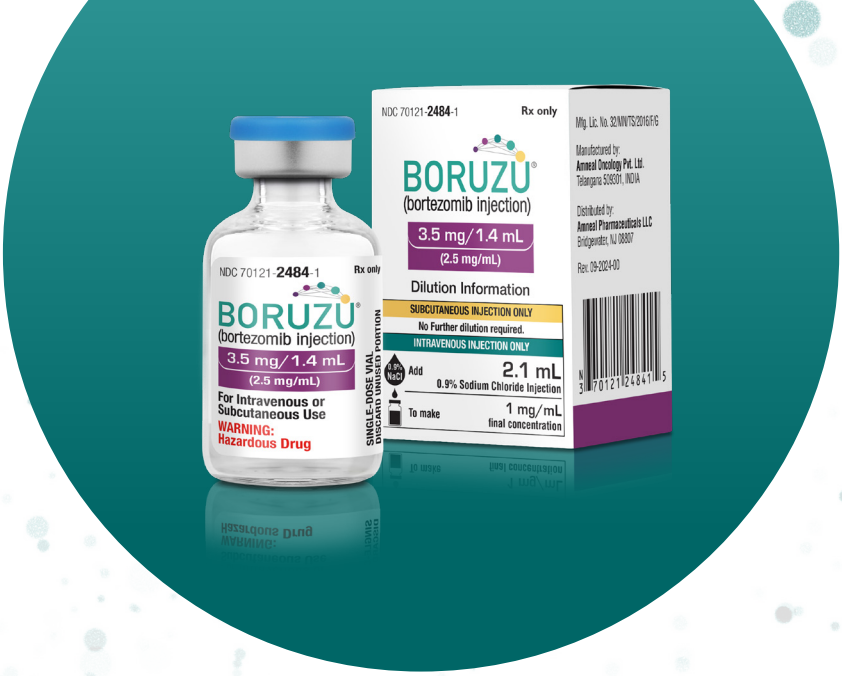
BORUZU®
(bortezomib injection)



Billing and coding information

The information provided is for informational purposes only and represents no statement, promise, or guarantee by Amneal Pharmaceuticals concerning reimbursement, payment, or charges. The information provided is not intended to increase or maximize reimbursement by any payer. Healthcare professionals are responsible for selecting appropriate codes used to file a claim. Codes should be based on the patient's diagnosis and the items and services furnished by the healthcare professional. All codes should be verified between the healthcare professional and the payer. Amneal Pharmaceuticals does not recommend using any particular diagnosis code in billing situations for **BORUZU® (bortezomib injection)**. The below codes are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

INDICATIONS

BORUZU® is a proteasome inhibitor indicated for the treatment of:

- Adult patients with multiple myeloma
- Adult patients with mantle cell lymphoma

DOSAGE AND ADMINISTRATION

BORUZU® is for subcutaneous (SC) or intravenous (IV) administration only. Because each route of administration has a different final concentration, caution should be used when calculating the volume to be administered.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- BORUZU® is contraindicated in patients with hypersensitivity (not including local reactions) to bortezomib, boron, or mannitol, including anaphylactic reactions.
- BORUZU® is contraindicated for intrathecal administration.

Please see back cover for additional Important Safety Information and Boruzu.us for full Prescribing Information.

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BORUZU®
(bortezomib injection)

National Drug Code for BORUZU®[1,2]

BORUZU® is a sterile, clear-to-light yellow solution supplied as a carton containing 1 single-dose vial.

11-Digit NDC	Strength	Vial size
70121-2484-**0**1*	3.5 mg/1.4 mL (2.5 mg/mL)	Single-dose vial, carton of 1

*FDA standard NDC has been "zero-filled" to create an 11-digit code that meets HIPAA standards. The zero-fill location is indicated in **bold**.

HCPCS code[3-5]

HCPCS Level II codes identify drugs, biologics, and other items, supplies, and services not included in the CPT® code set.

BORUZU® unique J-code	Description	Site(s) of care (POS codes)
J9054	Injection, bortezomib (boruzu), 0.1 mg	• Physician office (11) • Off-campus outpatient hospital (19) • On-campus outpatient hospital (22)

J-code billing unit conversion[1,4,6,7]

Each 0.1 mg of BORUZU® equals 1 billing unit. When billing for quantities greater than 0.1 mg, indicate the total amount used as a multiple of billing units on the claim form.

Example	
1 vial (1.4 mL) or 3.5 mg	35 billing units/single-dose vial

NOTE:
The total volume of drug administered will vary based on the patient's body surface area and dosage modifications. Multiple HCPCS codes are available for **bortezomib injection**, so please ensure the HCPCS code matches the product purchased and administered.

FDA, US Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System; HIPAA, Health Insurance Portability and Accountability Act; NDC, National Drug Code; POS, Place of Service.

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BORUZU®
(bortezomib injection)

CPT® drug administration codes[1,5,8]

CPT® codes are used to report medical services and procedures performed by physicians and other qualified healthcare professionals.

The concentration of bortezomib for subcutaneous administration (2.5 mg/mL) is greater than the diluted concentration of bortezomib for intravenous administration (1 mg/mL). **Use caution when calculating the volume to be administered because each route of administration has a different final concentration**.

Subcutaneous injection administration

CPT® code	Description	Site(s) of care
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic	• Physician office (11) • Off-campus outpatient hospital (19) • On-campus outpatient hospital (22)

Intravenous injection administration

CPT® code	Description	Site(s) of care
96409	Chemotherapy administration, intravenous, push technique, single or initial substance/drug	• Physician office (11) • Off-campus outpatient hospital (19) • On-campus outpatient hospital (22)
96411	Chemotherapy administration, intravenous, push technique, each additional substance/drug (list separately in addition to code for primary procedure)	

Route of administration modifier[9]

NOTE:
The -JA and -JB modifiers are required for drugs that have one HCPCS Level II code but multiple routes of administration. Drugs in this category must be billed using the -JB modifier for subcutaneous injection or the -JA modifier for intravenous infusion.

AMA, American Medical Association; CPT®, Current Procedural Terminology®; FAR, Federal Acquisition Regulation; HCPCS, Healthcare Common Procedure Coding System; HHSAR, Health and Human Services Acquisition Regulation.

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BORUZU®
(bortezomib injection)

Revenue codes[1,4-6,9-11]

Claim item	Revenue code	Description	Site(s) of care
BORUZU®	0636	Drugs requiring detailed coding	• Off-campus outpatient hospital (19) • On-campus outpatient hospital (22)
Drug administration	0331	Chemotherapy administration – injection	
	0335	Chemotherapy administration – IV	

BORUZU® is packaged as a single-dose vial. Medicare will pay for drug waste on single-use items that are medically necessary and appropriately documented in the patient's medical record. Medicare requires discarded drugs to be reported with the -JW modifier on a separate line; if there is no waste, BORUZU® must be billed on one line with the modifier -JZ. Medicare requires this; please ascertain if other payers require -JZ and -JW modifiers.

Reporting drug waste (modifier -JW):

Claim line 1: Report the amount of BORUZU® given to the patient using the appropriate number of billing units for the **J9054** HCPCS code and the modifier -JA or -JB, depending on the route of administration.

Claim line 2: Report modifier -JW with the **J9054** HCPCS code and the appropriate number of billing units for any amount of discarded drug.

Reporting zero drug waste (modifier -JZ):

Claim line 1: Report the amount of BORUZU® administered to the patient with the appropriate number of billing units for the **J9054** HCPCS code and -JZ modifier, indicating zero waste.

Contact the Amneal PATHways® Patient Support Program

Website:
https://amnealbiosciences.com/pathways/

Phone:
1-866-4-AMNEAL
(1-866-426-6325)

Portal:
https://www.pathwaysproviderportal.com/
(First-time users must register)

HCPCS, Healthcare Common Procedure Coding System.

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BORUZU®
(bortezomib injection)

International Classification of Disease diagnosis codes[1,12]

For drugs with multiple indications, it is best practice to code the most specific ICD-10-CM code within the indication to justify medical necessity. BORUZU® is a proteasome inhibitor indicated for:

- treatment of adult patients with multiple myeloma
- treatment of adult patients with mantle cell lymphoma

International Classification of Disease, Tenth Revision, Clinical Modification codes for BORUZU®

Indication	ICD-10-CM codes
Multiple myeloma	C90.00, C90.02
Mantle cell lymphoma	C83.10, C83.11, C83.12, C83.13, C83.14, C83.15, C83.16, C83.17, C83.18, C83.19

BORUZU® billing and coding information: ICD diagnosis codes by indication

The ICD-10-CM coding for BORUZU® varies greatly by payer. Please check with each payer to determine the best coding per their policy.

Multiple myeloma: ICD-10-CM diagnosis coding

ICD-10-CM code	Descriptor
C90.0	Multiple myeloma*
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

Mantle cell lymphoma: ICD-10-CM diagnosis coding

ICD-10-CM code	Descriptor
C83.1	Mantle cell lymphoma*
C83.10	Mantle cell lymphoma, unspecified site
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites

*Three-digit ICD-10-CM classification codes represent a broad category of diseases and are not advised for use in claim submissions. It is best practice to code to the highest level of specificity.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

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BORUZU®
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Sample CMS 1500 claim form (physician office)

In this example, an adult patient with a BSA of 1.85 m^2 received 2.405 mg of BORUZU® (1.3 mg/m^2) administered subcutaneously for multiple myeloma not having achieved remission.

Item 24A-B [Electronic Claim Form:
Item 24A (Loop 2400, Segment DTP/472)
Item 24B (Loop 2300/2400, Segment CLM05/SV105)]

In the non-shaded area, enter the appropriate date of service and place of service code. Example: ***Physician Office = 11.***

If required, in the shaded area, enter the N4 indicator first, then the 11-digit NDC code. In the third space, list the unit measurement code, and, last, the quantity.

Item 21 (Electronic Claim Form = Loop 2300, Segment HI01-2 through HI12-2):

Enter the patient's diagnosis from the patient's medical record.

An example code for this drug is ***C90.00 Multiple myeloma not having achieved remission.***

Use Box 21 B-L fields for secondary diagnoses.

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) — ICD Ind.
A. C90.00 B. C. D.
E. F. G. H.
I. J. K. L.

22. RESUBMISSION CODE — ORIGINAL REF. NO.
23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
N470121248401ML.962															
1 M	D	YY	M	D	YY	11		J9054	JB	A		25		NPI	
N470121248401ML.438															
2 M	D	YY	M	D	YY	11		J9054	JW	A		10		NPI	
3 M	D	YY	M	D	YY	11		96401		A		1		NPI	

SUPPLIER INFORMATION

Item 24D (Electronic Claim Form = Loop 2400, Segment SV101-2):

Enter the appropriate HCPCS code: ***J9054, Injection, bortezomib (boruzu), 0.1 mg***

BORUZU® is packaged as a single-dose vial. Medicare requires drug waste be reported with the -JW modifier on a separate line. If there is no waste, BORUZU® must be billed on one line with modifier -JZ. Medicare requires this; please ascertain if other payers require -JZ and -JW modifiers.

-JA and -JB modifiers are required for drugs that have one HCPCS Level II code but multiple routes of administration. Drugs in this category must be billed using the -JB modifier for subcutaneous injection or the -JA modifier for intravenous infusion.

For administration, enter the appropriate code or codes for subcutaneous or intravenous injection. As an example, ***chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic*** requires CPT® code ***96401.***

Item 24G (Electronic Claim Form = Loop 2400, SV104):

Enter the number of service units of each item.

Item 23 (Electronic Claim Form = Loop 2300, REF02):

Enter prior authorization number if one exists.

Item 24E (Electronic Claim Form = Loop 2400, Segment SV107-1):

Specify the diagnosis letter that corresponds with the drug and drug administration code(s) in Box 21.

BSA, body surface area; CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology®; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

Electronic Claims Reference: Palmetto GBA. ASC 837 v5010 to CMS-1500 crosswalk. Accessed February 19, 2025. https://www.palmettogba.com/Palmetto/Providers.Nsf/files/CMS1500_837v5010_Crosswalk.pdf/%24File/CMS1500_837v5010_Crosswalk.pdf

References: 1. BORUZU. Prescribing information. Amneal Pharmaceuticals LLC; 2024. **2.** FDA. National Drug Code database background information. Updated March 20, 2017. Accessed February 12, 2025. https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information **3.** CMS. Healthcare Common Procedure Coding System (HCPCS) Level II coding procedures. Updated December 2022. Accessed January 7, 2025. https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf **4.** CMS. Fourth quarter, 2024 HCPCS coding cycle. Updated January 10, 2025. Accessed February 12, 2025. https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-4-2024-drugs-and-biologicals.pdf **5.** CMS. Place of service code set. Updated May 2, 2024. Accessed January 7, 2025. https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets **6.** CMS. Billing and coding: approved drugs and biologicals; includes cancer chemotherapeutic agents. Updated November 2, 2023. Accessed January 7, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53049 **7.** CMS. First quarter, 2025 HCPCS quarterly update. December 17, 2024. Accessed February 26, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **8.** *CPT® 2025 Professional Edition*. 4th ed. AMA; 2024. **9.** CMS. Billing and coding: complex drug administration coding. Updated April 1, 2024. Accessed January 28, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58527 **10.** Noridian Healthcare Solutions. Revenue codes. Updated March 18, 2024. Accessed January 7, 2025. https://med.noridianmedicare.com/web/jfa/topics/claim-submission/revenue-codes **11.** CMS. Billing and coding: JW and JZ modifier billing guidelines. Updated March 21, 2024. Accessed January 7, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55932 **12.** *2025 ICD-10-CM Expert: Diagnosis Codes for Providers and Facilities*. AAPC; 2024.

Please see front and back covers for Important Safety Information and Boruzu.us for full Prescribing Information.

BORUZU®
(bortezomib injection)

Sample UB-04/CMS 1450 claim form (hospital outpatient)

In this example, an adult patient with a BSA of 1.85 m^2 received 2.405 mg of BORUZU® (1.3 mg/m^2) administered subcutaneously for multiple myeloma not having achieved remission.

Form Locator (FL) 42 (Electronic Claim Form = Loop 2400, Segment SV201):

List the appropriate revenue code for the drug. Match the descriptor for BORUZU® to your revenue code, ***0636.***

Additionally, enter an appropriate revenue code for the administration service, such as ***0331 for chemotherapy administration—injection.***

FL 45 (Electronic Claim Form = Loop 2400, Segment DTP/472/03):

Enter the date of service.

FL 46 (Electronic Claim Form = Loop 2400, SV205):

Enter the units for the HCPCS code billed.
Enter the number of service units for each item.

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0636	N470121248401ML.962	J9054-JB	MMDDYY	25				1
2	0636	N470121248401ML.438	J9054-JW	MMDDYY	10				2
3	0331	Chemotherapy administration - injection	96401	MMDDYY	1				3
4									4

FL 43 (NOT REQUIRED BY MEDICARE):

Enter the description of the procedure for the revenue code billed.

If required, list the N4 indicator first, then the 11-digit NDC code. In the third place, list the unit measurement code and, last, the quantity.

FL 44 [Electronic Claim Form = Loop 2400, SV202-2 (SV202-1=HC/HP)]:

Enter the appropriate HCPCS code: ***J9054, Injection, bortezomib (boruzu), 0.1mg***

BORUZU® is packaged as a single-dose vial. Medicare requires drug waste be reported with the -JW modifier on a separate line. If there is no waste, BORUZU® must be billed on one line with modifier -JZ. Medicare requires this; please ascertain if other payers require -JZ and -JW modifiers.

-JA and -JB modifiers are required for drugs that have one HCPCS Level II code but multiple routes of administration. Drugs in this category must be billed using the -JB modifier for subcutaneous injection or the -JA modifier for intravenous infusion.

For administration, enter the appropriate code or codes for subcutaneous or intravenous administration. As an example, chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic requires CPT® code 96401.

FL 63 (Electronic Claim Form = Loop 2300, REF/G1/02):

Enter treatment authorization code.

63 TREATMENT AUTHORIZATION CODES — 64 DOCUMENT CONTROL NUMBER — 65 EMPLOYER NAME

66 DX: C90.00 — 68

69 ADMIT DX — 70 PATIENT REASON DX — 71 PPS CODE — 72 ECI — 73

74 PRINCIPAL PROCEDURE CODE DATE — a. OTHER PROCEDURE CODE DATE — b. OTHER PROCEDURE CODE DATE — 75

c. OTHER PROCEDURE CODE DATE — d. OTHER PROCEDURE CODE DATE — e. OTHER PROCEDURE CODE DATE

80 REMARKS — 81CC a: B 314000000X — b — c — d

76 ATTENDING NPI QUAL — LAST FIRST
77 OPERATING NPI QUAL — LAST FIRST
78 OTHER NPI QUAL — LAST FIRST
79 OTHER NPI QUAL — LAST FIRST

UB-04 CMS-1450 — APPROVED OMB NO. 0938-0997 — NUBC National Uniform Billing Committee LIC9213257 — THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

FL 67A-Q [Electronic Claim Form = Loop 2300, HI01-2 (HI01-1=BK)]:

Enter a diagnosis code for the drug documented in the medical record. Be as specific as possible.

The code listed here is an example: ***C90.00 Multiple myeloma not having achieved remission.***

BSA, body surface area; CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology®; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

Electronic Claims Reference: Palmetto GBA. ASC 837I version 5010A2 institutional health care claim to the CMS-1450 claim form crosswalk. Accessed February 18, 2025. https://www.palmettogba.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$FILE/EDI_837I_v5010A2_crosswalk.pdf

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

- **Peripheral Neuropathy:** Peripheral neuropathy including severe cases may occur. Manage with dose modification or discontinuation. Starting BORUZU® subcutaneously may be considered for patients with preexisting or at high risk of peripheral neuropathy.
- **Hypotension:** Patients with a history of syncope, patients receiving medications known to be associated with hypotension, and patients who are dehydrated may be at increased risk of hypotension. Use caution when treating these patients.
- **Cardiac Toxicity:** Worsening and development of cardiac failure have occurred. Closely monitor patients with existing heart disease or risk factors for heart disease.
- **Pulmonary Toxicity:** Acute respiratory syndromes have occurred. Monitor patients closely for new or worsening symptoms and consider interrupting BORUZU® therapy.
- **Posterior Reversible Encephalopathy Syndrome (PRES):** PRES has occurred in some patients. Consider MRI upon onset of visual or neurological symptoms; discontinue BORUZU® if suspected.
- **Gastrointestinal Toxicity:** Nausea, diarrhea, constipation, vomiting, and other signs of gastrointestinal toxicity have occurred. Administration of antiemetic and antidiarrheal medications or fluid and electrolyte replacement may be required. Interrupt treatment with BORUZU® if severe symptoms occur.
- **Thrombocytopenia/Neutropenia:** BORUZU® is associated with thrombocytopenia and neutropenia that follow a cyclical pattern with nadirs occurring following the last dose of each cycle and typically recovering prior to initiation of the subsequent cycle. Monitor complete blood counts regularly throughout treatment.
- **Tumor Lysis Syndrome:** Tumor lysis syndrome has been reported with BORUZU® therapy. Patients at risk of tumor lysis syndrome are those with high tumor burden prior to treatment. Monitor patients closely and take appropriate precautions.
- **Hepatic Toxicity:** Cases of acute liver failure have been reported in patients receiving multiple concomitant medications and with serious underlying medical conditions. Monitor hepatic enzymes during treatment. Interrupt BORUZU® therapy to assess reversibility. There is limited rechallenge information in these patients.
- **Thrombotic Microangiopathy:** Cases, sometimes fatal, of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), have been reported in the postmarketing setting in patients who received BORUZU®. Monitor for signs and symptoms. Discontinue BORUZU® if suspected.
- **Embryo-Fetal Toxicity: BORUZU® can cause fetal harm. Advise females of reproductive potential to use effective contraception during treatment with BORUZU® and for 7 months following treatment. Advise males with female partners of reproductive potential to use effective contraception during treatment with BORUZU® and for 4 months following treatment. If BORUZU® is used during pregnancy or if the patient becomes pregnant during BORUZU® treatment, the patient should be apprised of the potential risk to the fetus.**

ADVERSE REACTIONS

- The most commonly reported adverse reactions (≥ 20%) in clinical studies include nausea, diarrhea, thrombocytopenia, neutropenia, peripheral neuropathy, fatigue, neuralgia, anemia, leukopenia, constipation, vomiting, lymphopenia, rash, pyrexia, and anorexia.

DRUG INTERACTIONS

- **Strong CYP3A4 Inhibitors:** Coadministration with a strong CYP3A4 inhibitor increases the exposure of bortezomib. Closely monitor patients with concomitant use.
- **Strong CYP3A4 Inducers:** Coadministration with a strong CYP3A4 inducer decreases the exposure of bortezomib. Avoid concomitant use.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** BORUZU® can cause fetal harm when administered to a pregnant woman. There are no studies with the use of BORUZU® in pregnant women to inform drug-associated risks. Advise pregnant women of the potential risk to the fetus.
- **Lactation:** There are no data on the presence of bortezomib or its metabolites in human milk, the effects of the drug on the breastfed child, or the effects of the drug on milk production. Advise nursing women not to breastfeed during treatment with BORUZU® and for 2 months after treatment.
- **Females and Males of Reproductive Potential:** BORUZU® can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with BORUZU® and for 7 months after the last dose. Males with female partners of reproductive potential should use effective contraception during treatment with BORUZU® and for 4 months after the last dose. BORUZU® may affect male and female fertility.
- **Pediatric Use:** Safety and effectiveness of BORUZU® have not been established in pediatric patients.
- **Geriatric Use:** Of the 669 patients enrolled in the relapsed multiple myeloma study, 245 (37%) were 65 years of age or older. No overall differences in safety or effectiveness were observed between patients ≥ age 65 years and younger patients receiving BORUZU®, but greater sensitivity of some older individuals cannot be ruled out.
- **Renal Impairment:** No starting dosage adjustment of BORUZU® is recommended for patients with renal impairment. In patients requiring dialysis, BORUZU® should be administered after the dialysis procedure.
- **Hepatic Impairment:** No starting dosage adjustment of BORUZU® is recommended for patients with mild hepatic impairment (total bilirubin ≤ 1 × ULN and AST > ULN, or total bilirubin > 1 to 1.5 × ULN and any AST). The exposure of bortezomib is increased in patients with moderate (total bilirubin ≥ 1.5 to 3 × ULN and any AST) and severe (total bilirubin > 3 × ULN and any AST) hepatic impairment. Reduce the starting dose in patients with moderate or severe hepatic impairment.
- **Patients With Diabetes:** During clinical trials, hypoglycemia and hyperglycemia were reported in diabetic patients receiving oral hypoglycemics. Patients on oral antidiabetic agents receiving BORUZU® treatment may require close monitoring of their blood glucose levels and an adjustment of the dose of their antidiabetic medication.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Biosciences, a division of Amneal Pharmaceuticals LLC at 1-877-835-5472 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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