONS: diarrhea, nausea, fatigue, constipation, peripheral neuropathy, vomiting, pyrexia, thrombocytopenia, anemia, headache, anorexia, cough, paresthesia, dyspnea, neutropenia, rash, insomnia, abdominal pain, bone pain, pain in limb, muscle cramps. more than one patient in the bortezomib group had additional grade 4 adverse events, including hypercalcemia, hyponatremia, sepsis,renal failure and gastrointestinal hemorrhage.

MARKETED BY:

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(Additional information is available on request)