Risk Management Plan Reconstitution poster

BORTEZOMIB SPC®

BORTEZOMIB 3.5 mg powder for solution for injection

Version no. 0001
Date: Jan. 2019

Reconstitution Poster

Reconstitution of Bortezomib SPC 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 Bortezomib SPC 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 Bortezomib SPC for a final concentration of 1.0 mg/mL

- The volume of diluent used to reconstitute Bortezomib SPC 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.
- Bortezomib SPC 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.
- Please report any adverse event experienced with the administration of Bortezomib SPC immediately.

Information for Adverse Drug Reaction reporting:

The National Pharmacovigilance Centre (NPC)

Saudi Food and Drug Authority (SFDA)
SFDA call center: 19999
Fax: +966-11- 205 7662
E-mail: npc.drug@sfda.gov.sa
Website: http://ade.sfda.gov.sa/

SUDAIR pharma Company (SPC)

Pharmacovigilance and Drug Safety Department

Toll phone: + 966 11 466 8193 **Ext.** 107
Fax: + (966) 11 466 8195
Mob: +(966) 54 603 0507
Email: Pharmacovigilance@SudairPharma.com
Website: www.sudairpharma.com