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<b>Duration of Response</b>	<b>Median</b>	<b>95% CI</b>
CR + CRu + PR (N=48)	9.3 months	(5.4, 13.8)
CR + CRu (N=12)	15.4 months	(13.4, 15.4)
PR (N=36)	6.1 months	(4.2, 9.3)

## 15 REFERENCES

1. "OSHA Hazardous Drugs". *OSHA*. <http://www.osha.gov/SLTC/hazardousdrugs/index.html>

## 16 HOW SUPPLIED/STORAGE AND HANDLING

Bortezomib Injection is a clear, colorless to slightly yellow ready-to-use, sterile solution supplied as individually cartoned 5 mL vials containing 3.5 mg/3.5 mL (1 mg/mL) or 2 mL vials containing 3.5 mg/1.4 mL (2.5 mg/mL) of Bortezomib Injection. 3.5 mg/3.5 mL (1mg/mL) in a single-dose 5 mL vial

NDC 70511-161-05

3.5 mg/1.4 mL (2.5 mg/mL) in a single-dose 2 mL vial

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Store Bortezomib Injection in a refrigerator at 2° to 8°C (36° to 46°F) in the original package to protect from light.

Follow guidelines for handling and disposal for hazardous drugs, including the use of gloves and other protective clothing to prevent skin contact<sup>1</sup>.

## 17 PATIENT COUNSELING INFORMATION

Discuss the following with patients prior to treatment with Bortezomib Injection:

### Peripheral Neuropathy

Advise patients to report the development or worsening of sensory and motor peripheral neuropathy to their healthcare provider [see *Warnings and Precautions* (5.1)].

### Hypotension

Advise patients to drink adequate fluids to avoid dehydration and to report symptoms of hypotension to their healthcare provider [see *Warnings and Precautions* (5.2)].

Instruct patients to seek medical advice if they experience symptoms of dizziness, light headedness or fainting spells, or muscle cramps.

### Cardiac Toxicity

Advise patients to report signs or symptoms of heart failure to their healthcare provider [see *Warnings and Precautions* (5.3)].

### Pulmonary Toxicity

Advise patients to report symptoms of ARDS, pulmonary hypertension, pneumonitis, and pneumonia immediately to their healthcare provider [see *Warnings and Precautions* (5.4)].

### Posterior Reversible Encephalopathy Syndrome (PRES)

Advise patients to seek immediate medical attention for signs or symptoms of PRES [see *Warnings and Precautions* (5.5)].

### Gastrointestinal Toxicity



constipation, or decreased appetite.

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