

DBL™ BORTEZOMIB POWDER FOR INJECTION

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 being given DBL Bortezomib Powder for Injection?

DBL Bortezomib Powder for Injection contains the active ingredient bortezomib. DBL Bortezomib Powder for Injection is used to treat multiple myeloma (cancer of the bone marrow) and mantle cell lymphoma (a type of cancer affecting the lymph nodes).

For more information, see Section [1. Why am I being given DBL Bortezomib Powder for Injection?](#) in the full CMI.

2. What should I know before I am given DBL Bortezomib Powder for Injection?

You will not be given DBL Bortezomib Powder for Injection if you have ever had an allergic reaction to bortezomib, boron, mannitol 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 am given DBL Bortezomib Powder for Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Bortezomib Powder for Injection 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 is DBL Bortezomib Powder for Injection given?

Your treatment with DBL Bortezomib Powder for Injection will be done under the supervision of a doctor. This medicine will be given by a healthcare professional (e.g. doctor or nurse) experienced in giving this type of 'oncology' medicine.

More instructions can be found in Section [4. How is DBL Bortezomib given?](#) in the full CMI.

5. What should I know while being given DBL Bortezomib Powder for Injection?

Things you should do	- Remind any doctor, dentist, nurse, or pharmacist you visit that you are receiving DBL Bortezomib Powder for Injection. - If you become pregnant, while taking this medicine, tell your doctor immediately.
Things to be careful of	If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
Driving or using machines	Be careful driving or operating machinery until you know how this medicine affects you. If you have symptoms of dizziness, light-headedness, tiredness, fainting, doubled or blurred vision do not drive, operate machinery, or do anything else that could be dangerous.
Drinking alcohol	Be careful when drinking alcohol while you are being treated with this medicine, as dizziness or light-headedness may be worse.

For more information, see Section [5. What should I know while being given DBL Bortezomib Powder for Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects include anaemia e.g. tiredness, weakness, headaches, dizziness, looking pale, nausea, vomiting, diarrhoea, constipation, loss of appetite and/or weight, fear of gaining weight, bleeding or bruising, sensitivity, numbness, tingling or burning sensation of the skin, fever, chills, sore throat, mouth ulcers, herpes virus or hepatitis infections, trouble sleeping, anxiety, confusion, depression, painful, swollen joints, pain in the limbs, back pain, bone pain, muscle cramps, temporary inflammation of the nerves, dehydration, cough, stomach pain, blockage in the intestine, bad taste in the mouth, low/high blood pressure, chest pain, hair loss, blurred vision, pneumonia, 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.

DBL™ BORTEZOMIB POWDER FOR INJECTION

Active ingredient(s): *bortezomib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Bortezomib Powder for Injection. **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 DBL Bortezomib Powder for Injection.**

Where to find information in this leaflet:

1. [Why am I being given DBL Bortezomib Powder for Injection?](#)
2. [What should I know before I am given DBL Bortezomib Powder for Injection?](#)
3. [What if I am taking other medicines?](#)
4. [How is DBL Bortezomib Powder for Injection given?](#)
5. [What should I know while being given DBL Bortezomib Powder for Injection?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given DBL Bortezomib Powder for Injection?

DBL Bortezomib Powder for Injection contains the active ingredient **bortezomib**. It belongs to a group of drugs called antineoplastic or cytotoxic medicines. These medicines are used to kill cancer cells.

DBL Bortezomib Powder for Injection is used to treat:

- multiple myeloma (cancer of the bone marrow)
- mantle cell lymphoma (a type of cancer affecting the lymph nodes).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that bortezomib is addictive.

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

2. What should I know before I am given DBL Bortezomib Powder for Injection?

Warnings

You should not be given DBL Bortezomib Powder for Injection if:

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

Tell your doctor if you have or have had any medical conditions, especially the following:

- blood disorder with a low level of red or white blood cells or platelets
- diarrhoea or vomiting
- 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)
- 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.

It may affect your developing baby if you use DBL Bortezomib Powder for Injection during pregnancy. This medicine is not recommended for use during pregnancy.

Both men and women receiving DBL Bortezomib Powder for Injection and their partners must use a reliable method of contraception.

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

It is not known whether DBL Bortezomib Powder for Injection passes into breast milk. Therefore, there is a possibility that your baby may be affected.

If you wish to restart breastfeeding after your DBL Bortezomib Powder for Injection 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.

Some medicines and DBL Bortezomib Powder for injection may interfere with each other.

These include:

- 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*).

These medicines may be affected by DBL Bortezomib Powder for Injection or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Bortezomib Powder for Injection.

4. How is DBL Bortezomib Powder for Injection given?

Your treatment with DBL Bortezomib Powder for Injection will be done under the supervision of a doctor. This medicine will be given by a healthcare professional (e.g. doctor or nurse) experienced in giving this type of 'oncology' medicine.

How much is given

- Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

How it is given

- DBL Bortezomib Powder for Injection will be dissolved in a sterile solution for injection. The solution is given as an injection into your vein (intravenously) over 3 to 5 seconds.
- The solution can also be given subcutaneously as an injection into your thighs or stomach.

When it is given

Multiple Myeloma

One cycle of treatment with DBL Bortezomib Powder for Injection 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.

Week/Day	One cycle of treatment	
Week 1 (Day 1-7)	day 1	day 4
Week 2 (Day 8-14)	day 8	day 11
Week 3 (Day 15-21)	day 15 to 21 break	

Note day 1 is the first dose you will receive your DBL Bortezomib Powder for Injection in a treatment cycle. Subsequent doses for the same treatment cycle will be

counted from day 1, e.g. your 3rd dose will be the 8th day (day 8).

When DBL Bortezomib Powder for Injection 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, DBL Bortezomib Powder for Injection is administered twice weekly (days 1, 4, 8 and 11).

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

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

Mantle Cell Lymphoma

When DBL Bortezomib Powder for Injection 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, DBL Bortezomib Powder for Injection 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 DBL Bortezomib Powder for Injection needed. This will depend on how you respond to treatment.

If too much DBL Bortezomib Powder for Injection is given

DBL Bortezomib Powder for Injection is given in a hospital or clinic under the supervision of a doctor, it is very unlikely that you will be given too much of the medicine. Your doctor or nurse will be monitoring your progress and checking the medicine that you are given.

If you think that you have been given too much DBL Bortezomib Powder for Injection, you may need urgent medical attention.

Symptoms of an overdose may include the side effects listed in Section [6. Are there any side effects?](#) but are usually of a more severe nature.

5. What should I know while being given DBL Bortezomib Powder for Injection?

Things you should do

- It is important to receive your doses of DBL Bortezomib Powder for Injection at the appropriate times according to your treatment cycle to get the best effects from your treatment. This will be explained to you by your doctor or nurse.
- **Please ensure that you follow 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 DBL Bortezomib Powder for Injection. You may also need to drink extra fluids if you experience vomiting and/or diarrhoea.

- Remind any doctor, dentist, nurse or pharmacist you visit that you are using DBL Bortezomib Powder for Injection.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine as it may affect the other medicines used during surgery.
- **Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests (such as blood or urine) from time to time to make sure the medicine is working and to prevent unwanted side effects.

DBL Bortezomib Powder for Injection 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. Avoid contact sports or other situations where you may bruise or get injured.

Call your doctor straight away if you:

- Become pregnant while taking this medicine.

Things to be careful of

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Bortezomib Powder for Injection affects you.

DBL Bortezomib Powder for Injection may cause dizziness, light-headedness, tiredness, fainting, double or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Be careful when drinking alcohol while you are taking this medicine.

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

Getting out of bed or standing up

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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
General Disorders and administration site conditions: • chest pain • redness of the skin or redness and pain at injection site Gastrointestinal System Disorders: • feeling sick (nausea) or vomiting • diarrhoea • constipation • uncomfortable feeling in the stomach, burping after eating or having hiccups • stomach pain • ulcers in the mouth or dry mouth • throat pain Psychiatric disorders: • trouble sleeping • anxiety • confusion • depression Musculoskeletal and connective tissue disorders: • aching muscles, muscle tenderness or weakness not caused by exercise • painful, swollen joints • pain in your limbs, bone pain, muscle cramps • sensitivity, numbness, tingling or burning sensation of the skin, or pain in the hands or feet Ear and labyrinth disorders: • dizziness Nervous system disorders: • headache • pins and needles and unpleasant sensations • bad taste in the mouth	Speak to your doctor if you have any of these common side effects and they worry you.

Common side effects	What to do
Metabolism and nutritional disorders: - loss of appetite, and/or weight, fear of gaining weight - dehydration Respiratory, thoracic and mediastinal disorders: - cough - blood nose or runny nose Vascular Disorders: - low blood pressure (dizziness, lightheadedness or fainting) - high blood pressure Eye Disorders: - blurred vision	

Serious side effects

Serious side effects	What to do
General Disorders and administration site conditions: - tiredness, generally feeling unwell, weakness - fever, chills, shivering Infections and Infestations: - herpes virus or hepatitis infections - small blisters in clusters on the skin (herpes) - pneumonia Blood and lymphatic system disorders: - thrombocytopenia, anaemia or neutropenia (conditions in which there are decreased numbers of platelets, red blood cells or white blood cells in your blood). These side effects can cause tiredness, headaches, being short of breath when exercising, dizziness, looking pale, bruising easily or unusual bleeding including in your poo or wee. Nervous system disorders: - temporary inflammation of the nerves, causing pain, weakness, and paralysis in the extremities and often progressing to the chest and face Musculoskeletal and connective tissue disorders:	Call your doctor straight away if you notice any of these serious side effects.

Serious side effects	What to do
- back pain Allergic Reaction: - 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 DBL Bortezomib Powder for Injection contains

Active ingredient (main ingredient)	bortezomib
Other ingredients (inactive ingredients)	mannitol nitrogen

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

DBL Bortezomib Powder for Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What DBL Bortezomib Powder for Injection looks like

DBL Bortezomib Powder for Injection is a white to off-white powder in a clear glass vial.

Each pack contains one single-use vial.

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

Australian Registration Numbers

DBL Bortezomib Powder for Injection 1 mg vial - AUST R 313359

DBL Bortezomib Powder for Injection 2.5 mg vial - AUST R 275710

DBL Bortezomib Powder for Injection 3 mg vial - AUST R 275706

DBL Bortezomib Powder for Injection 3.5 mg vial - AUST R
275708

**Who distributes DBL Bortezomib Powder for
Injection**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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