

Consumer Medicine Information**What is in this leaflet**

This leaflet answers some common questions about Bortezomib Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving this medicine against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Bortezomib Sandoz is used for

Bortezomib Sandoz 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 Sandoz 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 Sandoz 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.

Your doctor may have prescribed Bortezomib Sandoz for another reason.

Ask your doctor if you have any questions about why Bortezomib Sandoz has been prescribed for you.

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

Before you are given Bortezomib Sandoz**When you must not take it**

Do not use Bortezomib Sandoz if you are:

- allergic (hypersensitive) to bortezomib or boron or mannitol.

Some of the symptoms of an allergic reaction 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

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

It is not known whether the active ingredient in Bortezomib Sandoz passes into breast milk and therefore, there is a possibility that your baby may be affected.

Before you start to take it

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

- blood disorder with a low level of red or white blood cells or platelets. This disorder 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.
- any bleeding problems
- problems with your heart
- lung or breathing problems

Tell your doctor if you are pregnant, or intend to become pregnant.

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

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

It is not known whether Bortezomib Sandoz passes into breast milk. Therefore there is a possibility that the breastfed 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.

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

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

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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*).

These medicines may be affected by Bortezomib Sandoz or may affect how well Bortezomib Sandoz works. Your doctor or pharmacist can tell you what to do if you are using any of these medicines.

How Bortezomib Sandoz is given

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

How much 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 Sandoz 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 you receive.

How it is given

Bortezomib Sandoz 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 Sandoz must be given intravenously or subcutaneously only. Bortezomib Sandoz must not be given into the space around the spinal cord (intrathecally).

When it is given**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 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 the treatment.

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

If you take too much (overdose)

As Bortezomib Sandoz 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 Sandoz, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital. You may need urgent medical attention.

While you are using Bortezomib Sandoz

Things you must 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 Sandoz 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 Sandoz. 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 Sandoz.

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

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

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

Bortezomib Sandoz 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

Things to be careful of

Be careful driving or operating machinery until you know how Bortezomib Sandoz affects you.

Bortezomib Sandoz 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.

Side effects

Like all medicines, Bortezomib Sandoz can have side effects. Some of these effects may be serious. However there may be ways to reduce the discomfort of these effects. You may need medical treatment if you get some of the 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 Sandoz.

Below is a list of the more common side effects you could get while being treated with Bortezomib Sandoz:

- 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

If you think you are having an allergic reaction to Bortezomib Sandoz, tell your doctor immediately or go to Accident and Emergency 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

Other side effects not listed above may also occur in some people.

Tell your doctor, nurse or pharmacist if you notice any other effect that is making you feel unwell.

Product description

Storage

Bortezomib Sandoz should be kept in a cool dry place, protected from light, where the temperature stays below 25°C.

What it looks like

Bortezomib Sandoz is a white to off-white powder in a glass vial. Each pack contains one single-use vial.

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

Ingredients

Active ingredient:

- bortezomib 3.5 mg

Other ingredients:

- mannitol.

Supplier

Bortezomib Sandoz is supplied in Australia by:

Sandoz Pty Ltd
54 Waterloo Road
Macquarie Park NSW 2113
AUSTRALIA
Tel: 1800 726 369

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