Physician guide _ Reconstitution Poster

Important Safety Information

Bortada (BORTEZOMIB) 3.5 MG VIAL

(Powder / Solution) For subcutaneous (SC) or intravenous (IV) administration

	3.5 mg **Powder**	2.5 mg/ml **Solution**	
SC INJECTION	To reconstitute - add **1.4 mL** of sterile 0.9% sodium chloride solution into the vial of Bortezomib	**No reconstitution required.**	Final concentration: **2.5 mg/mL**
IV INJECTION	To reconstitute - add **3.5 mL** of sterile 0.9% sodium chloride solution into the vial of Bortezomib	To reconstitute – add **2.1 mL** of sterile 0.9% sodium chloride solution into the vial of Bortezomib	Final concentration: **1.0 mg/mL**

Objectives: the educational material is essential to ensure the safe and effective use of the product and appropriate management of the important selected risks. It is advised to be read carefully before prescribing/ dispensing/administering the product.

The volume of diluent used to reconstitute Bortezomib for SC administration (where required) is different from the volume for IV administration.

Due to the different volume added, the solutions after reconstitution differ in drug concentration. Bortezomib must be reconstituted (where required) 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/final product should be used immediately after preparation.

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.

Indication

Bortada® 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.

Bortada® 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 stemcell transplantation.

Bortada® 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 stemcell transplantation.
Bortada® 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

Reporting of suspected adverse reactions: 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 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://ade.sfda.gov.sa/
STADA QPPV : Alhanouf Alsunaytan \ E-mail : alhanouf.alsunaytan@stada.com
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Please report any adverse event experienced with the administration of Bortezomib immediately. Please refer to Summary of Product Characteristics for further instructions.