

# Bortezomib

Ready to use



**Bortezomib EVER Pharma is provided as a ready to use formulation for subcutaneous injection (SC), and after dilution for intravenous injection.**

Bortezomib is a protease inhibitor indicated for the treatment of progressive or untreated multiple myeloma, and mantle cell lymphoma.

- **Available as a “ready to use” liquid formulation** – with in use stability superior to powder formulations
- **2 fill sizes providing dosing flexibility, reducing wastage and saving costs** – the 2.5 mg/1 ml vial covers the most common patient doses for SC injection
- **Both vial sizes come in CytoWrap® protection** – for safer handling and transportation

# Bortezomib EVER Pharma has an in-use stability of 28 days at 25°C (protected from light)

## Indications

- As monotherapy or in combination with pegylated liposomal doxorubicin or dexamethasone is indicated for the treatment of adult patients with progressive multiple myeloma who have received at least 1 prior therapy and who have already undergone or are unsuitable for haematopoietic stem cell transplantation.
- In combination with melphalan and prednisone is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.
- In combination with dexamethasone, or with dexamethasone and thalidomide, is indicated for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.
- In combination with rituximab, cyclophosphamide, doxorubicin and prednisone is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation.

## 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®), vials may or may not be sleeved

## Strength

2.5 mg/ml solution for injection

## Presentations

2.5 mg/1 ml vial, 3.5 mg/ 1.4 ml vial

## Stability

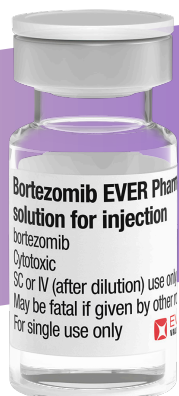
*Unopened:* 18 months at 2-8°C (protect from light)

*In-use stability:* Chemical and physical in-use stability after first opening and/or dilution has been demonstrated for 28 days when stored at 25°C (protected from light) and at 2-8°C (protected from light), or for 24 hours when stored at 25°C and normal indoor lighting conditions.

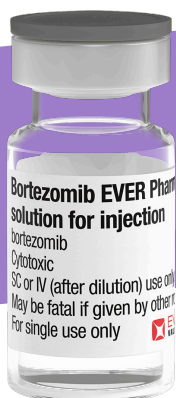
## Pack sizes

1 vial per pack, 5 vials per pack

## No reconstitution from powder required prior to preparing patient specific doses saving time and costs



**2.5 mg**  
**1 ml**



**3.5 mg**  
**1.4 ml**



**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**

- **Smaller 2.5 mg/ml presentation** reducing wastage on most common patient doses<sup>1,2</sup>, or for dose reductions
- **3.5 mg/1.4 ml** for larger patients. Can be used directly for SC injection or after dilution for intravenous injection

**Common patient doses**

BSA m <sup>2</sup>	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2	2.1
Std Dose mg/m <sup>2</sup>	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	<b>0.8</b>	<b>0.9</b>	<b>0.9</b>	<b>1.0</b>	<b>1.0</b>	1.1

1. Clark L, et al. Ideal vial size for bortezomib: real-world data on waste and cost reduction in treatment of multiple myeloma in Brazil. Value Health. 2011 Jul-Aug;14(5 Suppl 1):S82-4. doi: 10.1016/j.jval.2011.05.013.  
2. Overspending driven by oversized single dose vials of cancer drugs. BMJ 2016;352:i788.

