BORUZU®
(bortezomib injection)

A ready-to-use bortezomib for subcutaneous administration, with IV option[1]*

The unique HCPCS code for BORUZU® is J9054.[2]

Foundational

- Given as part of a multi-drug regimen, BORUZU® is a foundational component of multiple myeloma therapy for both transplant-eligible and transplant-ineligible patients[3]

National Comprehensive Cancer Network® (NCCN®) recommended

- Bortezomib is recommended as part of an NCCN **Category 1, preferred** regimen option for front-line transplant-eligible and transplant-ineligible patients with multiple myeloma[3]

Affordable

- Eligible† commercially insured patients may pay as little as $0 per treatment with BORUZU® through the Amneal PATHways® Patient Support Program

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.

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

*BORUZU® is supplied as a ready-to-use solution for subcutaneous use in patients with multiple myeloma and needs to be diluted for IV use. The correct route of administration depends on indication and other factors. See page 5 for more information.[1,3]

†Limits, terms, and conditions apply. See page 9 for more information.

HCPCS, Healthcare Common Procedure Coding System; IV, intravenous.

Please see pages 10-11 for Important Safety Information and Boruzu.us for full Prescribing Information.

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BORUZU® is a proteasome inhibitor with the same indications as Velcade® (bortezomib)[1,4]

BORUZU® was approved by the FDA via the 505(b)(2) pathway[5]

	BORUZU®[1]	Velcade® and generic formulations[4,6]
For use in adults with multiple myeloma	✓	✓
For use in adults with mantle cell lymphoma	✓	✓
For subcutaneous or intravenous use	✓	✓
Does not require reconstitution	✓	—
Does not require dilution for subcutaneous use*	✓	—

*No reconstitution or dilution is required for subcutaneous administration. BORUZU® needs to be diluted for IV use.[1] See page 5 for more information regarding different routes of administration.

FDA, US Food and Drug Administration; IV, intravenous.

Velcade® is a registered trademark of Millennium Pharmaceuticals, Inc.

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 pages 10-11 for Important Safety Information and Boruzu.us for full Prescribing Information.

BORUZU® warnings and precautions

BORUZU® (bortezomib injection)

Considerations for the treatment of special populations

Patients with renal impairment

- In patients requiring dialysis, BORUZU® should be administered after the dialysis procedure

Patients with 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
- Monitor blood glucose levels and adjust the antidiabetic medication as needed

Women of reproductive potential

- BORUZU® can cause fetal harm when administered to a pregnant woman
- Advise pregnant women of the potential risk to the fetus

Please see full Prescribing Information for dosing information.

Warnings and precautions[1]

- **Peripheral neuropathy:** Peripheral neuropathy including severe cases may occur. Manage with dose modification or discontinuation
- **Hypotension, cardiac toxicity, and pulmonary toxicity:** Use caution when treating hypotensive patients. Closely monitor patients with heart disease or pulmonary disease
- **Posterior reversible encephalopathy syndrome (PRES):** PRES has occurred in some patients. Monitor patients for PRES
- **Gastrointestinal toxicity:** Nausea, diarrhea, constipation, vomiting, and other signs of gastrointestinal toxicity have occurred
- **Thrombocytopenia/neutropenia:** BORUZU® is associated with thrombocytopenia and neutropenia. 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

Adverse reactions (ARs)[1]

- The most commonly reported ARs, occurring in ≥20% of patients in clinical studies, include nausea, diarrhea, thrombocytopenia, neutropenia, peripheral neuropathy, fatigue, neuralgia, anemia, leukopenia, constipation, vomiting, lymphopenia, rash, pyrexia, and anorexia

Advise patients to contact their physicians if they experience rash, severe injection site reactions, or skin pain.

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Supplied as a ready-to-use vial for subcutaneous use, BORUZU® needs to be diluted for IV use[1]*

BORUZU® is supplied at a concentration of 2.5 mg/mL

Store BORUZU® refrigerated at 2°C to 8°C (36°F to 46°F) in original package to protect from light

BORUZU® is a sterile, clear-to-light-yellow solution supplied as a single-dose vial; 1 vial is included in each carton

Stickers that indicate the route of administration are provided with each BORUZU® vial

With no dilution required, use of BORUZU® is independent of ancillary products, which may face market shortages.

*No reconstitution or dilution is required for subcutaneous administration. BORUZU® needs to be diluted for IV use.[1]
See page 5 for more information regarding different routes of administration.
IV, intravenous.

Please see pages 10-11 for Important Safety Information and Boruzu.us for full Prescribing Information.

Route of administration considerations for BORUZU®

BORUZU® (bortezomib injection)

Indication and other factors can influence clinical decisions regarding routes of administration[1,3,7]

	Multiple myeloma	Mantle cell lymphoma
Previously untreated disease	OR	
Relapsed or refractory disease	OR	OR
Pre-existing or at high risk of peripheral neuropathy	*	*
Hepatic impairment	OR	OR

Subcutaneous administration | IV administration

Please refer to the full Prescribing Information for direction regarding administration and dose modifications.

Subcutaneous administration is associated with lower rates of peripheral neuropathy[1,7]

- Rates of peripheral neuropathy (all grades) were 38% with subcutaneous administration of bortezomib compared with 53% for IV administration (*P*=0.044)

According to the NCCN, subcutaneous bortezomib is the preferred method of administration for patients with multiple myeloma.[3]

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*While it is possible to administer BORUZU® intravenously for patients who have or are at risk for peripheral neuropathy, subcutaneous administration is preferred.[1,3]
IV, intravenous.

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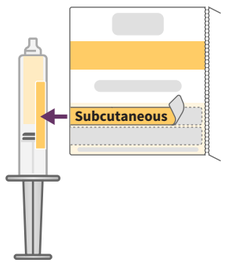
Subcutaneous administration instructions

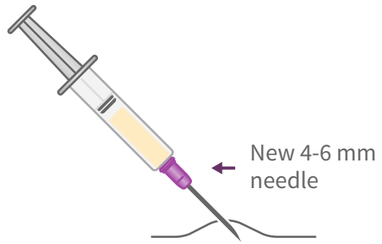
BORUZU® does not need to be reconstituted or diluted for subcutaneous administration[1]

1 Withdraw the appropriate BSA-based dose directly from the vial into a syringe.

- ✓ The recommended starting dose for BORUZU® is 1.3 mg/m^2.[1]
- ✓ **Subcutaneous administration requires no reconstitution or dilution.**[1]



2 Place included sticker on syringe to identify the correct method of administration.[1]



3 Attach a fresh needle (4-6 mm) to syringe with prepared medication. Administer BORUZU® to patients using institution protocol for subcutaneous administration of chemotherapeutic agents.[1,8]

Please refer to the full Prescribing Information for dose modification and treatment cycle recommendations.

According to the NCCN, subcutaneous bortezomib is the preferred method of administration for patients with multiple myeloma.[3]

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BSA, body surface area.

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Recommendations for subcutaneous administration

BORUZU® (bortezomib injection)

Injection site reactions may occur with subcutaneous administration of bortezomib[1]

When administering BORUZU® subcutaneously:

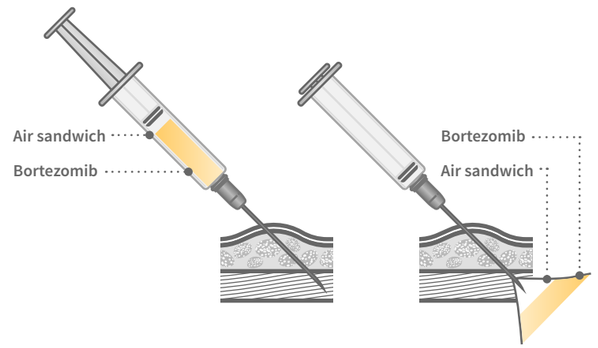
Rotate the sites for each injection (thigh or abdomen).[1]

Consider using the **air sandwich** (also known as **air lock**) injection technique.[8-10]

If a local injection site reaction occurs following administration, BORUZU® may be administered at a less concentrated dose (1 mg/mL instead of 2.5 mg/mL).[1]

Steps for air sandwich technique[8]:

1. Withdraw BORUZU® from the vial. *DO NOT* exceed the maximum volume of 2 mL per injection site.
2. Attach a new 4-6 mm needle to syringe with prepared medication.
3. *DO NOT* purge the needle of air.
4. Pull 0.5-1.0 mL of air into the syringe (air behind drug when inverted).
5. Invert syringe and inject contents at a 90° angle for needles 4-6 mm, or at a 45° angle for needles ≥8 mm, including the air behind the drug.



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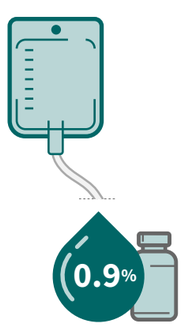
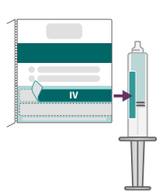
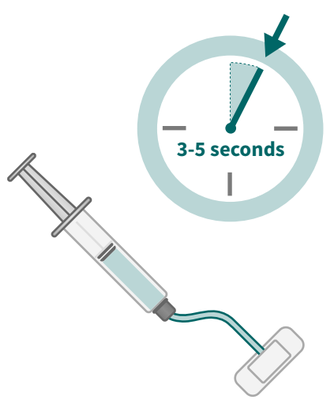
IV administration instructions[1]

BORUZU® must be diluted prior to IV administration



✓ Place included sticker on syringe to identify the correct method of administration.





1 **Dilute each vial with 2.1 mL of 0.9% sodium chloride injection only to obtain a final concentration of 1 mg/mL.**

2 Withdraw the appropriate BSA-based dose into a syringe.

✓ The recommended starting dose for BORUZU® is 1.3 mg/m^2.

3 Administer BORUZU® as a 3- to 5-second bolus IV injection.

Please refer to the full Prescribing Information for dose modification and treatment cycle recommendations.

Once diluted, BORUZU® may be stored in the original vial and/or syringe at room temperature (20°C to 25°C [68°F to 77°F]) for up to 8 hours prior to use when exposed to normal indoor lighting.

Use caution when calculating the volume to be administered.

BSA, body surface area; IV, intravenous.

Please see pages 10-11 for Important Safety Information and Boruzu.us for full Prescribing Information.

Access support

BORUZU®
(bortezomib injection)

Amneal PATHways® can help patients and providers with access to BORUZU® treatment

The Amneal PATHways® Patient Support Program is designed to help patients and providers stay on course toward accessible treatment. With its full suite of services and dedicated Program Access Specialists, PATHways allows stakeholders to more easily map a patient's personal treatment path together.

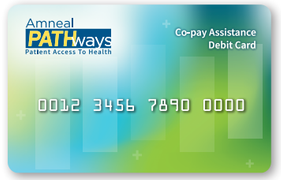
Amneal PATHways® Patient Access To Health

Get assistance with:

- Benefit investigation
- Prior authorization support
- Appeals
- Billing & coding
- Claims

Get information about:

- Patient assistance program
- Alternate coverage
- Co-pay savings program



The Amneal PATHways® Co-pay Assistance Card is available to eligible patients

- Eligible* commercially insured patients may pay **as little as $0 per treatment** with BORUZU®

Call 1-866-4AMNEAL (1-866-426-6325) to learn more.

*Limits, terms, and conditions apply. No income restrictions for patients to qualify. For information on enrollment, claims submissions, and reimbursement, log on to the PATHways provider portal at pathwaysproviderportal.com. Eligibility Criteria/Terms & Conditions: The PATHways Co-Pay Savings Program [Program] is NOT insurance. The Program is only available for residents of the US and Puerto Rico who have commercial health insurance with co-pay/co-insurance on each prescription fill per product. Uninsured and cash-pay individuals are NOT eligible for the Program nor are individuals with commercial insurance coverage that does not provide coverage for BORUZU® (bortezomib injection). Individuals with coverage for BORUZU® (bortezomib injection), in whole or in part, under any state or federally funded healthcare program, including but not limited to, Medicare, Medicare Advantage Plans, Medicare Part D (including Qualified Retiree Prescription Drug Plans), Medicaid, Medigap, VA, DoD, TRICARE, and the Puerto Rico Government Health Insurance Plan, are NOT eligible for the Program. Patients who move from commercial to state or federally funded insurance will no longer be eligible for the Program.

Patients may not combine this offer with any rebate, coupon, free trial, or similar offer. Patients must present a valid prescription for an eligible drug at a participating pharmacy. Federal and state laws and other factors may prevent or otherwise restrict eligibility. This offer is not valid where prohibited by law. Void if copied, transferred, purchased, altered, or traded. Amneal Pharmaceuticals LLC reserves the right to rescind, revoke or amend this offer or discontinue the Program at any time without notice. When submitting claims under the Program, patients are certifying that they understand the Program rules, regulations and terms and conditions, and will comply with the Program terms as set forth herein. Additionally, you are certifying that a claim has not been submitted under a state or federally funded healthcare program, including but not limited to, Medicare, Medicare Advantage Plans, Medicare Part D (including Qualified Retiree Prescription Drug Plans), Medicaid, Medigap, VA, DoD, TRICARE, and the Puerto Rico Government Health Insurance Plan. Limit one Program enrollment per individual.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

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

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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- BORUZU® is contraindicated for intrathecal administration.

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.**

Please see Boruzu.us for full Prescribing Information.

BORUZU®
(bortezomib injection)

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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How to order BORUZU®

HCPCS code[2]
J9054

Product information[1]

Unit of sale	Unit of sale quantity	NDC
3.5 mg/1.4 mL (2.5 mg/mL)	Single-dose vial	70121-2484-1

Coding and billing information

- When billing for BORUZU®, use the unique HCPCS code J9054[2]
- BORUZU® has been granted pass-through status indicator G under the Hospital Outpatient Prospective Payment System (OPPS)[11]

Order from your wholesaler or contact Amneal: toll-free 1-866-525-7270 | CustomerRelations@amneal.com

HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

References: 1. BORUZU. Prescribing information. Amneal Pharmaceuticals LLC; 2024. **2.** Centers for Medicare & Medicaid Services. Fourth quarter, 2024 HCPCS coding cycle. Accessed February 7, 2025. https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-4-2024-drugs-and-biologicals.pdf **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.1.2025. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed February 7, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. **4.** Velcade. Prescribing information. Millennium Pharmaceuticals, Inc.; 2022. **5.** Amneal Biosciences. Amneal and Shilpa announce U.S. FDA approval of BORUZU™, the first ready-to-use version of bortezomib for subcutaneous administration. September 5, 2024. Accessed February 7, 2025. https://investors.amneal.com/news/press-releases/press-release-details/2024/Amneal-and-Shilpa-Announce-U.S.-FDA-Approval-of-BORUZU-the-First-Ready-to-Use-Version-of-Bortezomib-for-subcutaneous-administration/default.aspx **6.** Bortezomib. Prescribing information. Hospira, Inc. 2022. **7.** Arnulf B, Pylypenko H, Grosicki S, et al. Updated survival analysis of a randomized phase III study of subcutaneous versus intravenous bortezomib in patients with relapsed multiple myeloma. *Haematologica*. 2012;97(12):1925-1928. **8.** Kurtin S, Knop CS, Milliron T. Subcutaneous administration of bortezomib: strategies to reduce injection site reactions. *J Adv Pract Oncol*. 2012;3(6):406-410. **9.** Boudreau A. Practical considerations for the integration of subcutaneous targeted therapies into the oncology clinic. *Can Oncol Nurs J*. 2019;29(4):267-270. **10.** Becze E. Make subcutaneous administration more comfortable for your patients. January 4, 2022. Accessed February 7, 2025. https://www.ons.org/publications-research/voice/news-views/01-2022/make-subcutaneous-administration-more-comfortable **11.** Centers for Medicare & Medicaid Services. Pub 100-04 Medicare claims processing, transmittal 13135. March 20, 2025. Accessed March 24, 2025. https://www.cms.gov/files/document/r13135cp-1.pdf

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