

Bortezomib Baxter

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 Baxter?

Bortezomib Baxter contains the active ingredient bortezomib. Bortezomib Baxter 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 Baxter 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. For more information, see Section [1. Why am I using Bortezomib Baxter?](#) in the full CMI.

2. What should I know before I use Bortezomib Baxter?

Do not use if you have ever had an allergic reaction to bortezomib 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 Baxter?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Bortezomib Baxter and affect how it works. Tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop. 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 Baxter?

Overall treatment with Bortezomib Baxter must be done under the supervision of a doctor. Your treatment with Bortezomib Baxter may be given by a healthcare professional (eg doctor or nurse) experienced in the administration of oncology medicines. More instructions can be found in Section [4. How do I use Bortezomib Baxter?](#) in the full CMI.

5. What should I know while using Bortezomib Baxter?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Bortezomib Baxter.• If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are having Bortezomib Baxter.• If you plan to have surgery, tell your doctor or dentist that you are having Bortezomib Baxter.• If you become pregnant or your partner becomes pregnant while being given Bortezomib Baxter, tell your doctor immediately.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Bortezomib Baxter affects you.• Bortezomib Baxter may cause tiredness, light-headedness, dizziness, fainting, double or blurred vision in some people. Make sure you know how you react to Bortezomib Baxter 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.
Drinking alcohol	<ul style="list-style-type: none">• If you drink alcohol, dizziness or light-headedness may be worse.

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

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. 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 Baxter

Active ingredient: *bortezomib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bortezomib Baxter. **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 Baxter.**

Where to find information in this leaflet:

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

1. Why am I using Bortezomib Baxter?

Bortezomib Baxter contains the active ingredient bortezomib. Bortezomib Baxter 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 Baxter 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 Baxter 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 Baxter?

Warnings

Do not use Bortezomib Baxter if:

- you are allergic to bortezomib or boron or mannitol, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include 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.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have blood disorder with a low level of red or white blood cells or platelets. This disorder may become worse during treatment with Bortezomib Baxter.
- are suffering from diarrhoea or vomiting as this may become worse during treatment with Bortezomib Baxter.
- have a history of fainting, dizziness or light-headedness.
- have kidney problems
- have liver problems, including hepatitis infection
- have problems with numbness, tingling or pain in the hands or feet (neuropathy). This effect may be worsened by treatment with Bortezomib Baxter.
- have seizures
- have any bleeding problems
- have problems with your heart
- have lung or breathing problems
- have any other medical conditions
- 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

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

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

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

It is not known whether Bortezomib Baxter 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 Baxter treatment, you must discuss this with your doctor or nurse, who will tell you when it is safe to do so.

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

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

If you have not told your doctor about any of the above, tell them before you start treatment with Bortezomib Baxter.

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 heartbeat
- 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*).

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

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 Baxter.

4. How do I use Bortezomib Baxter?

How much to use

Overall treatment with Bortezomib Baxter must be done under the supervision of a doctor. Your treatment with Bortezomib Baxter may be given by a healthcare professional (eg doctor or nurse) experienced in the administration of oncology medicines (see "How to take Bortezomib Baxter").

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 Baxter in people with severe kidney function problems had not been well-studied.

The usual starting dose is 1.3 milligrams per square meter body surface area.

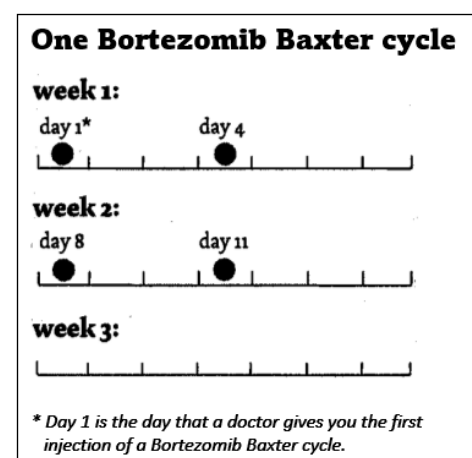
Your doctor may change the dose during treatment depending on your response.

Ask your doctor if you want to know more about the dose of Bortezomib Baxter you receive.

When to take Bortezomib Baxter

Multiple Myeloma

One cycle of treatment with Bortezomib Baxter 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 Baxter 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 Baxter is administered twice weekly (days 1, 4, 8 and 11).

When Bortezomib Baxter is given with dexamethasone, the treatment consists of a total of 4 cycles (12 weeks). Bortezomib Baxter will be administered twice weekly (days 1, 4, 8 and 11).

When Bortezomib Baxter 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 Baxter is administered twice weekly (days 1, 4, 8, 11, 22, 25, 29 and 32). In Cycles 5-9, Bortezomib Baxter is administered once weekly (days 1, 8, 22 and 29).

Mantle Cell Lymphoma

When Bortezomib Baxter 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 Baxter 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 Bortezomib Baxter needed. This will depend on how you respond to treatment.

How to take Bortezomib Baxter

Bortezomib Baxter will be dissolved in sterile 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 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 Baxter must be given intravenously or subcutaneously only. Bortezomib Baxter must not be given into the space around the spinal cord (intrathecally).

If you take too much Bortezomib Baxter

As Bortezomib Baxter 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 Bortezomib Baxter, tell your doctor or nurse immediately or go to the Emergency Department at your nearest hospital.

You may need urgent medical attention.

5. What should I know while using Bortezomib Baxter?

Things you should do

Call your doctor straight away if you

• **Develop any symptoms of an allergic reaction, which may include:**

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

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 Baxter 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 Baxter. 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 Bortezomib Baxter.

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

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

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

Bortezomib Baxter 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.

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

Driving or using machines

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

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

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

Getting up slowly may help.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

Bortezomib Baxter will be stored in the hospital pharmacy or on the hospital ward in a cool dry place, where the temperature stays below 30°C.

Getting rid of any unwanted medicine

Your doctor, nurse or pharmacist will dispose of any leftover medicine.

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.

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

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: <ul style="list-style-type: none">feeling sick (nausea) or vomitingdiarrhoeaconstipationloss of appetite, and/or weight, fear of gaining weightuncomfortable feeling in the stomach or belching after eatingstomach painblockage in the intestinebad taste in the mouth Physical pain and swelling related: <ul style="list-style-type: none">headachetiredness, generally feeling unwell, weakness Hair and skin related: <ul style="list-style-type: none">small blisters in clusters on the skin (herpes)rash, itchingredness of the skin or redness and pain at injection sitehair loss Blood pressure <ul style="list-style-type: none">low blood pressure (dizziness, light headedness or fainting)high blood pressure Other <ul style="list-style-type: none">dizzinessdehydrationcoughblurred vision	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Central nervous system related: <ul style="list-style-type: none">sensitivity, numbness, tingling or burning sensation of the skin, or pain in the hands or feetfever, chillstrouble sleeping, sweating, anxiety, mood swings, confusion or depression Blood and bruising related: <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 Physical pain and swelling related: <ul style="list-style-type: none">painful, swollen jointspain in your limbs, back pain, bone pain, muscle crampsswelling (around the eyes or in the ankles, wrists, arms, legs or face)pins and needles and unpleasant sensationsaching muscles, muscle tenderness or weakness not caused by exercisechest pain Infection related: <ul style="list-style-type: none">frequent infections such as fever, severe chills, sore throat or mouth ulcersherpes virus or hepatitis infectionspneumonia Other <ul style="list-style-type: none">difficulty in breathingallergic reaction	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.

If you think you are having an allergic reaction to Bortezomib Baxter, tell your doctor immediately or go to the Emergency Department 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

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 Baxter contains

Active ingredient (main ingredient)	bortezomib 3.5 mg (for Bortezomib Baxter 3.5 mg Vials)
Other ingredients (inactive ingredients)	Mannitol Nitrogen

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

What Bortezomib Baxter looks like

Bortezomib Baxter is a white to off-white powder in a glass vial.

The vial is contained in a carton. Each carton contains 1 single-use vial.

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

Bortezomib Baxter 3.5 mg vial (AUST R 379611)

Who distributes Bortezomib Baxter

Baxter Healthcare Pty Ltd
1 Baxter Drive
Old Toongabbie
NSW 2146, Australia

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