

BORTEZOMIB EVER PHARMA

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.

This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using BORTEZOMIB EVER PHARMA?

BORTEZOMIB EVER PHARMA contains the active ingredient bortezomib. BORTEZOMIB EVER PHARMA 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. It 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 EVER PHARMA?](#) in the full CMI.

2. What should I know before I use BORTEZOMIB EVER PHARMA?

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 EVER PHARMA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BORTEZOMIB EVER PHARMA 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 EVER PHARMA?

Overall treatment with BORTEZOMIB EVER PHARMA must be done under the supervision of a doctor. Your treatment with BORTEZOMIB EVER PHARMA 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 EVER PHARMA?](#) in the full CMI.

5. What should I know while using BORTEZOMIB EVER PHARMA?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using bortezomib. 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. Be sure to follow up your doctor's instructions about other medicines you should take, and other things you should do. If you become pregnant or your partner becomes pregnant while being given bortezomib, tell your doctor immediately.
	<ul style="list-style-type: none">•
Driving or using machines	Be careful driving or operating machinery until you know how bortezomib affects you. <ul style="list-style-type: none">• bortezomib 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.
Drinking alcohol	If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	<ul style="list-style-type: none">• Bortezomib should be kept refrigerated.

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

6. Are there any side effects?

Some common side effects include tiredness, generally feeling unwell, weakness; feeling sick (nausea) or vomiting; diarrhea; 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). 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 EVER PHARMA*

Active ingredient: *bortezomib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BORTEZOMIB EVER PHARMA. **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 EVER PHARMA.**

Where to find information in this leaflet:

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

1. Why am I using BORTEZOMIB EVER PHARMA?

BORTEZOMIB EVER PHARMA contains the active ingredient bortezomib. BORTEZOMIB EVER PHARMA 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 EVER PHARMA is used to 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 EVER PHARMA 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 EVER PHARMA?

Warnings

Do not use BORTEZOMIB EVER PHARMA if:

- you are allergic to bortezomib, 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 such as:
 - 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

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

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

It is not known whether BORTEZOMIB EVER PHARMA 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 EVER PHARMA 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 EVER PHARMA and their partners must use a reliable method of contraception during and for 3 months after receiving BORTEZOMIB EVER PHARMA.

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 EVER PHARMA 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 EVER PHARMA.

4. How do I use BORTEZOMIB EVER PHARMA?

How much to take / use

Overall treatment with BORTEZOMIB EVER PHARMA must be done under the supervision of a doctor. Your treatment with BORTEZOMIB EVER PHARMA may be given by a healthcare professional (eg doctor or nurse) experienced in the administration of oncology medicines (see "How it is given").

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 EVER PHARMA 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 EVER PHARMA you receive.

How it is given:

BORTEZOMIB EVER PHARMA 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 EVER PHARMA must be given intravenously or subcutaneously only. BORTEZOMIB EVER PHARMA must not be given into the space around the spinal cord (intrathecally).

When it is given:

Multiple Myeloma

One cycle of treatment with BORTEZOMIB EVER PHARMA 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 EVER PHARMA 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 EVER PHARMA is administered twice weekly (days 1, 4, 8 and 11).

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

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

Mantle Cell Lymphoma

When BORTEZOMIB EVER PHARMA 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 EVER PHARMA 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 EVER PHARMA needed. This will depend on how you respond to treatment.

If you use too much BORTEZOMIB EVER PHARMA

As BORTEZOMIB EVER PHARMA 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 EVER PHARMA, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital.

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.

5. What should I know while using BORTEZOMIB EVER PHARMA?

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 EVER PHARMA 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 EVER PHARMA. 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 EVER PHARMA.

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

If you plan to have surgery, tell your doctor or dentist that you are having BORTEZOMIB EVER PHARMA.

If you become pregnant or your partner becomes pregnant while being given BORTEZOMIB EVER PHARMA, tell your doctor immediately.

BORTEZOMIB EVER PHARMA 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BORTEZOMIB EVER PHARMA affects you.

Be careful driving or operating machinery until you know how BORTEZOMIB EVER PHARMA affects you.

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

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

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
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<p>Blood pressure effect: Dizziness postural, Hypertension, Hypotension, Hypotension orthostatic, Hypotension postural</p> <p>Cardiovascular and heart rhythm: Angina pectoris, Irregular heart rate</p> <p>Neurology related side effects: Rigors, Sciatica, Tremor, Ageusia, Vertigo, Hypoaesthesia, Jerky movements, Mononeuropathy, Polyneuropathy</p> <p>Bleeding: Epistaxis, Gingival bleeding, Haematoma, Haematuria, Oral mucosal petechiae, Post procedural haemorrhage</p> <p>Haematology abnormal: Anaemia, Red blood cell, count decreased, Thrombocytopenia, White blood cell count decreased</p> <p>Irritation and allergic reactions: Pruritus, Rash, Rash erythematous, Rash heat, Rash pruritic, Skin rash</p> <p>Urticaria, Burns, Dermatitis atopic, Eczema, Erythema, Eye irritation, Injection site erythema, Vasculitic rash, Pressure sore, Hypersensitivity.</p> <p>Inflammations: Blepharitis, Oesophagitis, Bronchitis, Conjunctivitis, Extravasation inflammation, Gastritis, Gastroenteritis, Hepatitis, Injection site phlebitis, Mucosal inflammation, Nasopharyngitis</p> <p>Phlebitis, Rhinitis, Rhinorrhoea, Sinusitis, Stomatitis, Upper respiratory tract infections</p> <p>Urinary tract infections.</p> <p>Infections: Oral candidiasis, Tongue coated, Varicella, Cytomegalovirus infection, Fungal infections</p> <p>Haemophilus infections, Herpes simplex, Infections, Infectious mononucleosis, influenza, Influenza like illness, Candidal infection.</p> <p>Abdominal other: Abdominal distension, Antibiotic associated colitis, Change in bowel habit, Colitis</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>	<p>Constipation, Diarrhoea, Dizziness, Dyspepsia, Dysphagia, Eructation, Faecal impaction, Flatulence</p> <p>Gastrointestinal events, Gastrointestinal motility disorder, Gastro-oesophageal reflux disease, Hiccups</p> <p>Irritable bowel syndrome, Loose stools, Malaise, Nausea, Retching, Vomiting, Appetite decreased, Appetite decreased, Abdominal discomfort</p> <p>Abnormal biochemistry: Alanine aminotransferase increased, Aspartate aminotransferase, increased, Blood bicarbonate decreased, Blood alkaline phosphatase increased, Blood amylase increased, Blood bilirubin increased, Blood creatinine increased, Blood lactate dehydrogenase, increased, Blood phosphate decreased, Blood urea increased, C-reactive protein increased, Gamma-glytanyltransferase increased, Hyperbilirubinaemia, Hypercalcaemia, Hyperkalaemia, hypernatraemia, Hyperuricaemia, Hypocalcaemia, Hypomagnesemia, Hyponatraemia, Hypophosphataemia, Hypoproteaemia, Liver function tests abnormal, Vitamin B12 deficiency.</p> <p>Eye and Ear abnormalities: Conjunctival hypereraemia, Dry eye, Eye discharge, Lacrimation increased</p> <p>Photophobia, Photosensitivity reaction, Vision abnormal, Vision blurred.</p> <p>Ear: Tinnitus, Hearing impaired, Hypoacusis</p> <p>Pain: Arthralgia, Abdominal pain Upper, Back pain, Back pain, Bone pain, Buttock pain, Chest pain,</p> <p>Chest wall pain, Eye pain, Gastrointestinal pain and abdominal pain, gingival pain, Groin pain, Headache, Loin pain, Migraine, Musculoskeletal pain, Myalgia, Neuralgia, Oral pain, Pain gastrointestinal, Pain in limb,</p>	
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<p>Pharyngolaryngeal pain, Post procedural pain, Sinus pain, Spleen pain,</p> <p>Testicular pain</p> <p>Swelling/Oedema: Nasal congestion, Oedema eyelid, Oedema, Oedema face, Oedema lower limb, Oedema peripheral, Periorbital oedema, Peripheral swelling, Swelling pain in jaw, Eye swelling, Joint swelling</p> <p>Sleep disorders: Abnormal dreams, Insomnia, Night sweats, Sleep disorders, Somnolence</p> <p>Mental and psychiatric disturbances/disorders: Anxiety, Cognitive disorder, Depression, Disturbance in attention, Increased activity, Irritability, Mental status changes, Mood swings, Restless leg syndrome, Restlessness, Agitation</p> <p>Muscular and connective tissues: Muscle cramps, Muscle cramps, Muscle sensation of heaviness,</p> <p>Muscle spasms, Muscle twitching, Joint stiffness</p> <p>Urology and renal functions: Oliguria, Proteinuria, Renal colic, Renal impairment, Urinary frequency, Urinary incontinence, Difficulty in micturition, Dysuria, Micturition urgency.</p> <p>Skin diseases: Ichthyosis, Psoriasis, Skin discolouration, Alopecia</p> <p>Other: Asthenia, Asthenic conditions (Fatigue, Malaise, weakness), Catheter related complications, catheter related infection, Chest discomfort, Chest pressure sensation, Chest tightness, Contusion, Cough, Cough productive, Dry mouth, Dry skin, Dysgeusia, Dyspnoea exertional</p> <p>Erectile dysfunction, Fatigue, Feeling cold, Hair texture abnormal, Hiatus hernia, Hoarseness, Lymphadenopathy, Muscle weakness, Nail disorder, Orthopnoea, Pyrexia, Salivary hypersecretion, Speech disorder, Sweating increased, Tenderness, Throat tightness, Tongue discoloration, Weakness</p>	
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<p>Weight decreased, Weight increased, Wheezing, Mouth ulceration, Hyperventillation, Fall.</p> <ul style="list-style-type: none"> • 	
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Serious side effects

Serious side effects	What to do
<p>Bleeding: Diarrhoea haemorrhagic, Eye haemorrhage, Haematemesis, Haemolytic anaemia, Haemorrhage gastrointestinal, Haemorrhage hepatic, Haemorrhage rectal, Intracranial haemorrhage</p> <p>Mucosal haemorrhage, Subarachnoid haemorrhage, Thrombocytopenic purpura</p> <p>CNS irritation: Convulsion, Rigors</p> <p>Disturbance of consciousness: Confusion, Delirium, Lethargy</p> <p>Heart failure, heart toxicity and heart rhythm abnormal: Cardiac failure, Decreased left ventricular, ejection fraction, new onset, Development or exacerbation of congestive heart failure, Ventricular hypokinesia, Atrioventricular block complete, Cardiac arrest, Syncope, Cardiac toxicity.</p> <p>Ischaemic heart disease: Angina unstable, Myocardial infarction</p> <p>Inflammations: Acute pancreatitis, Polyarthritis with rash, Stomatitis, Post-herpetic neuralgia, Proliferative glomerulonephritis.</p> <p>Irritations and allergies: Immunocomplex mediated hypersensitivity, Immunocomplex-potentially mediated reactions (such as serum-sickness), Pruritus generalised, Rash macular, Rash popular, Asthma.</p> <p>Infections: Bacteraemia, Herpes zoster, Sepsis, Bronchopneumonia, Lower respiratory/lung, infections, Pleural infection, Pneumonia.</p> <p>Haemocoagulation abnormal: Deep vein thrombosis, Thrombosis</p>	<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>

<p>Haematology abnormal: Febrile neutropenia, Leukopenia, Lymphopenia, Neutropenia, pancytopenia.</p> <p>Neuropathy, motor function deficits, neurosensory disturbances: Paraplegia, Paresis, Peripheral motor neuropathy, Peripheral neuropathy, Paraesthesia and dysaesthesia, Peripheral sensory neuropathy, deafness, hallucinations</p> <p>Respiratory failure and congestions: Acute pulmonary oedema, Pulmonary oedema, Pulmonary congestion, Respiratory arrest.</p> <p>Lung diseases: Pleural effusion, Dyspnoea</p> <p>Paralysis: Paralytic ileus</p> <p>Toxic damage of liver: Liver toxicity</p> <p>Renal failure and urinary functions abnormal: Renal failure, Renal failure acute, urinary retention</p> <p>Endocrine dysfunctions: Inappropriate antidiuretic hormone (ADH) secretion</p> <p>Metabolic abnormalities and abnormal biochemistry: Hypoxia, Alkalosis respiratory, Dehydration, Hyperglycaemia, Hypoglycaemia, Hypokalaemia</p> <p>Other: Anorexia, Cachexia, Tumour lysis syndrome</p>	
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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 EVER PHARMA contains

Active ingredient (main ingredient)	bortezomib
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • mannitol (E 421) • sodium chloride • Sodium hydroxide (for pH adjustment) • Hydrochloric acid (for pH adjustment) • Water for injection

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

What BORTEZOMIB EVER PHARMA looks like

BORTEZOMIB EVER PHARMA is a colourless to light yellow solution in a glass vial.

It is provided in packs of either one single use vial or 5 single use vials.

BORTEZOMIB EVER PHARMA 3.5 mg/1.4 mL solution per vial (AUST R 345130)

BORTEZOMIB EVER PHARMA 2.5 mg/1 ml solution per vial (AUST R 345128)

Not all presentations may be supplied.

Who distributes BORTEZOMIB EVER PHARMA

InterPharma Pty Ltd
Suite 103, 39 East Esplanade
MANLY NSW 2095 Australia

This leaflet was prepared in September 2020].