



## IMPORTANT SAFETY INFORMATION

# RECONSTITUTION, DOSING AND ADMINISTRATION OF BORVIX® (BORTEZOMIB) 3.5MG POWDER FOR SOLUTION FOR INJECTION

## SUBCUTANEOUS (SC) AND INTRAVENOUS (IV) USE

### Objective

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

### Correct Reconstitution

Borvix® (Bortezomib) 3.5mg powder for solution for injection is available for intravenous or subcutaneous administration.

Subcutaneous or Intravenous use only  
Do not give by other routes  
Intrathecal administration has resulted in death

This medicine must be reconstituted by a Health Care Professional.

Where required, each vial of Bortezomib must be carefully reconstituted by a Health Care Professional using a syringe of the appropriate size, without removing the vial stopper. Aseptic technique must be strictly observed throughout the preparation because no preservative is present.

### Avoiding the Potential Risk of Administration Errors

In order to avoid dosing errors, caution is required when preparing Borvix® (Bortezomib) 3.5mg powder for solution for injection as the volume required for reconstitution for the SC route is lower (1.4 mL) than that used for IV use (3.5 mL) giving a higher concentration of diluted drug.

As the drug concentration after reconstitution differs between the SC and IV preparations, special care is required when calculating the volume of reconstituted drug, which will be administered to the patient according to the prescribed dose.

Some examples of dosing for the different routes are given below.

## Subcutaneous Route of Administration

### • Preparation of the 3.5 mg vial

Each 3.5 mg vial of Borvix® (Bortezomib) must be reconstituted with 1.4 mL sterile sodium chloride 9 mg/mL (0.9 %) solution for injection – complete dissolution of the lyophilised powder takes less than 2 minutes.

Reconstitute the powder with 1.4 mL sodium chloride: inject the sodium chloride solution into the vial containing the lyophilised Bortezomib.

**Table 1: Reconstitution of 3.5 mg Borvix® powder for solution for injection for SC injection**

Route of administration	Pack size	Reconstitution volume	Final concentration
Subcutaneous use only	3.5 mg	1.4 mL	2.5 mg/mL



Reconstitution volume is less than for IV, giving a more concentrated drug solution for injection

The final solution should be clear and colourless. The solution must be inspected visually for particulate matter and discolouration prior to administration. If any discolouration or particulate matter is observed, the solution must be discarded.

**The final concentration is 2.5 mg/mL**

The final drug concentration, when prepared for SC administration (2.5 mg/mL), is 2.5 times higher than that for the IV route (1 mg/mL) and therefore the volume required is lower when the SC route of administration is used.

For use, withdraw the appropriate amount of the drug solution: according to the calculated dose based upon the patient's Body Surface Area (BSA).

**To avoid administration errors, syringes for SC and IV use should be labelled differently**

## Intravenous Route of Administration

### • Preparation of the 3.5 mg vial

Each 3.5 mg vial of Borvix® (Bortezomib) must be reconstituted with 3.5 mL sterile sodium chloride 9 mg/mL (0.9%) solution for injection – complete dissolution of the lyophilised powder takes less than 2 minutes.

Reconstitute the powder with 3.5 mL sodium chloride: inject the sodium chloride solution into the vial containing the lyophilised Bortezomib.

**Table 2: Reconstitution of 3.5 mg Bortezomib solution for IV injection**

Route of administration	Pack size	Reconstitution volume	Final concentration
Intravenous use only	3.5 mg	3.5 mL	1.0 mg/mL



Reconstitution volume is more than for SC, giving a less concentrated drug solution for injection

The reconstituted solution should be clear and colourless. The reconstituted solution must be inspected visually for particulate matter and discolouration prior to administration. If any discolouration or particulate matter is observed, the reconstituted solution must be discarded.

**The final concentration is 1.0 mg/mL**

Once dissolved, withdraw the appropriate amount of the reconstituted drug solution: according to calculated dose based upon the patient's Body Surface Area (BSA).

**To avoid administration errors, syringes for SC and IV use should be labelled differently**

### Dosing Examples for SC & IV Administration

Calculate the Body Surface Area (BSA) using the slide rule. Additional examples are provided with the dosing slide rule.

**BSA: 1.7 m<sup>2</sup>, Dose: 1.3 mg/m<sup>2</sup>**

Intravenous Sample patient (1.7 m <sup>2</sup> )	Subcutaneous Sample patient (1.7 m <sup>2</sup> )
Vial size: 3.5 mg lyophilisate Diluent volume: 3.5 ml saline	Vial size: 3.5 mg lyophilisate Diluent volume: 1.4 ml saline
Final concentration 1 mg/ml	Final concentration 2.5 mg/ml
Dose: 1.3 mg/m <sup>2</sup> Total dose for patient: 2.21 mg	Dose: 1.3 mg/m <sup>2</sup> Total dose for patient: 2.21 mg
Total volume* applied to the patient: 2.2 ml	Total volume* applied to the patient: 0.9 ml
Injected IV (3-5 seconds push)	Injected SC

\*Total volume rounded

If the calculated IV volume is used with the SC concentration, the patient will be overdosed.

If the calculated SC volume is used with the IV concentration the patient will be underdosed.

**BSA: 1.95 m<sup>2</sup>, Dose: 1.3 mg/m<sup>2</sup>**

<b>Intravenous</b> Sample patient (1.95 m <sup>2</sup> )	<b>Subcutaneous</b> Sample patient (1.95 m <sup>2</sup> )
Vial size: 3.5 mg lyophilisate Diluent volume: 3.5 ml saline	Vial size: 3.5 mg lyophilisate Diluent volume: 1.4 ml saline
Final concentration 1 mg/ml	Final concentration 2.5 mg/ml
Dose: 1.3 mg/m <sup>2</sup> Total dose for patient: 2.54 mg	Dose: 1.3 mg/m <sup>2</sup> Total dose for patient: 2.54 mg
Total volume* applied to the patient: 2.5 ml	Total volume* applied to the patient: 1 ml
Injected IV (3-5 seconds push)	Injected SC

\*Total volume rounded

If the calculated IV volume is used with the SC concentration, the patient will be overdosed.

If the calculated SC volume is used with the IV concentration the patient will be underdosed.

**BSA: 1.6 m<sup>2</sup>, Dose: 1.0 mg/m<sup>2</sup>**

<b>Intravenous</b> Sample patient (1.60 m <sup>2</sup> )	<b>Subcutaneous</b> Sample patient (1.60 m <sup>2</sup> )
Vial size: 3.5 mg lyophilisate Diluent volume: 3.5 ml saline	Vial size: 3.5 mg lyophilisate Diluent volume: 1.4 ml saline
Final concentration 1 mg/ml	Final concentration 2.5 mg/ml
Dose: 1.0 mg/m <sup>2</sup> Total dose for patient: 1.6 mg	Dose: 1.3 mg/m <sup>2</sup> Total dose for patient: 1.6 mg
Total volume* applied to the patient: 1.6 ml	Total volume* applied to the patient: 0.64 ml
Injected IV (3-5 seconds push)	Injected SC

\*Total volume rounded

If the calculated IV volume is used with the SC concentration, the patient will be overdosed.

If the calculated SC volume is used with the IV concentration the patient will be underdosed.

## General Information about Bortezomib

### General Precautions

Bortezomib is a cytotoxic agent. Therefore, caution should be applied when handling and preparing Bortezomib. The use of gloves and other protective clothing to prevent skin contact is recommended.

Please report any adverse event experienced with the administration of Bortezomib immediately.

**Subcutaneous or Intravenous use only**  
**Do not give by other routes**  
**Intrathecal administration has resulted in death**

### Reconstituted solution

Bortezomib is for single use only. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

The reconstituted product is preservative free and should be used immediately after preparation. It is not necessary to protect the reconstituted medicinal product from light.

## Correct Administration for SC & IV Bortezomib

### How to administer Bortezomib SC

Confirm the dose in the syringe prior to use (check that the syringe is marked as SC administration). Inject the solution subcutaneously, at a 45-90 °angle.

The reconstituted solution should be administered subcutaneously in the thighs or abdomen and injection sites should be rotated for successive injections.

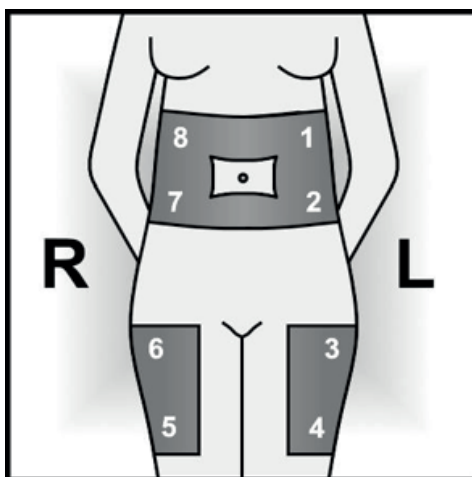
• **Injections at the same site should be avoided**

• **Alternate between:**

- right and left abdomen (upper or lower quadrant)
- right and left thigh (proximal and distal sites)

Consider antiviral prophylaxis.

### Injection site rotation



## How to Administer Bortezomib IV

Confirm the dose in the syringe prior to use (check that the syringe is marked for IV administration).

Inject the solution as a 3-5 second bolus intravenous injection through a peripheral or central intravenous catheter into a vein. The use of IV hydration and an antiemetic medication as concomitant therapy prior to administration of IV Bortezomib is recommended.

Flush the peripheral or intravenous catheter with sterile 9 mg/ml (0.9 %) sodium chloride solution.

Consider antiviral prophylaxis

**Please immediately report any adverse event experienced with the administration of Borvix® (Bortezomib)**

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](mailto:pharmacovigilance@mspharma.com)

Website: [www.mspharma.com](http://www.mspharma.com)

Phone No: + 966112790122 Ext. 6013

• **The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA)**

Email: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)

Call Center: 19999

Website: <https://ade.sfda.gov.sa/>

QR Code:

