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 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 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 using a syringe of the appropriate size, without removing the vial stopper and utilising 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 to 23976000 or pv@ammangion.com

VELCADE® (bortezomib)

A.M. MANGION LTD

janssen PHARMACEUTICAL COMPANIES OF Johnson&Johnson

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