

BORTEZOMIB ACCORD

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 Accord?

Bortezomib Accord contains the active ingredient bortezomib. Bortezomib Accord is used to treat adults with multiple myeloma (cancer of the bone marrow). Bortezomib Accord 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 Accord?](#) in the full CMI.

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

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 Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Bortezomib Accord 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 Accord?

Bortezomib Accord is an injection and will be given to you by your doctor or nurse.

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

5. What should I know while using Bortezomib Accord?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Bortezomib Accord.• Be sure to keep all your doctor's appointments so your progress can be checked.• Keep follow up appointments with your doctor. It is important to have your follow-up doses of Bortezomib Accord at the appropriate times to get the best effects from your treatments.
Driving or using machines	<ul style="list-style-type: none">• Bortezomib Accord may cause tiredness, light-headedness, dizziness, fainting, double or blurred vision in some people. This may affect your ability to drive or operate machinery.

For more information, see Section [5. What should I know while using Bortezomib Accord?](#) 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.

Some of the more common side effects are included in full below in the CMI. Speak to your doctor if you have any of these common side effects and they worry you.

A serious side effect is:

- Sudden onset of signs of allergy such as: 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.

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 ACCORD

Active ingredient: *bortezomib*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Bortezomib Accord?

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

Warnings

Do not use Bortezomib Accord 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 or have had:

- a blood disorder with a low level of red or white blood cells or platelets. This disorder may become worse during treatment with Bortezomib Accord.

- diarrhoea or vomiting as this may become worse during treatment with Bortezomib Accord.
- 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 Accord.
- seizures.
- any bleeding problems.
- problems with your heart.
- lung or breathing problems.

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.

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

As with many medicines, Bortezomib Accord may harm your developing or breastfeeding baby.

Males: tell your doctor if your partner intends to become pregnant while you are using Bortezomib Accord or shortly after you have stopped using Bortezomib Accord.

You should use some kind of birth control while you are using Bortezomib Accord and for at least 3 months after you stop using it. Bortezomib Accord may cause birth defects if either the male or female is using it at the time of conception.

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.

Some medicines may interfere with Bortezomib Accord and affect how it works or Bortezomib Accord may affect how they work.

- 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*)

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 Accord.

4. How do I use Bortezomib Accord?

How much to use

Bortezomib Accord is given to you as an injection into your vein (intravenously) over 3 to 5 seconds or subcutaneously as an injection into your thighs (right or left), or abdomen (right or left) by your doctor or nurse.

Your doctor will decide what dose of Bortezomib Accord, 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 usual starting dose is 1.3 milligrams per square metre body surface area.

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

When to use Bortezomib Accord

It is very important that you continue to receive Bortezomib Accord for as long as your doctor prescribes it. Your doctor will decide how many cycles of treatment you need.

If you use too much Bortezomib Accord

It is unlikely that you will receive an overdose of Bortezomib Accord because a trained nurse or doctor will give it. If you think that you have been given too much Bortezomib Accord, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**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 Accord?

Things you should do

- Be sure to keep all your doctor's appointments so your progress can be checked. Your doctor may want to do some blood, urine and other tests from time to time to check on your progress and detect any unwanted side effects.

- You may need to drink extra fluids if you experience vomiting and/or diarrhoea.
- Keep follow up appointments with your doctor. It is important to have your follow-up doses of Bortezomib Accord at the appropriate times to get the best effects from your treatments. If you forget a hospital appointment immediately contact your doctor.
- Tell your doctor if you realise that you are pregnant while taking Bortezomib Accord.
- Remind any doctor, dentist or pharmacist you visit that you are using Bortezomib Accord.

Precautions to take

- 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 driving or operating machinery until you know how Bortezomib Accord affects you.

Bortezomib Accord may cause tiredness, light-headedness, dizziness, fainting, double or blurred vision in some people. Make sure you know how you react to Bortezomib Accord before you drive a car, operate machinery, or do anything else that could be dangerous.

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

The hospital will store Bortezomib Accord under the correct conditions.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Bortezomib Accord that may be left over.

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.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> 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 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> Sudden onset of signs of allergy such as: 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 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you are having an allergic reaction.</p>

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 Accord contains

Active ingredient (main ingredient)	bortezomib
Other ingredients (inactive ingredients)	Mannitol Water for Injection (Bortezomib Accord Solution Injection only)

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

What Bortezomib Accord looks like

Bortezomib Accord Powder for Injection is a white to off-white powder supplied in glass vials. (1 mg Aust R 315491, 3.5 mg Aust R 315488).

Bortezomib Accord Solution for Injection is a clear colourless solution supplied in glass vials (2.5 mg/1 mL Aust R 369470; 3.5 mg/1.4 mL: Aust R 369472)

Who distributes Bortezomib Accord

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

This leaflet was prepared in June 2022.