CONSUMER INFORMATION
Product Monograph Part III

PrVELCADE*
bortezomib
3.5 mg/vial, lyophilized powder for injection

Janssen-Ortho Inc.

Submission Control No. 090084

The Consumer Information Section (Part III) of the Product Monograph for VELCADE has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on January 27, 2005 and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

PART III: CONSUMER INFORMATION

VELCADE for use in patients with multiple myeloma, has been approved with conditions, pending the results of studies to verify its clinical benefit. For more information, patients are advised to contact their healthcare provider.

What is a Notice of Compliance with Conditions (NOC/c)?
An NOC/c is a form of market approval granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada.

Products approved under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed-upon time frame.

[Pr]VELCADE[*]
bortezomib

This leaflet is Part III of a three-part "Product Monograph" published when VELCADE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VELCADE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
VELCADE is used for the treatment of adults with cancer of the bone marrow (multiple myeloma).

What it does:
VELCADE is a chemotherapy medicine, which is medicine used to kill cancer cells.

When it should not be used:
Do not use VELCADE if you are allergic (hypersensitive) to the active substance or to any of the other ingredients of VELCADE.

What the medicinal ingredient is:
The medicinal ingredient is bortezomib mannitol boronic ester.

What the nonmedicinal ingredients are:
The nonmedicinal ingredient is mannitol.

What dosage forms it comes in:
VELCADE is supplied as a powder which will be dissolved in a sterile, sodium chloride (salt) solution before being injected into your vein. After reconstitution, 1 mL of solution for injection contains 1 mg bortezomib.

Each pack of VELCADE contains one glass vial. Each vial contains 3.5 mg of bortezomib (as a mannitol boronic ester).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
Your treatment with VELCADE will take place in a specialized medical facility, under the supervision of a qualified healthcare professional who is experienced in the use of chemotherapy medicines.

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

BEFORE you use VELCADE talk to your doctor or pharmacist if:

- you have a low level of red blood cells, platelets, or white blood cells, as these conditions may become worse during treatment with VELCADE;
- you are suffering from diarrhea or vomiting, as this may become worse during VELCADE treatment;
- you have a history of fainting, dizziness or light-headedness;
- you have any problems with your kidneys;
- you have any problems with your liver;
- you have had any problems in the past with numbness, tingling, or pain in the hands or feet (neuropathy); (This effect may become worse during VELCADE treatment.)
- you have had any bleeding problems;
- you have any problems with your heart;
- you have an allergic reaction to the active and non-active ingredients of VELCADE;
- you have been diagnosed in the past with a condition called amyloidosis (abnormal protein deposition in tissues).

VELCADE has not been studied in children or adolescents.

Contraception:
Both men and women must ensure that contraceptive precautions are taken while receiving VELCADE, and for 3 months after treatment.

Pregnancy:
It is advised that you are not given VELCADE if you are pregnant. You must make sure that you do not become pregnant while receiving VELCADE, but if you do, inform your doctor immediately.

Breast-feeding:
It is advised that you 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.

Driving and using machines:
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.

INTERACTIONS WITH THIS MEDICATION

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

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.

PROPER USE OF THIS MEDICATION

Method and route of administration:
Your 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.

Usual dose:
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 to 5 seconds, and the injection syringe will then be rinsed through with a small quantity of sterile, sodium chloride (salt) solution.

Frequency of treatment:
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 the treatment.

Your doctor may change the dosage during the treatment, and will decide the total number of cycles that you need. It all depends on your response to the treatment.

Overdose:
If you think that you have been given VELCADE more frequently than you should, or too high a dose, tell your healthcare provider immediately.

Missed dose:
If you think that you have missed a dose of VELCADE, tell your healthcare provider immediately. Your doctor will not make up missed doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, VELCADE can have side effects. If you experience any of the following, inform your doctor or nurse as soon as possible. Some of these effects may be serious. However, there might be ways to reduce discomfort of these effects.

The following are the most commonly reported side effects (≥10%):

Blood and lymph disorders
- you may be more prone to bruising, or bleeding (internal or external)
- changes in the number of red blood cells (anemia) or white blood cells

Eye disorders
- blurred vision

Gastrointestinal disorders
- feeling sick in the stomach or loss of appetite
- diarrhea
- constipation
- vomiting
- abdominal pain
- heartburn, stomach ulcers

General disorders
- general ill feeling, tiredness, or a feeling of weakness
- fever
- swelling (around the arms, legs or face)
- shivering

Infections
- viral infection, shingles or flu-like symptoms
- chest and other infections

Metabolism and nutrition disorders
- dehydration
- losing weight

Musculoskeletal disorders
- joint or muscle stiffness
- muscle cramps
- muscle or bone pain
- back pain

Nervous system disorders
- numbness, tingling or burning sensation in the hands or feet
- headache
- dizziness

Psychiatric disorders
- difficulty in sleeping
- anxiety or depression (feeling down)
- confusion

Respiratory disorders
- shortness of breath
- cough

Skin disorders
- rash and/or itching, hives, redness
- pain at the injection site

Cardiovascular disorders
- sudden fall of blood pressure on standing which may lead to fainting

If you notice any other effects not mentioned in this leaflet, inform your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	**Talk with your doctor or pharmacist**	
	Only if severe	**In all cases**
Common		
fever		✓
chest and other infections		✓
diarrhea	✓	
vomiting	✓	
dehydration		✓
nausea	✓	
difficulty breathing/breathlessness	✓	
altered sensation/pins and needles in hand or feet	✓	
pain and altered sensation		✓
bleeding from gums or other sites or abnormal bruising		✓
tiredness/lethargy	✓	
joint pain and muscle cramps	✓	
headache	✓	
low blood pressure(dizziness or fainting)		✓
Uncommon		
swelling of face or neck		✓
swelling of ankles	✓	
chest palpitations/awareness of abnormal heart rhythm	✓	
angina (chest pain)	✓	
loss of appetite	✓	
constipation	✓	
yellowing of skin or whites of eyes		✓
skin rash	✓	
difficulty moving limbs, walking or speaking, stroke		✓
confusion		✓
seizure (fits)		✓
loss of control of or inability to pass urine		✓

This is not a complete list of side effects. For any unexpected effects while taking VELCADE, contact your doctor or pharmacist.

HOW TO STORE IT

VELCADE should be kept out of the reach and sight of children.

VELCADE will be stored in the hospital pharmacy and will not be taken home by the patient.

VELCADE should be stored between 15 to 30°C. Keep the container in the outer carton in order to protect from light. Do not use after the expiry date stated on the vial and the carton.

The reconstituted solution may be stored for 8 hours at 25°C stored in the original vial and/or a syringe prior to administration, with a maximum of 3 hours in the syringe.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone:	866-234-2345
toll-free fax:	866-678-6789
By email:	cadrmp@hc-sc.gc.ca

By regular mail:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Health Canada
Address Locator: 0701C
Ottawa, ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be found at:
http://www.janssen-ortho.com
or by contacting the sponsor, Janssen-Ortho Inc., at:
1-800-567-3331

This leaflet was prepared by
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