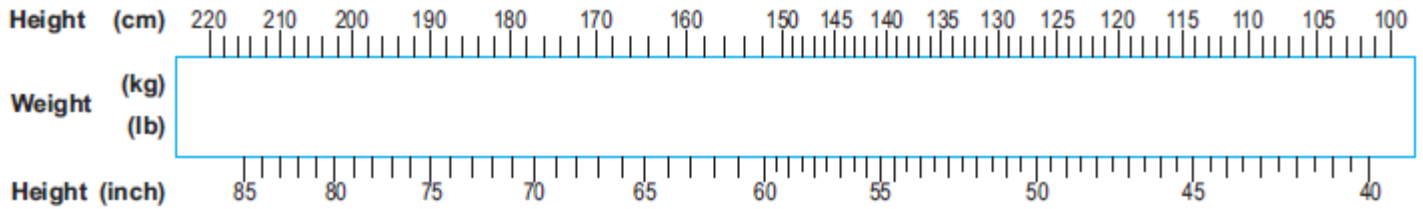
Amarox

Slide Rule
Prescriber Guide

Instructions for use **1. Set Weight and Height** using the appropriate units of measure.



2. Read **Body Surface Area** at arrow.

For Subcutaneous injection.
The powder for solution for injection is 2.5 mg/ml.
For intravenous injection dilution is necessary.
See Table 2

Table 1: Bortezomib for SC injection

Route of administration	Pack size	Dilution	Concentration
Subcutaneous use	3.5 mg	1.4 ml	2.5 mg/ml

Table 2: Dilution for Bortezomib for IV injection

Route of administration	Pack size	Dilution volume	Final concentration
Intravenous use	3.5 mg	3.5 ml	1.0 mg/ml

Total Volume is greater than used for SC giving
A less concentrated drug solution for injection

Subcutaneous or Intravenous use only.
Do not give by other routes.

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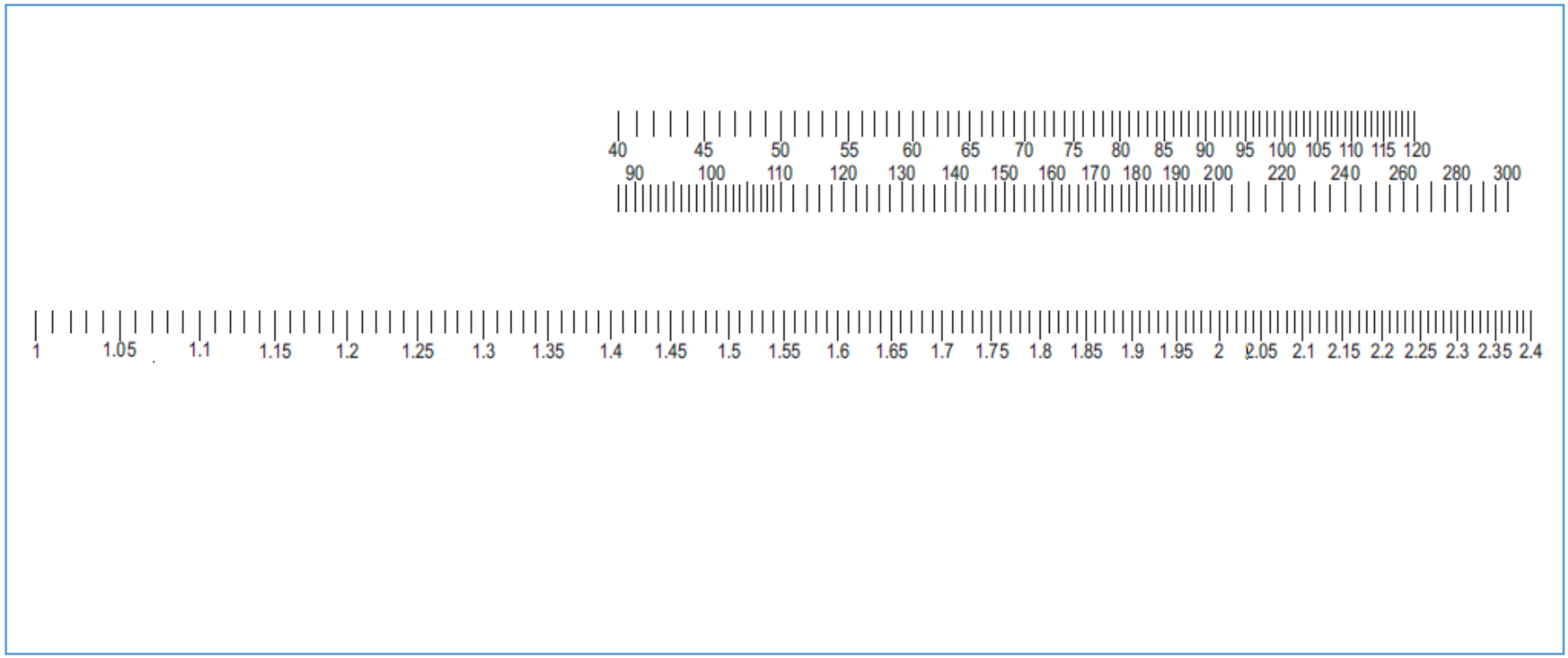

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Method of administration

IV administration:

The reconstitution 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:

For SC administration, Bortezomib reconstitution solution.
It is administered subcutaneously in the thighs (right or left, Proximal and distal sites) or abdomen (right or left, upper or Lower quadrant).
Injection sites should be rotated for successive injections.

Example

Body surface m^2	Total dose required (in mg) With 1.3 mg/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

Please refer to Precautions, Posology and method of administration sections in SPC for dose modification information.

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Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via

The National Pharmacovigilance Centre
Saudi Food and Drug Authority
Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/

Saudi Amarox contact details:

Razan Almalki- Qualified Person for Pharmacovigilance
Al Jamiyah Street, Al Malaz - Riyadh code 12629, Saudi Arabia
E-mail: r.almalki@Amaroxpharma.com
Phone: +966 11 226 8850
Mobile: +966531215235

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