**Bortezomib**

**Generic name:** Bortezomib

**Brand name:** VELBORTE®

**Dosage form:** lyophilized powder for solution for infusion 3.5 mg

**Drug class:** Proteasome inhibitors

**Indications:**

Bortezomib is used to treat multiple myeloma and mantle cell lymphoma.

* Treatment of multiple myeloma (a kind of red bone marrow malignancy) in patients who continue to develop their disease despite a previous treatment period.
* Treatment of Mantle cell lymphoma (Mantle cell lymphoma). This type of lymphoma is a non-Hodgkin's lymphoma that captures white blood cells.

Bortezomib may also be used for purposes not listed in this medication guide.

**Contraindications**

Bortezomib should not be prescribed for patients with the following conditions:

* In patients with a known hypersensitivity or allergy to Gemcitabine or any of the other ingredients of VELBORTE®.
* Pregnancy or breastfeeding.
* Acute infiltrative pulmonary disease and pericardial disease.

**Mechanism of action**

Bortezomib is a proteasome inhibitor. The proteasomal system plays a vital role in cellular protein turnover, which is essential for the homeostasis of cells. Bortezomib reversibly binds to the chymotrypsin-like subunit of the 26S proteasome, resulting in its inhibition and preventing the degradation of various pro-apoptotic factors. The accumulation will eventually activate the programmed cell death via caspase-mediated pathways in the neoplastic cells that are usually dependent on the suppression of pro-apoptotic pathways for their proliferation and survival.

**Warning and precautions**

* This medicine is prescribed for your current condition. So do not use it in similar cases or recommend it to others.
* Take this medicine according to the treatment plan prescribed by the doctor and with the strict observance of the hours and intervals mentioned.
* Discontinue the use of medication only with a doctor and avoid abstinence.
* Bortezomib should not be given to patients who are allergic to Bortezomib or any of the other ingredients of this product.
* This medication should only be prescribed by specialist physicians. The injection of this drug should be done at approved centers for the administration of oncological drugs.
* It should be treated with this drug in accordance with the instructions for use with cytotoxic drugs.
* This medicine may cause fatigue, dizziness, and changes in vision. Take caution when driving or doing things that require vigilance.
* During treatment with Velborte® control blood count (CBC) periodically.
* Due to the condition of hypotension, blood pressure, especially in patients taking low blood pressure medications, is monitored.
* Control the blood glucose level carefully in patients who receive oral hypoglycemic agents along with Velborte®.
* Monitor patients with moderate or severe liver disorder who take this medicine to prevent liver toxicity.
* This drug should be used with caution in people with heart disease or history of heart disease.
* Avoid becoming dehydrated if you have any vomiting or diarrhea. Talk with your doctor about how best to keep yourself hydrated.
* Bortezomib can harm an unborn baby or cause birth defects if the mother or the father is using this medicine.
* You may need to have a negative pregnancy test before starting this treatment.
* If you are a woman, do not use Bortezomib if you are pregnant. Use effective birth control to prevent pregnancy while you are using this medicine and for at least 7 months after your last dose.
* If you are a man, use effective birth control if your sex partner is able to get pregnant. Keep using birth control for at least 4 months after your last dose.
* Tell your doctor right away if a pregnancy occurs while either the mother or the father is using Bortezomib.
* This medicine may affect fertility (ability to have children) in both men and women. However, it is important to use birth control to prevent pregnancy because Bortezomib may harm the baby if a pregnancy does occur.
* Patients treated with Bortezomib need to be managed with antiviral prophylaxis as reactivation of herpes zoster is a real possibility.
* Bortezomib can cause peripheral neuropathy, especially when combined with other medications like isoniazid, amiodarone, and HMG-CoA reductase inhibitors. Thus, close monitoring of neurological deficits is a strong recommendation.
* In elderly population should take great precautions when administering Bortezomib because of the risk of toxicity.

**How is Bortezomib given?**

Bortezomib is given as an infusion into a vein. A healthcare provider will give you this injection.

You may be given medication to prevent nausea or vomiting while you are receiving Bortezomib.

Bortezomib can lower blood cells that help body fight infections and help blood to clot. The blood will need to be tested often. The cancer treatments may be delayed based on the results of these tests**.**

The liver function and nerve function may also need to be checked.

**What should I avoid while receiving Bortezomib?**

* Avoid becoming dehydrated if you have any vomiting or diarrhea. Talk with your doctor about how best to keep yourself hydrated.
* Avoid being near people who are sick or have infections. Tell your doctor at once if you develop signs of infection.
* Bortezomib may cause blurred vision and may impair your reactions. Avoid driving or hazardous activity until you know how this medicine will affect you.
* Avoid getting up too fast from a sitting or lying position, or you may feel dizzy.

**Bortezomib side effects**

Taking any medication may cause side effects. In some cases, patients do not experience any side effects or the side effects of the drug disappear after a short time of taking the drug. Talk to your doctor if you experience any side effects while taking this medicine.

Get emergency medical help if you have signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Bortezomib may cause a serious viral infection of the brain that can lead to disability or death. Call your doctor right away if you have a severe headache, buzzing in your ears, vision problems, weakness, confusion, thinking problems, or a seizure (convulsions).

**The following are adverse events seen with Bortezomib**

* Central Nervous System: Peripheral neuropathy, fatigue, neuralgia, headache, paresthesia, dizziness
* Gastrointestinal: Diarrhea, nausea, constipation, vomiting, anorexia, abdominal pain, decreased appetite
* Hematologic and Oncologic: Thrombocytopenia, neutropenia anemia, leukopenia, hemorrhage
* Cardiovascular: Hypotension, cardiac disease, acute pulmonary edema, cardiac failure, cardiogenic shock, pulmonary edema
* Respiratory: Dyspnea, pneumonia
* Infection: Herpes zoster, herpes simplex infection, herpes zoster
* Dermatologic: Rash
* Local: Injection site reaction (mostly redness) and irritation at the injection site
* Neuromuscular and Skeletal: Weakness
* Hepatic: Ascites, hepatic failure, hepatic hemorrhage, hepatitis, hyperbilirubinemia
* Fever
* Dehydration symptoms, feeling very thirsty or hot, being unable to urinate, heavy sweating, or hot and dry skin

**Drug Interactions**

Consult your doctor about all the medications you are taking. VELBORTE® may interact with other medications.

* Blood pressure reduces blood pressure by taking other blood pressure-lowering drugs at the same time.
* Co-administration with enzyme inhibitors CYP3A4 Increase the side effects of the drug.
* Co-administration with enzyme inducers CYP3A4 Reduce the effectiveness of the drug.
* Co-administration of oral anti-diabetic drugs increase or decrease blood sugar.
* Medications that cause peripheral neuropathy, such as amiodarone, antiviral, isoniazid, nitrofurantoin, statins, and concomitant use of this drug can exacerbate neuropathy.

Keep a list with you of all the medicines you use (including any prescription or nonprescription medicine, herbal preparation and vitamins) and show this list your doctor.

**Bortezomib use while Pregnancy and Breastfeeding**

Pregnancy: Category D

Using Bortezomib during pregnancy is strongly discouraged and patients should take precautions to avoid pregnancy.

Patients must not breast-feed while they are treated with VELBORTE® and Do not restart breast-feeding, unless doctor has allowed.

**Storage conditions**

* Store the medicine at temperatures below 30° C and stored away from light and moisture.
* Keep the medicine in the box until it is consumed.
* Keep the medicine out of the reach of children.
* The solution prepared for injection should be taken immediately. The maximum storage time of the prepared solution at room temperature (25° C) should not exceed 8 hours.