UNIJAB 1 Vial

Bortezomib
Biomib™

2.5 mg Lyophilized Powder for Solution for Injection (10/BX)
For Intravenous and Subcutaneous Use Only
Chemotherapy

Each vial contains:
Active ingredient: Bortezomib ..... 2.5 mg
Each mL after reconstitution: 2.5 mg

PRODUCT DESCRIPTION

Bortezomib is a white lyophilized powder contained in single-dose, glass vials per vial. The reconstituted solution is a clear and colorless solution, with a final pH of 5.0-7.

INDICATIONS AND USAGE

PARENTERAL

Bortezomib is indicated for adult patients with multiple myeloma or mantle cell lymphoma.

Multiple Myeloma (MM)

Bortezomib is indicated for treatment of adult patients with multiple myeloma who have not previously taken bortezomib and who have not undergone hematopoietic stem cell transplantation (HSCT) and who are eligible for high dose chemotherapy with HSCT.

Bortezomib is indicated for treatment of adult patients with multiple myeloma who have not previously taken bortezomib and who are not candidates for HSCT.

Bortezomib is indicated for treatment of adult patients with multiple myeloma who have not previously taken bortezomib and who are not candidates for HSCT, in combination with bortezomib, melphalan, and prednisone.

Bortezomib is indicated for treatment of adult patients with multiple myeloma who have not previously taken bortezomib and who are not candidates for HSCT, in combination with bortezomib, thalidomide, and dexamethasone.

Bortezomib is indicated for treatment of adult patients with multiple myeloma who have not previously taken bortezomib and who are not candidates for HSCT, in combination with bortezomib, doxorubicin, and dexamethasone.

Bortezomib is indicated for treatment of adult patients with multiple myeloma who have not previously taken bortezomib and who are not candidates for HSCT, in combination with bortezomib, cyclophosphamide, and dexamethasone.

Mantle Cell Lymphoma (MCL)

Bortezomib is indicated for treatment of adult patients with mantle cell lymphoma who have not previously taken bortezomib and who are not candidates for HSCT.

Bortezomib is indicated for treatment of adult patients with mantle cell lymphoma who have not previously taken bortezomib and who are not candidates for HSCT, in combination with bortezomib, rituximab, cyclophosphamide, doxorubicin, and dexamethasone.

Bortezomib is indicated for treatment of adult patients with mantle cell lymphoma who have not previously taken bortezomib and who are not candidates for HSCT, in combination with bortezomib, rituximab, cyclophosphamide, vincristine, and prednisone.

CONTRAINDICATIONS

Hypersensitivity to bortezomib, boron and mannitol.

Hypersensitivity to bortezomib, boron and mannitol.

WARNINGS AND PRECAUTIONS

Peripheral Neuropathy

Peripheral neuropathy is a common adverse event associated with bortezomib. Most of the events of peripheral neuropathy are sensory. Severe sensory neuropathy has been observed. Bortezomib administration should be discontinued if a severe or painful peripheral neuropathy develops. Patients with pre-existing peripheral neuropathy may be at higher risk of developing peripheral neuropathy when receiving bortezomib treatment.

Peripheral neuropathy has been observed in patients who received bortezomib in combination with other medicinal products that are associated with peripheral neuropathy. Patients with severe peripheral neuropathy should receive bortezomib treatment only if the potential benefit outweighs the risk.

Peripheral neuropathy and peripheral neuralgia have been reported in patients who received bortezomib in combination with other medicinal products associated with peripheral neuropathy. There is an increase of complete thromboplastin and neuropathy.

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