# VELCADE® (bortezomib) for Subcutaneous Administration Site Tracker

Patient name_____ Date_____

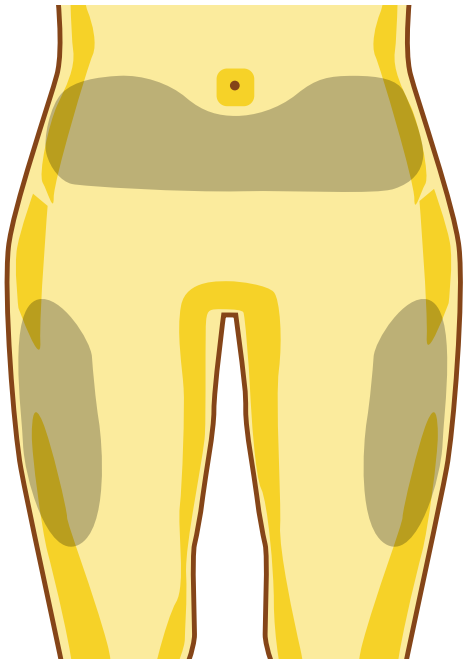
This diagram illustrates appropriate sites for subcutaneous administration of VELCADE (bortezomib). Subcutaneous injections should be given in accordance with your institution's established policies.

- The volume of 0.9% sodium chloride solution used to reconstitute VELCADE for subcutaneous administration is different from the volume for IV administration. The reconstituted concentration for subcutaneous administration (2.5 mg/mL) is greater than the reconstituted concentration for IV administration (1 mg/mL). For proper reconstitution and dosing information, please see the full Prescribing Information for VELCADE available at VELCADEHCP.com. Visit **VELCADEinject.com** to download a PDF of the Reconstitution and Dosing for Subcutaneous and Intravenous Administration guide
- The recommended starting dose of VELCADE for patients with multiple myeloma is 1.3 mg/m$^2$. Please see accompanying full Prescribing Information for additional information on dosing and administration
- Use the abdomen or thighs as sites for subcutaneous injections. Rotate injection sites
- Administer new injections at least 1 inch from an old site and never into areas where the skin is tender, bruised, erythematous, or indurated
- If local injection site reactions occur following administration of VELCADE subcutaneously, a less concentrated VELCADE solution (1 mg/mL instead of 2.5 mg/mL) may be administered subcutaneously. Alternatively, consider the IV route of administration. In the clinical trial, the most common reaction was redness, occurring in 57% of patients.[1] Injection site reactions were reported in 6% of patients as an adverse reaction, with 1% being serious and leading to dose modification or discontinuation. All events resolved in a median of 6 days

VELCADE® (bortezomib) FOR INJECTION

**Documenting your patient's injection history:**

- When an injection is administered, record the injection number in the corresponding area of the diagram below, and record the date and any comments in the table
- Place this sheet in your patient's file and refer to it when mapping future sites



| Injection number | Date | Comments |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |
| 9 | | |
| 10 | | |
| 11 | | |
| 12 | | |

VELCADE is indicated for the treatment of patients with multiple myeloma.

VELCADE is contraindicated in patients with hypersensitivity (not including local reactions) to bortezomib, boron, or mannitol, including anaphylactic reactions.

VELCADE is contraindicated for intrathecal administration. Fatal events have occurred with intrathecal administration of VELCADE.

**Please see Important Safety Information on back and accompanying full Prescribing Information, also available at VELCADE-hcp.com.**

# Important Safety Information for VELCADE® (bortezomib)

**CONTRAINDICATIONS:** VELCADE (bortezomib) is contraindicated in patients with hypersensitivity (not including local reactions) to bortezomib, boron, or mannitol, including anaphylactic reactions. VELCADE is contraindicated for intrathecal administration. Fatal events have occurred with intrathecal administration of VELCADE.

**WARNINGS AND PRECAUTIONS:** VELCADE is for subcutaneous or IV administration only. Because each route of administration has a different reconstituted concentration, caution should be used when calculating the volume to be administered.

- **Peripheral neuropathy,** including severe cases, may occur. Patients should be monitored for symptoms and managed with dose modification or discontinuation. Patients with preexisting symptoms may experience worsening peripheral neuropathy (including ≥Grade 3). Starting with VELCADE subcutaneously may be considered for patients who either have preexisting or are at high risk for peripheral neuropathy.
- **Hypotension:** Caution should be used when treating patients receiving antihypertensives, those with a history of syncope, and those who are dehydrated.
- **Cardiac toxicity,** including acute development or exacerbation of congestive heart failure and new onset of decreased left ventricular ejection fraction, has occurred. Isolated cases of QT-interval prolongation have been reported. Patients with risk factors for, or existing, heart disease should be closely monitored.
- **Pulmonary toxicity:** Acute respiratory distress syndrome (ARDS) and acute diffuse infiltrative pulmonary disease of unknown etiology have occurred (sometimes fatal). Pulmonary hypertension, in the absence of left heart failure or significant pulmonary disease, has been reported. In the event of new or worsening cardiopulmonary symptoms, consider interrupting VELCADE until a prompt and comprehensive diagnostic evaluation is conducted.
- **Posterior reversible encephalopathy syndrome** has occurred. Consider MRI imaging for onset of visual or neurological symptoms; discontinue VELCADE if suspected.
- **Gastrointestinal toxicity,** including nausea, diarrhea, constipation, and vomiting, has occurred and may require use of antiemetic and antidiarrheal medications or fluid replacement. Interrupt VELCADE for severe symptoms.
- **Thrombocytopenia/Neutropenia:** Manage with dose and/or schedule modifications. Complete blood counts should be monitored frequently during treatment. There have been reports of gastrointestinal and intracerebral hemorrhage. Support with transfusions and supportive care, according to published guidelines.
- **Tumor lysis syndrome:** Closely monitor patients with high tumor burden and take appropriate precautions.
- **Hepatic toxicity:** Monitor hepatic enzymes during treatment. Upon occurrence, interrupt therapy with VELCADE to assess reversibility.
- **Embryo-fetal risk:** Women should avoid breast-feeding or becoming pregnant while on VELCADE.
- **Patients with diabetes** may require close monitoring and adjustment of the antidiabetic medications.

**DRUG INTERACTIONS:** Closely monitor patients receiving VELCADE in combination with strong CYP3A4 inhibitors. Avoid concomitant use of strong CYP3A4 inducers.

**ADVERSE REACTIONS**

- **Previously untreated multiple myeloma (MM):** In the phase 3 study of VELCADE administered intravenously with melphalan and prednisone (MP) vs MP alone, the most commonly reported adverse reactions (ARs) were thrombocytopenia (48% vs 42%), neutropenia (47% vs 42%), peripheral neuropathy (46% vs 1%), nausea (39% vs 21%), diarrhea (35% vs 6%), neuralgia (34% vs <1%), anemia (32% vs 46%), and leukopenia (32% vs 28%).
- **Relapsed MM:** In the phase 3 study of VELCADE administered intravenously vs dexamethasone, the most commonly reported ARs were nausea (52% vs 9%), diarrhea (52% vs 11%), fatigue (39% vs 25%), peripheral neuropathies (35% vs 4%), thrombocytopenia (33% vs 3%), constipation (30% vs 8%), vomiting (29% vs 3%), and anorexia (21% vs 2%). The most commonly reported serious ARs were diarrhea (3%), dehydration, herpes zoster, pyrexia, nausea, vomiting, dyspnea, and thrombocytopenia (2% each) in the VELCADE treatment group and pneumonia (4%), hyperglycemia (3%), pyrexia, and psychotic disorder (2% each) in the dexamethasone treatment group.
- **Relapsed MM subcutaneous vs IV:** In the phase 3 study of VELCADE administered subcutaneously vs intravenously in relapsed MM, safety data were similar between the two treatment groups. The most commonly reported ARs in the subcutaneous vs IV treatment groups were peripheral neuropathy (37% vs 50%) and thrombocytopenia (30% vs 34%). The incidence of serious ARs was similar in the subcutaneous treatment group (20%) and the IV treatment group (19%). The most commonly reported serious ARs were pneumonia and pyrexia (each 2%) in the subcutaneous treatment group and pneumonia, diarrhea, and peripheral sensory neuropathy (each 3%) in the IV treatment group.

**Please see accompanying full Prescribing Information, also available at VELCADE-hcp.com.**

Takeda ONCOLOGY



**Reference: 1.** Moreau P, Pylypenko H, Grosicki S, et al. Subcutaneous versus intravenous administration of bortezomib in patients with relapsed multiple myeloma: a randomised, phase 3, non-inferiority study. *Lancet Oncol.* 2011;12(5):431-440.

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**Please see full Prescribing Information at**

**velcade.com/Files/PDFs/VELCADE_PRESCRIBING_INFORMATION.pdf**