



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Bortezomib Fresenius Kabi (*bortezomib*)

An overview of Bortezomib Fresenius Kabi and why it is authorised in the EU

What is Bortezomib Fresenius Kabi and what is it used for?

Bortezomib Fresenius Kabi is a medicine used to treat multiple myeloma, a blood cancer, in the following groups of patients:

- previously untreated adults who cannot have high-dose chemotherapy with a blood stem-cell transplant. In these patients, Bortezomib Fresenius Kabi is used in combination with melphalan and prednisone;
- previously untreated patients who are going to receive high-dose chemotherapy followed by a blood stem-cell transplant. In this group of patients, Bortezomib Fresenius Kabi is used in combination with dexamethasone, or with dexamethasone plus thalidomide;
- adults whose disease is getting worse after at least one other treatment and who have already had, or cannot undergo, a blood stem-cell transplant. Bortezomib Fresenius Kabi is either used on its own in these patients or in combination with pegylated liposomal doxorubicin or dexamethasone.

Bortezomib Fresenius Kabi is also used to treat mantle cell lymphoma, another blood cancer, in untreated adults who cannot have blood stem-cell transplantation. For mantle cell lymphoma, Bortezomib Fresenius Kabi is used in combination with rituximab, cyclophosphamide, doxorubicin and prednisone.

Bortezomib Fresenius Kabi is a 'generic medicine'. This means that Bortezomib Fresenius Kabi contains the same active substance, bortezomib, and works in the same way as a 'reference medicine' already authorised in the EU called Velcade. For more information on generic medicines, see the question-and-answer document [here](#).

How is Bortezomib Fresenius Kabi used?

Bortezomib Fresenius Kabi is available in vials (3.5 mg) as a powder to be made up into a solution for injection.

The medicine can only be obtained with a prescription and treatment should only be started and given under the supervision of a doctor who has experience in the use of cancer medicines. Bortezomib

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Fresenius Kabi is only given by injection into a vein or under the skin. Bortezomib Fresenius Kabi must not be given by other routes.

The recommended starting dose depends on the patient's height and weight. When given into a vein, the solution is given as a three- to five-second injection through a catheter (a thin sterile tube). When injected under the skin, it is given in the thigh or abdomen (belly).

Doses of Bortezomib Fresenius Kabi are given intermittently, with rest periods in between doses, in treatment cycles of three to six weeks depending on whether Bortezomib Fresenius Kabi is given alone or in combination with other medicines. If a patient develops severe side effects after a treatment cycle, the treatment must be suspended, delayed or the dose adjusted.

Patients with moderately or severely impaired liver function should be treated with lower doses.

For more information about using Bortezomib Fresenius Kabi, see the package leaflet or contact your doctor or pharmacist.

How does Bortezomib Fresenius Kabi work?

The active substance in Bortezomib Fresenius Kabi, bortezomib, is a proteasome inhibitor. It blocks the proteasome, which is a system within the cells that breaks down proteins when they are no longer needed. When the proteins in the cancer cells, such as the proteins that control the growth of the cells, are not broken down, the cells are affected and they eventually die.

How has Bortezomib Fresenius Kabi been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Velcade, and do not need to be repeated for Bortezomib Fresenius Kabi.

As for every medicine, the company provided studies on the quality of Bortezomib Fresenius Kabi. There was no need for 'bioequivalence' studies to investigate whether Bortezomib Fresenius Kabi is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because when Bortezomib Fresenius Kabi is given by injection into a vein the active substance is delivered straight into the bloodstream. Additionally, when Bortezomib Fresenius Kabi is given under the skin, the active substance in both products, which have the same composition, is expected to be absorbed in the same way.

What are the benefits and risks of Bortezomib Fresenius Kabi?

Because Bortezomib Fresenius Kabi is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Bortezomib Fresenius Kabi authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Bortezomib Fresenius Kabi has been shown to be comparable to Velcade. Therefore, the Agency's view was that, as for Velcade, the benefits of Bortezomib Fresenius Kabi outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Bortezomib Fresenius Kabi?

The company that markets Bortezomib Fresenius Kabi will ensure that healthcare professionals receive educational material explaining how to calculate the dose and how to prepare and administer the medicine.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Bortezomib Fresenius Kabi have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Bortezomib Fresenius Kabi are continuously monitored. Side effects reported with Bortezomib Fresenius Kabi are carefully evaluated and any necessary action taken to protect patients.

Other information about Bortezomib Fresenius Kabi

Bortezomib Fresenius Kabi received a marketing authorisation valid throughout the EU on 14 November 2019.

Further information on Bortezomib Fresenius Kabi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/bortezomib-fresenius-kabi. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 11-2019.