

## Conditional Approval Of VELCADE\*

### FACT SHEET

**What is VELCADE?** VELCADE is a type of anticancer medicine, known as a proteasome inhibitor.

Health Canada has approved VELCADE with conditions, under the Notice of Compliance with Conditions policy. This authorization reflects the promising nature of the clinical evidence which must be verified and/or extended with further studies. Products approved under Health Canada's NOC/c policy have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment.

**What is VELCADE used for?** VELCADE is used for the treatment of adults with cancer of the bone marrow (multiple myeloma) who have received at least one prior therapy and have already undergone or are unsuitable for stem cell transplantation.

Effectiveness and safety have not been established in children or adolescents.

**What is multiple myeloma?** Multiple myeloma is a cancer of the blood in which cancerous plasma cells are overproduced in the bone marrow – the tissue inside the bone which manufactures all blood cells. Plasma cells are a form of white blood cells. The growth of cancerous plasma cells in the bone marrow decreases the production of normal red and white blood cells. Multiple myeloma may cause multiple defects seen on X-rays of bones and may spread to other tissues of the body to produce tumours.

**What are the symptoms of multiple myeloma?** The most common symptoms of multiple myeloma include:

- Bone pain in the back, rib cage, pelvis, arms or legs;
- Weakened bones and fractures that can occur with relatively minor stress or injury;
- Fatigue and anemia occurring because of the disease or its complications;
- Infections due to a lowering of the normal antibodies of the immune system;
- Kidney problems due to an abnormal protein produced by myeloma cells, dehydration or high calcium levels in the blood;
- High levels of calcium in the blood that may result in symptoms including thirst, nausea, vomiting, confusion and constipation.

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Symptoms do not always appear in the early stages of multiple myeloma. Moreover, having the above signs and symptoms does not necessarily mean you have multiple myeloma. If you have any of these symptoms, it is best to talk to your doctor.

**What are the phases of multiple myeloma?**

The typical course of multiple myeloma is characterized by:

- a phase without symptoms;
- a phase with symptoms which may last months or several years and include some or all symptoms listed under “What are the symptoms of multiple myeloma?”;
- an aggressive terminal phase.

**How is multiple myeloma diagnosed?**

Abnormal blood tests or bone X-rays may lead to the diagnosis of multiple myeloma.

**How does VELCADE work?**

VELCADE blocks the proteasome, a structure that exists in all cells and plays an important role in breaking down proteins that control how the cell lives and grows.

By blocking the proteasome, VELCADE disrupts processes related to the growth and survival of cancer cells.

**What other treatments have been used to treat multiple myeloma?**

This section is intended to provide you with some information on the treatment of multiple myeloma. It cannot obviously cover all aspects of multiple myeloma treatment; you should speak to your doctor if you have any particular questions or concerns.

The treatment offered will be determined based on a patient’s general health and may include treatment with various anticancer medicines, stem cell transplantation, or best supportive care (management of pain, etc.).

**What are the advantages of VELCADE over other therapies?**

VELCADE works differently than other anticancer medicines. It is the first proteasome inhibitor that is approved for the treatment of multiple myeloma patients who have received at least one prior therapy and who have already undergone or are unsuitable for stem cell transplantation.

**What do patients need to know about using VELCADE?**

Treatment with VELCADE will take place in a specialized medical facility, under the supervision of a qualified physician who is experienced in the use of chemotherapy medicines.

Inform your doctor, medical personnel or pharmacist about all medicines you are taking, whether prescribed for you or bought without a prescription.

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If you are a patient on oral anti-diabetic medication while receiving VELCADE treatment, check your blood sugar level frequently. Call your doctor if you notice an unusual change.

Before you use or while you are using VELCADE, you should talk to your doctor if:

- you have a low level of red blood cells, platelets, or white blood cells;
- you are suffering from diarrhea, constipation, nausea or vomiting;
- you have a history of fainting, dizziness or lightheadedness, or use of fluid pills;
- you have any problems with your kidneys or liver;
- you have had any problems in the past with numbness, tingling, or pain in the hands or feet (neuropathy);
- you have had any bleeding problems;
- you have any problems with your heart or with your blood pressure;
- you have had an allergic reaction to the active or non-active ingredients of VELCADE;
- you have been diagnosed in the past with a condition called amyloidosis (abnormal protein deposition in tissues).

All patients must ensure that contraceptive precautions are taken while receiving VELCADE, and for 3 months after treatment. It is advised that you are not given VELCADE if you are pregnant. You must ensure that you do not become pregnant while receiving VELCADE. Do not breast-feed while you are receiving VELCADE. If you wish to restart breast-feeding after your VELCADE treatment, you must discuss this with your doctor or nurse, who will tell you when it is safe to do so.

VELCADE might cause low blood pressure that may lead to tiredness, dizziness, fainting or blurred vision. Do not drive or operate any dangerous tools or machines if you experience such side effects. Even if you have not felt these effects, you must still be cautious.

**What are the side effects and how serious are they?**

Like all medicines, VELCADE can have side effects. The most common serious side effects are:

- Numbness, tingling, or burning sensation in hands or feet, which often does not go away
- Sudden fall of blood pressure on standing, causing dizziness or fainting
- Bleeding (internal such as brain or gastrointestinal, or external, bruising)

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- Fever
- Infections (chest and others)
- Diarrhea
- Nausea and vomiting
- Dehydration (as a result of excessive fluid loss through diarrhea/vomiting)
- Difficulty breathing
- Fatigue/lethargy/feeling of weakness
- Headache
- Joint pain or stiffness, muscle pain, cramps or stiffness

Less common serious side effects include, but are not limited to:

- Chest palpitations/awareness of abnormal heart rhythm
- Chest pain
- Yellowing of skin or whites of eyes
- Difficulty moving limbs, walking or speaking, stroke
- Confusion
- Seizure
- Swelling of face, neck, arms or ankles
- Loss of appetite
- Constipation
- Loss of control or inability to pass urine

Other common side effects include:

- Lowering of red or white blood cells
- Blurred vision
- Abdominal pain, heartburn or stomach ulcers
- Shivering
- Infections (viral, shingles or flu-like symptoms)
- Weight loss
- Bone or back pain
- Psychiatric disorders such as difficulty sleeping, anxiety or depression
- Cough
- Skin disorders such as rashes or itching, hives, redness and pain at injection site

Some of these effects may be serious; however, there might be ways to reduce the discomfort of these effects. You should discuss these effects with your doctor.

### **Who can be treated with VELCADE?**

VELCADE has been approved for the treatment of patients with multiple myeloma who have received at least one prior therapy and who have already undergone or are unsuitable for stem cell

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transplantation.

**How is VELCADE taken?**

Treatment with VELCADE will take place in a specialized medical facility, under the supervision of a doctor experienced in the use of chemotherapy agents.

The powder for solution will be dissolved in 0.9% sodium chloride (salt) for injection. The reconstituted solution is injected into a vein.

The dose will be calculated from your height and weight. The usual starting dose is 1.3 milligrams per square metre body surface area. The injection will take 3-5 seconds, and the injection syringe will then be rinsed through with a small quantity of sterile sodium chloride (salt) solution.

One cycle of treatment with VELCADE consists of a total of 4 doses and will be given over 3 weeks. Doses are given on Days 1, 4, 8, and 11, followed by a 10-day break from treatment. For treatments extended beyond 8 cycles (24 weeks), your schedule may change to a maintenance schedule. On a maintenance schedule, VELCADE will be administered once weekly for 4 weeks (Days 1, 8, 15 and 22) followed by a 13-day break from treatment (Days 23 to 35). This 5-week period, 22 days for treatment and 13 days for rest, is considered a cycle.

The doctor may change the dosage during treatment, and will decide the total number of cycles that the patient needs. It will depend on the patient's response to the VELCADE treatment.

**Where can I learn more about VELCADE?**

<http://www.janssen-ortho.com>

Contact the Janssen-Ortho Medical Information Department at 1-800-567-3331.

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