

PART III: CONSUMER INFORMATION

^{Pr}Bortezomib for Injection

1 mg / vial bortezomib[§]
(as bortezomib mannitol boronic ester)

2.5 mg / vial bortezomib
(as bortezomib mannitol boronic ester)

3 mg / vial bortezomib[§]
(as bortezomib mannitol boronic ester)

3.5 mg / vial bortezomib[§]
(as bortezomib mannitol boronic ester)

Antineoplastic Agent

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

§ not commercially available in Canada

ABOUT THIS MEDICATION

What the medication is used for:

Bortezomib for Injection is used for the treatment of adult patients with:

- Previously untreated Multiple Myeloma (MM) who are unsuitable for stem cell transplantation as part of combination therapy. MM is a cancer of the bone marrow
- Previously untreated MM who are suitable for stem cell transplantation as part of a medically recognized combination therapy for initial treatment prior to stem cell transplant.
- Relapsed MM
- Previously untreated mantle cell lymphoma who are unsuitable for stem cell transplantation. Bortezomib for Injection will be given as part of a medically recognized combination therapy. Mantle cell lymphoma is a cancer of the blood that affects the white blood cells.
- Relapsed/refractory mantle cell lymphoma.

What it does:

Bortezomib for Injection is a chemotherapy medicine, which is medicine used to kill cancer cells.

When it should not be used:

Do not use Bortezomib for Injection if you are allergic (hypersensitive) to bortezomib, boron or to any of the other ingredients of Bortezomib for Injection

Bortezomib for Injection must not be given intrathecally.

What the medicinal ingredient is:

bortezomib (as mannitol boronic ester)

What the nonmedicinal ingredients are:

mannitol

What dosage forms it comes in:

Bortezomib for Injection is available as a powder which will be dissolved in a sterile sodium chloride solution before being injected.

Each pack of Bortezomib for Injection contains one glass vial. Each vial contains either 1 mg[§], 2.5 mg, 3 mg[§] or 3.5 mg[§] of bortezomib (as a mannitol boronic ester).

The vial stopper is free of natural rubber latex.

§ not commercially available in Canada

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Bortezomib for Injection must be administered under the supervision of a physician qualified in the use of anti-cancer drugs.

Overdose (≥ 2X recommended dose) could result in death.

Serious side effects that may occur with Bortezomib for Injection include:

- Low blood pressure and other serious heart disorders
- Bleeding into the brain or gastrointestinal tract (stomach or bowel)
- Muscle weakness due to nerve damage (severe motor neuropathy)
- Acute lung disease (acute diffuse infiltrative pulmonary disease)

BEFORE you use Bortezomib for Injection, talk to your doctor or pharmacist if:

- you have had any bleeding problems, a low level of red blood cells, platelets, or white blood cells, as these conditions may become worse during treatment with Bortezomib for Injection;
- you are suffering from diarrhea, constipation, nausea or vomiting, as this may become worse during Bortezomib for Injection treatment;
- you have any problems with your heart or blood pressure including 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 Bortezomib for Injection treatment.);

- you have been diagnosed in the past with a condition called amyloidosis (abnormal protein deposition in tissues);
- you have shortness of breath with activity (progressively worsens), cough, and difficulty breathing; (Symptoms may develop or worsen during Bortezomib for Injection treatment.)
- you are pregnant, planning to become pregnant or breast-feeding.

Bortezomib for Injection has not been studied in children or adolescents.

Contraception and Pregnancy:

Both men and women must use effective contraception while receiving Bortezomib for Injection, and for 3 months after their treatment. You must make sure that you do not become pregnant while receiving Bortezomib for Injection, but if you do, inform your doctor immediately. Bortezomib for Injection may cause harm to your unborn baby.

Breast-feeding:

It is advised that you do not breast-feed while you are receiving Bortezomib for Injection. If you wish to restart breast-feeding after your Bortezomib for Injection 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:

Bortezomib for Injection 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 antidiabetic medication while receiving Bortezomib for Injection treatment, check your blood sugar level frequently. Call your doctor if you notice an unusual change.

PROPER USE OF THIS MEDICATION

Bortezomib for Injection is to be given to you as an injection.

Bortezomib for Injection may be injected:

- into the vein (intravenous injection). The injection will take 3 to 5 seconds, or
- under the skin (subcutaneous injection) of the thigh (right or left) or abdomen (right or left). The site of injection should be rotated for each following injection. New injections should be at least one inch (2.5 cm) from an old site and never into the areas where the site is tender, bruised, red, or hard.

Usual dose:

The dose will be calculated from your height and weight. The usual dose is 1.3 mg/m² body surface area.

Frequency of treatment:

Previously Untreated Multiple Myeloma

The treatment consists of nine 6-week treatment cycles. Each treatment cycle consists of 6 weeks. In cycles 1 -4, Bortezomib for Injection is given twice weekly on days 1, 4, 8, 11, 22, 25, 29 and 32. In cycles 5-9, Bortezomib for Injection is given once a week on days 1, 8, 22 and 29.

Patients Suitable for Stem Cell Transplantation

If you have not been treated before for multiple myeloma, you will receive Bortezomib for Injection together with other medicines as initial treatment before you receive high dose chemotherapy and bone marrow transplantation. Bortezomib for Injection will be given on days 1, 4, 8 and 11, followed by a rest period without treatment. The dose may be adjusted based on how you respond to the treatment.

Your doctor will choose the other chemotherapy medicines for you.

Relapsed Multiple Myeloma and Relapsed/Refractory Mantle Cell Lymphoma

Bortezomib for Injection is given twice weekly on days 1, 4, 8 and 11 of a 3-week treatment cycle. In maintenance treatment, Bortezomib for Injection is given once a week for 4 weeks on days 1, 8, 15 and 22.

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.

Previously Untreated Mantle Cell Lymphoma

If you have not been treated before for mantle cell lymphoma you will receive Bortezomib for Injection together with other chemotherapy agents as prescribed by your doctor. Bortezomib for Injection is given on days 1, 4, 8 and 11, followed by a 'rest period' without treatment. The duration of a treatment cycle is 21 days (3 weeks). You might receive up to 8 cycles (24 weeks).

Overdose:

If you think that you have been given Bortezomib for Injection more frequently than you should, or too high a dose, or in case of drug overdose, contact a health practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you think that you have missed a dose of Bortezomib for Injection, tell your healthcare provider immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Bortezomib for Injection can have side effects. The following are the most commonly reported side effects (≥10%):

Blood and lymph disorders: Low red blood cells, white blood cells or platelets causing anemia, bruising or bleeding

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: shingles (herpes zoster virus), 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 when injected under the skin

Cardiovascular disorders: sudden fall of blood pressure on standing which may lead to fainting, pericarditis or inflammation of the lining around the heart, increase in blood pressure

The types of side effects that may be experienced are similar whether Bortezomib for Injection is given by subcutaneous injection or by intravenous injection.

If you notice these or 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 including shingles		√
Diarrhea	√	
Vomiting	√	
Dehydration (dry mouth, excessive thirst, dark yellow urine)		√
Nausea	√	
Difficulty breathing/breathlessness	√	
Altered sensation/pins and needles in hands 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)		√
Increase in blood pressure		√
Uncommon		
Swelling of face or neck		√
Swelling of ankles	√	
Chest palpitations/awareness of abnormal heart rhythm/abnormal electrical signal from an electrocardiogram (ECG) reading		√
Angina (chest pain)	√	
Loss of appetite	√	
Severe abdominal pain with or without bleeding		√
Constipation	√	
Yellowing of skin or whites of eyes		√
Skin rash		√
Difficulty moving limbs, walking or speaking, stroke		√
Confusion		√
Seizure (fits)		√
Loss of control or inability to pass urine		√
Muscle weakness	√	
New onset or worsening neurological signs or symptoms such as confusion or problems thinking, loss of balance, blurred vision or loss of vision, decreased strength or weakness in an arm or leg or change in the way of walking or talking (these may be signs of a serious brain infection and your doctor may suggest further testing and follow-up)		√

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
Anaphylactic (allergic) reaction		√
Very Rare		
Blood clot in very small blood vessels (also called ‘thrombotic microangiopathy’), which is usually associated with bleeding, bruising, and kidney injury.		√

Two cases of sudden death have been reported in clinical trials with Bortezomib for Injection.

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

HOW TO STORE IT

Bortezomib for Injection should be kept out of the reach and sight of children.

Bortezomib for Injection should be stored between 15°C to 30°C. Keep the container in the outer carton in order to protect it 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 15°C to 25°C in the original vial or a syringe prior to administration, with a maximum of 8 hours in the syringe.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>.
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or
- Mail to: Canada Vigilance Program
Health Canada Postal
Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be found by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001.

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