RECONSTITUTION OF VELCADE® (bortezomib) 3.5 mg vial

FOR SUBCUTANEOUS (SC) OR INTRAVENOUS (IV) ADMINISTRATION

SUBCUTANEOUS ADMINISTRATION

To reconstitute
add **1.4 mL**

of sterile 0.9% sodium chloride solution into the vial of VELCADE® for a final concentration of

2.5 mg/mL

INTRAVENOUS ADMINISTRATION

To reconstitute
add **3.5 mL**

of sterile 0.9% sodium chloride solution into the vial of VELCADE® for a final concentration of

1.0 mg/mL

- The volume of diluent used to reconstitute VELCADE® for SC administration is different from the volume for IV administration. Due to the different volume added, the solutions after reconstitution differ in drug concentration.
- VELCADE® must be reconstituted by a Health Care Professional utilizing strict aseptic techniques since no preservative is present.
- The reconstituted product should be used immediately after preparation. However, the chemical and physical in-use stability of the reconstituted solution stored in the original vial and/or syringe has been demonstrated for 8 hours at 25°C. It is not necessary to protect the reconstituted medicinal product from light.
- To avoid administration errors, syringes for SC and IV use should be labelled differently.
- **Subcutaneous or Intravenous use only. Do not give by other routes.**
- VELCADE® 1 mg for IV use only. For reconstitution instructions, please refer to the package leaflet.
- Please report any adverse event experienced with the administration of VELCADE® immediately.

VELCADE® (bortezomib)

Any suspected adverse drug reactions can be reported to:
Medicines Authority Post-Licensing Directorate, 203 Level 3, Rue D'Argens, Gzira GZR1368, Malta, or at http://medicinesauthority.gov.mt/pub/adr.doc

For more information contact:
A.M. Mangion Ltd, Mangion Buildings, New Street in Valletta Road, Luqa LQA 6000, Malta Tel. 00 356 2397 6000.

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Please refer to Summary of Product Characteristics (SmPC) for further instructions