Bortezomib-AFT

Bortezomib
3.5 mg Powder for injection

What is in this leaflet

Please use this leaflet carefully before you are given Bortezomib-AFT.

This leaflet answers some common questions about Bortezomib-AFT. 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 being given Bortezomib-AFT against the benefits they expect it will have for you.

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

Keep this leaflet with you. You may need to read it again.

What Bortezomib-AFT is used for

Bortezomib-AFT is used in adults to treat 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-AFT 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.

Your doctor may have prescribed Bortezomib-AFT for another reason.

Ask your doctor if you have any questions about why Bortezomib-AFT have been prescribed for you.

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

This medicine is not addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you are given Bortezomib-AFT

When you must not be given it

Do not use Bortezomib-AFT if:
- you know you are allergic (hypersensitive) to bortezomib or boron or mannitol.

If you are not sure if you are allergic to any of the above, ask your doctor.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or to other parts of the body; skin rash, itching or hives.

Before you start to use it

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; this disorder may become worse during treatment with Bortezomib-AFT
- if you are suffering from diarrhoea or vomiting as this may become worse during treatment with Bortezomib-AFT
- a history of fainting, dizziness or light-headedness
- kidney problems

- liver problems
- problems with numbness, tingling or pain the in hands or feet (neuropathy); this effect may be worsened by treatment with Bortezomib-AFT
- any bleeding problems
- problems with your heart
- lung or breathing problems
- seizures
- symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath.

Tell your doctor if you are pregnant or intend to become pregnant. Like most medicines used to treat cancer, Bortezomib-AFT is not recommended for use during pregnancy.

Tell your doctor if you are breastfeeding or intent to breastfeed. It is not known whether Bortezomib-AFT passes into breast milk. Therefore, there is a possibility that the breast-fed baby may be affected. If you wish to restart breastfeeding after your treatment with Bortezomib-AFT, 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-AFT and their partners need to use a reliable method of contraception during and for 3 months after receiving Bortezomib-AFT.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are receiving Bortezomib-AFT.

Some medicines may interfere with Bortezomib-AFT. These include:
- 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, an antibiotic used with other medicine to treat 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-AFT or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while being given Bortezomib-AFT.

How Bortezomib-AFT is given

Overall treatment with Bortezomib-AFT must be done under the supervision of a doctor. Your treatment with Bortezomib-AFT may be given by a healthcare professional (e.g. 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.

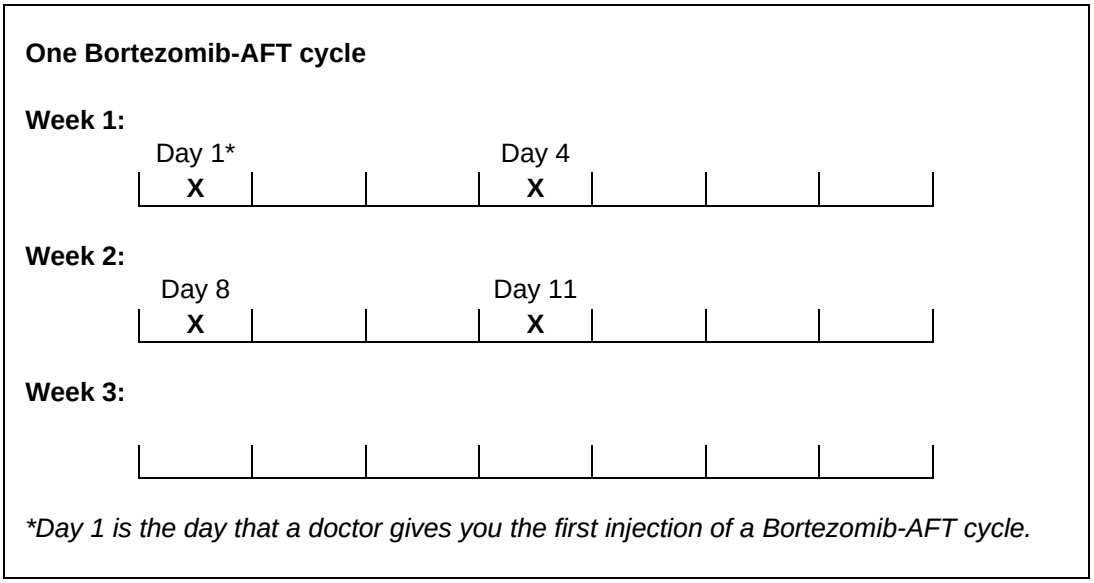
The usual starting dose is 1.3 milligrams per square meter body service area. It is given either as a relatively large volume of fluid into the vein, or an injection into the thigh or abdomen.

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-AFT you receive.

When it is given

One cycle of Bortezomib-AFT 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 10-day break from the treatment.



When Bortezomib-AFT is given with thalidomide and dexamethasone, one cycle of treatment is 3 weeks and the treatment consist of a total of 3 cycles (9 weeks) for the induction stage. For the consolidation stage, one cycle of treatment is 5 weeks and the treatment consist of a total of 2 cycles (10 weeks). During the induction stage, Bortezomib-AFT is administered twice weekly (days 1, 4, 8 and 11). During the consolidation stage, Bortezomib-AFT is administered once weekly (days 1, 8, 15 and 22).

When Bortezomib-AFT is given with dexamethasone, one treatment cycle is 3 weeks and the treatment consist of a total of 4 cycles (12 weeks). Bortezomib-AFT will be administered twice weekly (days 1, 4, 8 and 11).

When Bortezomib-AFT is given with melphalan and prednisone, one cycle of treatment is 6 weeks and the treatment consist of a total of 9 cycles (54 weeks). In Cycles 1 – 4, Bortezomib-AFT is administered twice weekly (days 1, 4, 8, 11, 22, 25, 29 and 32). In Cycles 5 – 9, Bortezomib-AFT is administered once weekly (days 1, 8, 22 and 29).

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

How it is given

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

While you are being given Bortezomib-AFT

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.

K**eep follow up appointments with your doctor.** It is important to have your follow-up doses of Bortezomib-AFT 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-AFT. 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-AFT.

If you are about to be started any new medicine, tell your doctor, dentist or pharmacist that you are receiving Bortezomib-AFT.

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

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

Bortezomib-AFT 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-AFT affects you.

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

In case of overdose

If too much is given (overdose)

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Bortezomib-AFT.

Like other medicines, Bortezomib-AFT can cause some side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have. **Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with Bortezomib-AFT.**

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

- 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
- 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)
- chest pain
- small blisters in clusters on the skin (herpes)
- rash, itching
- redness of the skin or redness and pain at injection site
- blurred vision
- pneumonia
- allergic reaction

If you think you are having an allergic reaction to Bortezomib-AFT, 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 adverse effects not listed here may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

After being given Bortezomib-AFT

Storage

Bortezomib-AFT is stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 30 °C. Once the powder is dissolved in sterile normal sodium chloride (salt) solution for injection, it can be kept in the fridge (between 2 – 8 °C) for up to 8 hours).

Store all medicine out of reach of children.

Disposal
The hospital staff will dispose of any leftover Bortezomib-AFT.

Product description

What Bortezomib-AFT look like*:*
A 10 mL glass vial of Bortezomib-AFT contains 3.5 mg of bortezomib as a white to off-white cake or powder.

Each carton contains 1 vial for single use in one patient only.

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

Ingredients:
Active ingredient:
- Bortezomib

Inactive ingredients:
- Mannitol
- Nitrogen

Sponsor details

Bortezomib-AFT is supplied in New Zealand by:

AFT Pharmaceuticals Ltd
Level 1, 129 Hurstmere Road
Takapuna
Auckland 0622
NEW ZEALAND

Phone: 0800 423 823

Date of preparation

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