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Bortezomib Accord (*bortezomib*)

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

What is Bortezomib Accord and what is it used for?

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

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

Bortezomib Accord 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 Accord is used in combination with rituximab, cyclophosphamide, doxorubicin and prednisone.

Bortezomib Accord contains the active substance bortezomib.

Bortezomib Accord is a 'generic medicine'. This means that Bortezomib Accord contains the same active substance 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 Accord used?

Bortezomib Accord 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 chemotherapy.

Bortezomib Accord is available as a 1 mg injection to be given into a vein or a 3.5 mg injection to be injected into a vein or under the skin. Bortezomib Accord must not be given in any other way.

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The dose of Bortezomib Accord is calculated using the patient's height and weight. When given into a vein, it is injected through a catheter (a thin sterile tube) over 3 to 5 seconds. At least 72 hours must pass between two doses of Bortezomib Accord. When injected under the skin, it is given in the thigh or abdomen (belly).

Doses of Bortezomib Accord are given with rest periods between doses, in treatment cycles of 3 to 6 weeks depending on whether Bortezomib Accord is given alone or in combination with other medicines. If a patient develops severe side effects, the treatment must be stopped, delayed or the dose adjusted.

For more information about using Bortezomib Accord, see the package leaflet or contact a doctor or pharmacist.

How does Bortezomib Accord work?

The active substance in Bortezomib Accord, bortezomib, is a proteasome inhibitor. It blocks the proteasome system, which breaks down proteins within cells that are no longer needed. Blocking the proteasome system causes the cell to die. Cancer cells are more sensitive to disruption by proteasome inhibitors than normal cells and, therefore, to the effects of bortezomib.

How has Bortezomib Accord been studied?

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

What are the benefits and risks of Bortezomib Accord?

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

Why is Bortezomib Accord authorised in the EU?

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

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

The company that markets Bortezomib Accord will supply educational material to healthcare professionals which explains how to calculate the dose and how to prepare and give the medicine.

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

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

Other information about Bortezomib Accord

Bortezomib Accord received a marketing authorisation valid throughout the EU on 20 July 2015.

Further information on Bortezomib Accord can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 04-2018.