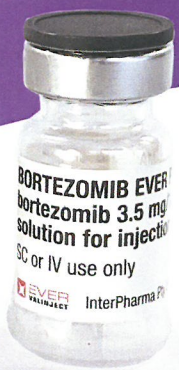
BORTEZOMIB EVER PHARMA

NOW AVAILABLE
The First Bortezomib Ready-To-Use Solution in Australia.



3.5 mg
1.4 ml

CytoWrap®
Plastic sleeving for safer handling

- Bortezomib EVER Pharma is provided as a ready to use formulation for subcutaneous injection (SC), and after dilution for intravenous injection.
- No reconstitution from powder required prior to preparing patient specific doses saving time and costs
- No dilution needed prior to SC injection - most patient doses are given SC as this route of administration has become a standard of care for patients with multiple myeloma

Common patient doses

BSA m^2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2	2.1
Std Dose mg/m^2	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
Patient Dose mg	1.69	1.82	1.95	2.08	2.21	2.34	2.47	2.6	2.73
Strength mg/ml	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
SC Injection volume ml	0.7	0.7	0.8	0.8	0.9	0.9	1.0	1.0	1.1

EVER VALINJECT

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Suite 103, 39 East Esplanade, Manly NSW 2095 · Phone 02 9976 6876
www.interpharma.com.au

BORTEZOMIB EVER PHARMA

Active Ingredient	Bortezomib (as a mannitol boronic ester)
Excipients	Mannitol (E421), Sodium chloride, Sodium hydroxide,Hydrochloric acid
Primary Packaging	Clear, glass vial closed with a grey bromobutyl rubber stopper sealed with an aluminium cap covered with a plastic flip-off cap
Secondary Packaging	Plastic safety sleeving (CytoWrap®)
Strength	2.5 mg/ml solution for injection
Presentations	2.5 mg/1 ml vial, 3.5 mg/ 1.4 ml vial
Stability	Extended stability after vial opening and/or on dilution available on request

MIMINUM PRODUCT INFORMATION.

PLEASE REVIEW FULL PRODUCT INFORMATION BEFORE PRESCRIBING. FULL PRODUCT INFORMATION IS AVAILABLE FROM: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2016-PI-01700-1&d=20160502161146224 83

BORTEZOMIB EVER PHARMA bortezomib (as a mannitol boronic ester) 2.5 mg/1 mL (AUST R 345128) 1 and 5 vials. The 1 mL vial contains an overfill of up to 1.2 mL to allow for withdrawal of the full required volume. BORTEZOMIB EVER PHARMA bortezomib (as a mannitol boronic ester) 3.5 mg/1.4 mL (AUST R 345130) 1 and 5 vials. The 1.4 mL vial contains an overfill of up to 1.6 mL to allow for withdrawal of the full required volume. **Special Handling Instructions:-** Bortezomib is an antineoplastic. Caution should be used during handling and preparation. Proper aseptic technique should be used. Use of protective clothing to prevent skin contact is recommended. Pregnant personnel should not handle this medicine. Any unused product or waste material should be disposed of as per requirements for cytotoxic agents.**Therapeutic Indications:-** In combination with melphalan and prednisone, for the treatment of patients with previously untreated multiple myeloma who are not candidates for high dose chemotherapy. As part of combination therapy, for induction therapy prior to high dose chemotherapy with autologous stem cell rescue for patients under 65, with previously untreated multiple myeloma. Also for the treatment of multiple myeloma patients who have received at least one prior therapy, and who have progressive disease. In combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma. **Contraindications:-** Patients with hypersensitivity to bortezomib, boron or mannitol. **Special Warnings And Precautions For Use:-** Overall treatment with bortezomib must be done under the supervision of a physician, however administration of the drug product may be done by a healthcare professional experienced in the administration of oncology medications. Overall, the safety profile of patients treated with bortezomib in monotherapy was similar to that observed in patients treated with bortezomib in combination with melphalan and prednisone. There have been fatal cases of inadvertent intrathecal administration of bortezomib. BORTEZOMIB EVER PHARMA is for IV or SC use only. **DO NOT ADMINISTER INTRATHECALLY. Peripheral neuropathy:** Bortezomib treatment causes a peripheral neuropathy (PN) that is predominantly sensory. However, cases of severe motor neuropathy with or without sensory peripheral neuropathy have been reported. Patients should be monitored for symptoms of neuropathy. Patients experiencing new or worsening peripheral neuropathy may require a change in dose, schedule or route of administration to SC. **Hypotension:** Patients developing orthostatic hypotension on bortezomib did not have evidence of orthostatic hypotension prior to treatment. Most patients required treatment. A minority of patients with orthostatic hypotension experienced syncopal events. Orthostatic/postural hypotension was not acutely related to bolus infusion of bortezomib. **Cardiac disorders:** Acute development or exacerbation of congestive heart failure, and/or new onset of decreased left ventricular ejection fraction has been reported, including reports in patients with few or no risk factors for decreased left ventricular ejection fraction. Patients with risk factors for, or an existing heart disease should be closely monitored. **Pulmonary disorders:** There have been rare reports of acute diffuse infiltrative pulmonary disease of unknown aetiology such as pneumonitis, interstitial pneumonia, lung infiltration and Acute Respiratory Distress Syndrome (ARDS). Some of these events have been fatal. A higher proportion of these events have been reported in Japan. In the event of new or worsening pulmonary symptoms, a prompt diagnostic evaluation should be performed and patients treated appropriately. **Thrombotic Microangiopathy:** There have been cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura and haemolytic uraemic syndrome (TTP/HUS) reported in patients who received proteasome inhibitors. Some of these events have been fatal. Monitor patients for signs and symptoms of TTP/HUS. **Seizures:** Seizures have been uncommonly reported in patients without previous history of seizures or epilepsy. **Tumour lysis syndrome:** Because bortezomib is a cytotoxic agent and can rapidly kill malignant cells the complications of tumour lysis syndrome may occur. Patients at risk of tumour lysis syndrome are those with high tumour burden prior to treatment. Monitor patients closely and take appropriate precautions. **Herpes zoster virus reactivation:** Antiviral prophylaxis is recommended. **Use in hepatic impairment:** Patients with moderate and severe hepatic impairment should be treated with caution at reduced starting doses and closely monitored for toxicities. **Use in renal impairment:** The incidence of serious undesirable effects may increase in patients with renal impairment. Renal complications are frequent in patients with multiple myeloma. Close monitoring is required. **For all precautions refer to the full PI. Interactions With Other Medicines And Other Forms Of Interactions:** In vitro and animal ex vivo studies indicate that bortezomib is a weak inhibitor of cytochrome P450 (CYP) isozymes 1A2, 2C9, 2C19, 2D6, and 3A4 (refer to the full PI). Patients on oral antidiabetic agents may require close monitoring of their blood glucose levels and adjustment of the dose of their antidiabetic medication. Patients should be cautioned about the use of concomitant medications that may be associated with peripheral neuropathy or with a decrease in blood pressure **(refer to full PI).** Use in pregnancy Category C:- Women of child bearing potential should avoid becoming pregnant while being treated with bortezomib. Patients should be advised to use effective contraceptive measures to prevent pregnancy. **Use in lactation :-** Women should be advised against breast-feeding. **Laboratory tests:-** Complete blood counts (CBC) should be frequently monitored. **Adverse Effects (Undesirable Effects):- Very common:** thrombocytopenia, appetite decreased, peripheral neuropathy, peripheral sensory neuropathy; headache, paraesthesia. dyspnoea. nausea, diarrhoea, vomiting, constipation, rash, myalgia, fatigue, pyrexia. Common: leukopenia, lymphopenia, herpes zoster, pneumonia, herpes simplex, hyperglycaemia, hypokalaemia, peripheral neuropathy aggravated, polyneuropathy, hypoaesthesia, tremor, blurred vision, vertigo, orthostatic and postural hypotension, phlebitis, haematoma, epistaxis, dyspnoea exertional, abdominal pain, dyspepsia, pharyngolaryngeal pain, sweating increased, muscle cramps, muscle weakness, musculoskeletal pain, renal impairment, dysuria, rigors, malaise, oedema, asthenia, weight decreased, blood lactate dehydrogenase increased **(refer to full PI). Dose And Method Of Administration:-** Bortezomib must be prepared by a healthcare professional. Bortezomib is for single use in one patient on one occasion only. **IV:-** Bortezomib is administered as a 3-5 second bolus intravenous injection through a peripheral or central intravenous catheter followed by a flush with 0.9% sodium chloride solution for injection. **SC:-**The solution is injected into the thighs (right or left) or abdomen (right or left). Injection sites should be rotated for successive injections **(refer to full PI). Name And Address of the Sponsor:** InterPharma Pty Ltd, Suite 103, 39 East Esplanade, MANLY NSW 2095; Ph: 02 9976 6876; admin@interpharma.com.au. **Date of First Inclusion in the ARTG:** 13 Sep 2021. **PBS Information:**
This product is listed on the PBS
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