



When VELCADE is given with melphalan and prednisone, one cycle of treatment is 6 weeks and the treatment consists of a total of 9 cycles (54 weeks). In Cycles 1-4, VELCADE is administered twice weekly (days 1, 4, 8, 11, 22, 25, 29 and 32). In Cycles 5-9, VELCADE is administered once weekly (days (1, 8, 22 and 29).

#### Mantle Cell Lymphoma

When VELCADE is given with rituximab, cyclophosphamide, doxorubicin and prednisone, one cycle is 3 weeks and the treatment consists of a total of up to 8 cycles (24 weeks). For each cycle, VELCADE is given on days 1, 4, 8 and 11, followed by a ten day break from the treatment.

Your doctor will decide on the number of cycles of VELCADE needed. This will depend on how you respond to treatment.

*What do I do if I receive too much? (overdose):*

**As VELCADE is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However if you experience any side effects after being given VELCADE, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital.**

You may need urgent medical attention.

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#### While you are using VELCADE

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*Things you must do:*

**Be sure to keep all your doctor's appointments so your progress can be checked.**

Your doctor will want to do some blood, urine and other tests from time to time to check on your progress and detect any unwanted side effects.

**Keep follow up appointments with your doctor.**

It is important to have your follow-up doses of VELCADE at the appropriate times to get the best effects from your treatment.

**Be sure to follow up your doctor's instructions about other medicines you should take, and other things you should do.**

You may need to take other medicines to help prevent unwanted effects of VELCADE. You may also need to drink extra fluids if you experience vomiting and/or diarrhoea. Ask your doctor or pharmacist if you have any questions.

**Tell any other doctors, dentists and pharmacists who are treating you that you are having VELCADE.**

**If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are having VELCADE.**

**If you plan to have surgery, tell your doctor or dentist that you are having VELCADE.**

**If you become pregnant or your partner becomes pregnant while being given VELCADE, tell your doctor immediately.**

**VELCADE can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:**

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it's painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums.

Check with your doctor before having any dental work.

- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.

*Things to be careful of*

**Be careful driving or operating machinery until you know how VELCADE affects you.**

VELCADE may cause tiredness, light-headedness, dizziness, fainting, double or blurred vision in some people. Make sure you know how you react to VELCADE before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy, light headed or have double or blurred vision. If you drink alcohol, dizziness or light-headedness may be worse.

**You may feel dizzy or faint when you get up quickly after sitting or lying down.**

Getting up slowly may help.

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#### Side effects

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Like all medicines, VELCADE can have side effects. Some of these effects may be serious. However there may be ways to reduce the discomfort of these effects. You may need medical treatment if you get some of the side effects.

**Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with VELCADE.**

Below is a list of the more common side effects you could get while being treated with VELCADE:

- tiredness, generally feeling unwell, weakness
- feeling sick (nausea) or vomiting
- diarrhoea
- constipation
- loss of appetite, and/or weight, fear of gaining weight
- bleeding or bruising more easily than normal
- sensitivity, numbness, tingling or burning sensation of the skin, or pain in the hands or feet
- fever, chills
- anaemia (a condition in which there is a decreased number of red blood cells)
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- herpes virus or hepatitis infections
- headache
- trouble sleeping, sweating, anxiety, mood swings, confusion or depression
- painful, swollen joints
- pain in your limbs, back pain, bone pain, muscle cramps
- swelling (around the eyes or in the ankles, wrists, arms, legs or face)
- pins and needles and unpleasant sensations
- difficulty in breathing
- dizziness
- dehydration
- cough
- aching muscles, muscle tenderness or weakness not caused by exercise
- uncomfortable feeling in the stomach or belching after eating
- stomach pain
- blockage in the intestine
- bad taste in the mouth

- low blood pressure (dizziness, light headedness or fainting)
- high blood pressure
- chest pain
- small blisters in clusters on the skin (herpes)
- rash, itching
- redness of the skin or redness and pain at injection site
- hair loss
- blurred vision
- pneumonia
- allergic reaction

**If you think you are having an allergic reaction to VELCADE, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.**

**Symptoms usually include some or all of the following:**

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

Other side effects not listed above may also occur in some people.

**Tell your doctor, nurse or pharmacist if you notice any other effect that is making you feel unwell.**

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#### Product description

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##### *Storage*

VELCADE should be kept in a cool dry place, protected from light, where the temperature stays below 25°C.

##### *What it looks like:*

VELCADE is a white to off-white powder in a glass vial.

Each pack contains one single-use vial.

Before injection, VELCADE powder is dissolved in a small quantity of sterile, sodium chloride solution. The solution for injection is clear and colourless.

VELCADE 3.5 mg vial (AUST R 104542)

VELCADE 3 mg vial (AUST R 238257)

VELCADE 1 mg vial (AUST R 148329).

Not all presentations may be supplied.

##### *Ingredients*

Active ingredient:

- bortezomib 3.5 mg (for VELCADE 3.5 mg Vials) OR
- bortezomib 3.0 mg (for VELCADE 3.0 mg Vials) OR
- bortezomib 1.0 mg (for VELCADE 1.0 mg Vials)

Other ingredients:

- mannitol (E 421)
- nitrogen

##### *Sponsor*

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