Important Safety Information

Bortada(BORTEZOMIB) 3.5 mg
Powder/Solution Vial

IV administration:

The reconstituted solution is administered as a 3-5 second bolus intravenous injection through a peripheral or central intravenous catheter followed by a flush with sodium chloride 9 mg/ml (0.9%) solution for injection.

SC administration:

The reconstituted solution is administered subcutaneously in the thighs (right or left, proximal and distal sites) or abdomen (right or left, upper or lower quadrant). Injection sites sould be rotated for successive injections.

Example

Body surface m^2	Total dose required (in mg) with 1.3mg/m^2	Applied volume with IV use (in ml)	Applied volume with SC use (in ml)
1.5	1.95	1.95	0.78
1.6	2.08	2.08	0.83
1.7	2.21	2.21	0.88
1.8	2.34	2.34	0.94
1.9	2.47	2.47	0.99
2.0	2.60	2.60	1.04
2.1	2.73	2.73	1.09

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Physician Guide

INSTRUCTIONS:

Objectives: the educational material is essential to ensure the safe and effective use of the product and appropriate management of important selected risks.

Pull out and match patient weight with patient height.

Read **Body Surface Area** at arrow.

Please see Precautions and Posology and Method of Administration sections of SmPC for dose modification information.

By reporting side effects you can help provide more information on the safety of this medicine.If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider,or pharmacist. the National Pharmacovigilance Centre (NPC): SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa (Website: https://adc.sfda.gov.sa)
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Subcutaneous or intravenous use only. Do not give by other routes.

Reconstitution of Bortezomib solution for IV injection			
Route of administration	Pack size	Reconstitution volume	Final concentration
Intravenous use only	3.5 mg Powder	3.5 ml	1.0 mg/ml
Intravenous use only	2.5mg/ml Solution	2.1 ml	1.0 mg/ml

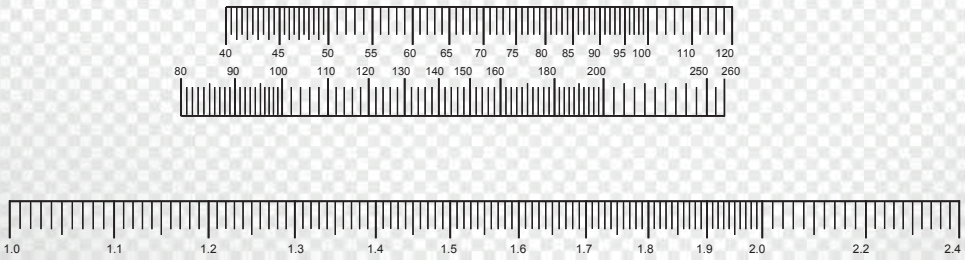
Reconstitution of Bortezomib solution for SC injection			
Route of administration	Pack size	Reconstitution volume	Final concentration
Subcutaneous use only	3.5 mg Powder	1.4 ml	2.5 mg/ml
Subcutaneous use only	2.5mg/ml Solution	n/a	2.5 mg/ml

Bortezomib must be reconstituted by a Health Care Professional.
Each vial of Bortezomib must be carefully reconstituted by using a syringe of the appropriate size (Bortezomib 3.5 mg), without removing the vial stopper.
Aseptic technique must be strictly observed throughout the handling of Bortezomib since no preservative is present.

From the formula of Dubois and Dubois,
Arch Intern Med 1916;17:863

Body Surface Area (m^2)

BORTEZOMIB 3.5 mg Powder/Solution Vial


40 45 50 55 60 65 70 75 80 85 90 95 100 110 120
80 90 100 110 120 130 140 150 160 180 200 250 260
1.0 1.1 1.2 1.3 1.4 1.5 1.6 1.7 1.8 1.9 2.0 2.2 2.4