VELCADE® (bortezomib) frequently asked questions

If I have multiple myeloma can I receive VELCADE (bortezomib) after stem cell transplant?

Yes. The FDA has approved VELCADE® (bortezomib) for treatment of patients with multiple myeloma. In relapsed multiple myeloma the clinical trial included patients who had received a stem cell transplant. Talk to your doctor or healthcare team about whether VELCADE may be right for you.

VELCADE is also approved as an initial treatment for patients with previously untreated multiple myeloma.

If I have or am at high risk of getting peripheral neuropathy, might subcutaneous VELCADE (bortezomib) be an alternative to intravenous VELCADE?

Yes, patients with preexisting peripheral neuropathy (PN) or those who are at a high risk for it may be started on VELCADE therapy subcutaneously. PN is caused by nerve damage that results in tingling or numbness in hands, arms, feet, or legs; a burning feeling in feet or hands; and pain or weakness in the arms or legs.

A clinical trial showed differences in occurrence of PN between patients treated with intravenous VELCADE (bortezomib) and those treated with subcutaneous VELCADE. This trial included 222 relapsed patients who had been previously treated for multiple myeloma.

In this study:

- The rates of peripheral neuropathy were 37% with subcutaneous VELCADE compared to 50% with VELCADE given intravenously for all levels of severity.
- For more severe cases, the rates were 6% with subcutaneous VELCADE compared to 15% of patients who received intravenous VELCADE.

More about possible side effects

What if I need help with transportation to and from my appointments?

If you need help getting to or from your appointments, we may be able to connect you with the help that you need. There are numerous national organizations that provide transportation to and from medical appointments for patients with multiple myeloma and relapsed mantle cell lymphoma who are in need of financial assistance.

For more information, click here.

How often should I receive VELCADE (bortezomib)?

Your treatment schedule will vary depending upon your diagnosis.
How long should I take VELCADE (bortezomib) if I have previously untreated multiple myeloma?

For patients who were not eligible for a stem cell transplant, a clinical trial compared VELCADE (bortezomib) in combination with 2 drugs, melphalan and prednisone (MP), versus MP alone. There were 682 patients involved in this study, all of whom had not been treated:

- **At the 5-year evaluation of this clinical trial, patients initially taking VELCADE plus MP lived longer than patients taking MP alone**
- **In this trial, 28% of complete responses were achieved after 24 weeks of VELCADE (bortezomib) therapy. Half of the patients on VELCADE therapy continued to receive VELCADE for at least 50 weeks out of 54 weeks planned for the trial**
- **In this clinical trial, the most common side effects reported by patients receiving VELCADE included abnormal blood cell counts; numbness, tingling, burning, or weakness in hands or feet; nausea; diarrhea; and nerve pain**
- **VELCADE can cause serious side effects, including peripheral neuropathy, low blood pressure, heart problems, lung problems, liver problems, posterior reversible encephalopathy syndrome (PRES), gastrointestinal problems, neutropenia (low levels of neutrophils, a type of white blood cell), thrombocytopenia (low levels of platelets), and tumor lysis syndrome (TLS)**

How long should I take VELCADE (bortezomib) if I have relapsed multiple myeloma?

In a clinical trial of patients with relapsed multiple myeloma, VELCADE (bortezomib) was compared to dexamethasone. There were 669 patients involved in this study:

- **At 1 year, patients treated with VELCADE had a higher survival rate (80%) than patients treated with dexamethasone (66%)**
- **In this clinical trial, the most common side effects reported by patients receiving VELCADE included nausea; diarrhea; fatigue; numbness, tingling, burning, or weakness in hands or feet; decrease from normal number of platelets; and constipation**
VELCADE can cause serious side effects, including peripheral neuropathy, low blood pressure, heart problems, lung problems, liver problems, posterior reversible encephalopathy syndrome (PRES), gastrointestinal problems, neutropenia (low levels of neutrophils, a type of white blood cell), thrombocytopenia (low levels of platelets), and tumor lysis syndrome (TLS)

In this clinical trial, 31% of patients responded to treatment with VELCADE

In this clinical trial, the most commonly reported side effects in patients with relapsed mantle cell lymphoma were nausea; numbness, tingling, burning, or weakness in hands or feet; fatigue (tiredness); diarrhea; constipation; vomiting; and rash

VELCADE can cause serious side effects, including nausea, vomiting, abdominal pain, fainting, fever, pneumonia, and infection

How long should I take VELCADE (bortezomib) if I have relapsed mantle cell lymphoma?

Based on a large clinical trial of 155 patients, VELCADE (bortezomib) is approved by the FDA for patients with mantle cell lymphoma who have already received at least one treatment
Is there any financial assistance that can help me pay for VELCADE (bortezomib)?

VELCADE (bortezomib) has a comprehensive Reimbursement Assistance Program (VRAP). Dedicated VELCADE case managers can help patients and caregivers learn more about:

- Understanding insurance and coverage
- Alternative and supplemental insurance coverage options
- Information on co-payment foundation support
- Referrals for transportation resources

If you don’t have insurance coverage for VELCADE, you may be eligible for the VELCADE Patient Assistance Program. If you qualify, your VELCADE will be delivered without charge to your physician. For more information, or to enroll, contact a VELCADE case manager.

**VELCADE Reimbursement Assistance Program (VRAP)**
1-866-VELCADE (835-2233), option 2
9 AM to 7 PM (ET), Monday through Friday

You may also be eligible for co-pay assistance through third-party companies. Click here to learn more about foundations that may be able to help.

*VRAP does not file or appeal claims for callers and cannot guarantee that you will be successful in obtaining reimbursement.

Indications and Important Safety Information for VELCADE® (bortezomib)

What is VELCADE used for?
VELCADE (bortezomib) is approved for the treatment of patients with multiple myeloma (a cancer of the plasma cells). VELCADE is also approved for the treatment of patients with mantle cell lymphoma (a cancer of the lymph nodes) who have
already received other treatments.

How is VELCADE administered?

VELCADE is prescribed by a physician experienced in the use of medications to treat cancer. It is administered by a healthcare professional as an injection into your vein (intravenously, or IV) or under your skin (subcutaneously). VELCADE must not be administered into your spinal fluid (intrathecally).

Who should not receive VELCADE?

Before you receive treatment with VELCADE, tell your doctor about all of your medical conditions. You should not receive VELCADE if you are allergic to bortezomib, boron, or mannitol.

What are the possible side effects of VELCADE?

VELCADE (bortezomib) can cause serious side effects, including:

- **Peripheral neuropathy.** VELCADE can cause damage to the nerves, a condition called peripheral neuropathy. You may feel muscle weakness, tingling, burning, pain, and loss of feeling in your hands and feet, any of which can be severe. Tell your doctor if you notice any of these symptoms. Your doctor may change the dose and/or schedule of VELCADE or stop it altogether. If you have peripheral neuropathy before starting VELCADE, your doctor could consider giving you VELCADE subcutaneously.

- **Low blood pressure.** VELCADE can cause a drop in blood pressure. Tell your doctor if you have low blood pressure, feel dizzy, or feel as though you might faint. If you are taking drugs that lower blood pressure, your medications might need to be adjusted. If you are not drinking enough liquids, your doctor may need to administer IV fluids.

- **Heart problems.** Treatment with VELCADE can cause or worsen heart rhythm problems and heart failure. Your doctor may closely monitor you if you have, or are at risk for, heart disease. Tell your doctor if you experience chest pressure or pain, palpitations, swelling of your ankles or feet, or shortness of breath.

- **Lung problems.** There have been reports of lung disorders in patients receiving VELCADE. Some of these events have been fatal. Tell your doctor if you experience any cough, shortness of breath, wheezing, or difficulty breathing.

- **Liver problems.** If you have liver problems, it can be harder for your body to get rid of VELCADE. VELCADE has caused sudden liver failure in patients who were taking many medications or had other serious medical conditions. Symptoms of liver problems include a yellow discoloration of the eyes and skin (jaundice) and changes in liver enzymes measured in blood tests. Your doctor will closely monitor if you have liver disease.

- **Posterior reversible encephalopathy syndrome (PRES).** There have been reports of a rare, reversible condition involving the brain, called PRES, in patients treated with VELCADE. Patients with PRES can have seizures, high blood pressure, headaches, tiredness, confusion, blindness, or other vision problems. Treatment with VELCADE should be stopped in cases of PRES.

- **Gastrointestinal problems.** VELCADE (bortezomib) treatment can cause nausea, vomiting, diarrhea, and constipation. If your symptoms are severe, your doctor may recommend IV fluids and/or medications.

- **Neutropenia (low levels of neutrophils, a type of white blood cell).** VELCADE can cause low levels of white blood cells (infection-fighting cells). If your white blood cells become low, you can be at higher risk for infections. Tell your doctor if you develop a fever or believe you have an infection.

- **Thrombocytopenia (low levels of platelets).** VELCADE can cause low levels of platelets (clot-forming cells). If platelets become very low, there is an increased risk of bleeding. Your doctor may recommend a platelet transfusion.

You will have regular blood tests to check your cell counts during your treatment with VELCADE. If the number of these cells is very low, your doctor may change the dose and/or schedule of VELCADE.

- **Tumor lysis syndrome (TLS).** TLS is a syndrome that causes a chemical imbalance in the blood that could lead to heart and/or kidney problems. TLS can occur with cancer treatments, and your doctor will be monitoring your blood and urine for any signs of this syndrome. If you develop TLS, your doctor will take appropriate steps to treat it.

More than 1 in 5 patients (20%) receiving VELCADE have experienced the following side effects: nausea, diarrhea, thrombocytopenia, neutropenia, peripheral neuropathy, fatigue, neuralgia (nerve pain), anemia, leukopenia (low levels of white blood cells), constipation, vomiting, lymphopenia (low levels of a certain type of white blood cells), rash, pyrexia (fever), and anorexia.

What other information should you discuss with your doctor?

Women should avoid becoming pregnant or breast-feeding while being treated with VELCADE (bortezomib). Discuss with your
doctor when it is safe to restart breast-feeding after finishing your treatment.

You should also tell your doctor if you:

Have kidney disease. If you are on dialysis, your doctor will administer VELCADE after the dialysis procedure.

Are taking medication for diabetes. VELCADE can affect your blood glucose levels. Your doctor may require close monitoring of your blood glucose levels and change the dose of your diabetes medicine while you are being treated with VELCADE.

Have liver disease.

Are using any other medications, including prescription and over-the-counter drugs, herbal or dietary supplements, or holistic treatments. St. John’s wort should be avoided.

Develop a rash of any type while receiving VELCADE.

The side effects of VELCADE may impair your ability to drive or operate machinery.

These are not all of the possible side effects with VELCADE. It is important to always contact your doctor if you experience any side effects while on VELCADE. If you have any questions about VELCADE, contact your doctor. Additional information is available on the Web site VELCADE.com.

Please see the full Prescribing Information for VELCADE, including Warnings and Precautions.

VELCADE® (bortezomib) Information Line: 1-866-835-2233

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