# **M**5pharma **RECONSTITUTION OF BORVIX® (BORTEZOMIB) 3.5 MG POWDER** FOR SOLUTION FOR INJECTION

## **Objective**

The educational material is essential to ensure the safe and effective use of the product and appropriate management of the Medication error.

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 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 for a final concentration of

#### 1.0 mg/mL

- The volume of diluent used to reconstitute Bortezomib 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 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.
- 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 immediately.
- Please refer to Summary of Product Characteristics (SmPC) for further instructions.

# Reporting of Side effects

Please report any suspected adverse drug reactions associated Borvix® (Bortezomib) to:

- · Local representative at MS Pharma Saudi
- Email: pharmacovigilance@mspharma.com
- Website: www.mspharma.com
- Phone No: + 966112790122 Ext. 6013
- The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA)
- Email: npc.drug@sfda.gov.sa
- Call Center: 19999
- Website: https://ade.sfda.gov.sa/



<sup>1.</sup> Borvix® (Bortezomib) SmPC and leaflet.

<sup>2.</sup> Reconstitution Poster - Bortezomib 2.5mg/ml Solution for Injection (3.5mg total content). (2019). Retrieved 9 July 2020, from https://www.medicines.org.uk/emc/rmm/1428/