

Bortezomib-Teva®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Bortezomib-Teva?

Bortezomib-Teva contains the active ingredient bortezomib. Bortezomib-Teva is used to treat adults with multiple myeloma (cancer of the bone marrow). It is also used to treat those not previously treated for mantle cell lymphoma (a type of cancer affecting the lymph nodes) in adults in combination with the medicines rituximab, cyclophosphamide, doxorubicin and prednisone,

For more information, see Section [1. Why am I using Bortezomib-Teva?](#) in the full CMI.

2. What should I know before I use Bortezomib-Teva?

Do not use if you have ever had an allergic reaction to Bortezomib-Teva or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Bortezomib-Teva?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Bortezomib-Teva and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Bortezomib-Teva?

- Your doctor will decide what dose you will receive. The dose will be calculated from your height and weight, as well as factors such as kidney function, liver function and other medicines you are being given.
- The doctor will determine the number of cycles of treatment also.

More instructions can be found in Section [4. How do I use Bortezomib-Teva?](#) in the full CMI.

5. What should I know while using Bortezomib-Teva?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Bortezomib-Teva.• Keep all doctor's appointments and follow doctor's instruction. You may need to take other medicines to help prevent unwanted effects of bortezomib.
Things you should not do	<ul style="list-style-type: none">• Bortezomib can lower the number of white blood cells and platelets in your blood, meaning you have an increased chance of getting an infection or bleeding. Avoid contact with infected individuals and be careful with objects (such as razors) that may predispose you to bleeding.
Driving or using machines	<ul style="list-style-type: none">• Bortezomib-Teva may cause tiredness, light-headedness, dizziness,

	fainting, double or blurred vision in some people. Make sure you know how you react to bortezomib before you drive, operate machinery, or do anything else that could be dangerous.
Looking after your medicine	<ul style="list-style-type: none"> • Bortezomib-Teva should be kept in a cool dry place, away from moisture and heat and protected from light, where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using Bortezomib-Teva?](#) in the full CMI.

6. Are there any side effects?

Side effects may include headache, nausea, bruising easily, diarrhoea and pain at injection site.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Bortezomib-Teva

Powder for injection

Active ingredient: *Bortezomib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bortezomib-Teva. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Bortezomib-Teva.**

Where to find information in this leaflet:

- [1. Why am I using Bortezomib-Teva?](#)
- [2. What should I know before I use Bortezomib-Teva?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Bortezomib-Teva?](#)
- [5. What should I know while using Bortezomib-Teva?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Bortezomib-Teva?

Bortezomib-Teva contains the active ingredient bortezomib. Bortezomib-Teva belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines. These medicines are used to kill cancer cells.

Bortezomib-Teva is used to treat adults with multiple myeloma (cancer of the bone marrow). It is prescribed for patients who have not been previously treated for multiple myeloma. It is also prescribed for patients who have received one or more prior treatments and whose cancer is still progressing.

Bortezomib is also used for the treatment of mantle cell lymphoma (a type of cancer affecting the lymph nodes) in adults in combination with the medicines rituximab, cyclophosphamide, doxorubicin and prednisone, for patients whose disease has not been previously treated.

2. What should I know before I use Bortezomib-Teva?

Warnings

Do not use Bortezomib-Teva if:

- you are allergic to bortezomib, boron, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions, especially the following:
- blood disorder with a low level of red or white blood cells or platelets. This disorder may become worse during treatment with bortezomib.

- if you are suffering from diarrhoea or vomiting as this may become worse during treatment with bortezomib.
- a history of fainting, dizziness or light-headedness.
- kidney problems
- liver problems, including hepatitis infection
- problems with numbness, tingling or pain in the hands or feet (neuropathy). This effect may be worsened by treatment with bortezomib.
- seizures
- any bleeding problems
- problems with your heart
- lung or breathing problems
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, bortezomib is not recommended for use during pregnancy.

Tell your doctor if you are trying to make your partner pregnant.

Both men and women receiving bortezomib and their partners must use a reliable method of contraception during and for 3 months after receiving bortezomib.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether bortezomib passes into breast milk. Therefore there is a possibility that the breast-fed baby may be affected.

If you wish to restart breast-feeding after your bortezomib treatment, you must discuss this with your doctor or nurse, who will tell you when it is safe to do so.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking any of the following:

- amiodarone, a medicine used to treat irregular heart beat
- medicines used to treat viral infections such as flu, herpes and HIV
- isoniazid, a medicine used to treat tuberculosis
- nitrofurantoin, a medicine used to treat urinary tract infections

- ketoconazole, a medicine used to treat fungal infections
- ritonavir, a medicine used to treat HIV infection
- rifampicin, a medicine used to treat infections such as tuberculosis
- medicines used to treat high cholesterol levels in the blood
- medicines used to treat diabetes
- medicines that may lower blood pressure
- medicine used to treat epilepsy such as carbamazepine and phenobarbital
- phenytoin, a medicine used in preventing seizures
- St John's Wort (*Hypericum perforatum*).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Bortezomib-Teva.

4. How do I use Bortezomib-Teva?

How much to take / use

- Your doctor will decide what dose you will receive.
- The dose will be calculated from your height and weight. It will also depend on factors such as kidney function, liver function and other medicines you are being given.
- The safety of treatment with bortezomib in people with severe kidney function problems has not been well-studied.

- The usual starting dose is 1.3 milligrams per square meter body surface area.
- Your doctor may change the dose during treatment depending on your response.

When to take / use Bortezomib-Teva

Multiple Myeloma

- One cycle of treatment with bortezomib may consist of a total of 4 doses given over 3 weeks. Doses are given on days 1, 4, 8 and 11 followed by a ten day break from the treatment.
- When bortezomib is given with thalidomide and dexamethasone, the treatment consists of a total of 3 cycles (9 weeks) for the induction stage). During the induction stage, bortezomib is administered twice weekly (days 1, 4, 8 and 11).
- When bortezomib is given with dexamethasone, the treatment consists of a total of 4 cycles (12 weeks). Bortezomib will be administered twice weekly (days 1, 4, 8 and 11).
- When bortezomib 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, bortezomib is administered twice weekly (days 1, 4, 8, 11, 22, 25, 29 and 32). In cycles 5-9, bortezomib is administered once weekly (days 1, 8, 22 and 29).

Mantle Cell Lymphoma

- When bortezomib 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, bortezomib is given on days 1, 4, 8 and 11, followed by a ten day break from treatment.

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

How Bortezomib-Teva is administered

- Overall treatment with bortezomib must be done under the supervision of a doctor. Your treatment with bortezomib may be given by a healthcare professional (eg doctor or nurse) experience in the administration of oncology medicines.
- Bortezomib will be dissolved in sterile normal sodium chloride (salt) solution for injection. The solution is given as an injection into your vein (intravenously) over 3 to 5 seconds. The injection tube will be rinsed with a small quantity of sterile normal sodium chloride (salt) solution.
- The solution can also be given subcutaneously as an injection into your thighs (right or left), or abdomen (right or left).
- Bortezomib must be given intravenously or subcutaneously only.

- Bortezomib must not be given into the space around the spinal cord (intrathecally).

If you use too much Bortezomib-Teva

As bortezomib is given to you under the supervision of a doctor, it is very unlikely that you will receive too much. However, if you think that you have used too much Bortezomib-Teva, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre
In Australia by calling 13 11 26 or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Bortezomib-Teva?

Things you should 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 bortezomib 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 bortezomib. 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.

Remind any doctor, dentist or pharmacist you visit that you are using Bortezomib-Teva.

Things you should not do

Bortezomib can lower the number of white blood cells and platelets in your blood. This means 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Bortezomib-Teva affects you.

Bortezomib-Teva may cause tiredness, light-headedness, dizziness, fainting, double or blurred vision in some people. Make sure you know how you react to bortezomib 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.

Looking after your medicine

Bortezomib-Teva should be kept in a cool dry place, away from moisture and heat and protected from light, where the temperature stays below 30°C.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: <ul style="list-style-type: none">• feeling sick (nausea) or vomiting• diarrhoea• constipation• loss of appetite, and/or weight, fear of gaining weight	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● uncomfortable feeling in the stomach or belching after eating ● stomach pain ● blockage in the intestine ● bad taste in the mouth <p>Physical pain and swelling related:</p> <ul style="list-style-type: none"> ● headache ● tiredness, generally feeling unwell, weakness <p>Hair and skin related:</p> <ul style="list-style-type: none"> ● small blisters in clusters on the skin (herpes) ● rash, itching ● redness of the skin or redness and pain at injection site ● hair loss <p>Blood pressure</p> <ul style="list-style-type: none"> ● low blood pressure (dizziness, light headedness or fainting) ● high blood pressure <p>Other</p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● dizziness ● dehydration ● cough ● blurred vision 	

Serious side effects

Serious side effects	What to do
<p>Central nervous system related:</p> <ul style="list-style-type: none"> ● sensitivity, numbness, tingling or burning sensation of the skin, or pain in the hands or feet ● fever, chills <p>Blood and bruising related:</p> <ul style="list-style-type: none"> ● anaemia (a condition in which there is a decreased number of red blood cells) ● bleeding or bruising more easily than normal <p>Physical pain and swelling related:</p> <ul style="list-style-type: none"> ● painful, swollen joints 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 ● aching muscles, muscle tenderness or weakness not caused by exercise ● chest pain <p>Infection related:</p> <ul style="list-style-type: none"> ● frequent infections such as fever, severe chills, sore throat or mouth ulcers ● herpes virus or hepatitis infections ● pneumonia <p>Other</p> <ul style="list-style-type: none"> ● difficulty in breathing ● allergic reaction 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Bortezomib-Teva contains

Active ingredient (main ingredient)	Bortezomib
Other ingredients (inactive ingredients)	mannitol (E 421) nitrogen

Do not take this medicine if you are allergic to any of these ingredients.

What Bortezomib-Teva looks like

Bortezomib-Teva is a white to off-white powder in a glass vial. (AUST R 293593).

Each pack contains one single-use vial.

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

Who distributes Bortezomib-Teva

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

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