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**EPAR summary for the public**

# Bortezomib Accord

bortezomib

This is a summary of the European public assessment report (EPAR) for Bortezomib Accord. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Bortezomib Accord.

For practical information about using Bortezomib Accord, patients should read the package leaflet or contact their doctor or pharmacist.

## 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 undergo, blood stem-cell transplantation. Bortezomib Accord is either used on its own in these patients 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.

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Bortezomib Accord is a 'generic medicine'. This means that Bortezomib Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called Velcade. For more information on generic medicines, see the question-and-answer document here.

Bortezomib Accord contains the active substance bortezomib.

## 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 in vials as a 3.5 mg powder to be made up into a solution for injection into a vein or under the skin. Bortezomib Accord must not be given by other routes.

The recommended starting dose is 1.3 mg per square metre body surface area (calculated using 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). At least 72 hours must pass between two consecutive doses of Bortezomib Accord. When injected under the skin, it is given in the thigh or abdomen (tummy).

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

Patients with moderate or severe liver problems should be treated with lower doses. For more information on the use of Bortezomib Accord see the summary of product characteristics (also part of the EPAR).

## How does Bortezomib Accord work?

The active substance in Bortezomib Accord, bortezomib, is a proteasome inhibitor. It blocks the proteasome system, which is a system within the cells that regulates certain proteins and is necessary for the cell to survive. 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?

The company provided data from the published literature on bortezomib. No additional studies were needed as Bortezomib Accord is a generic medicine that is given by injection and contains the same active substance as the reference medicine, Velcade.

## 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 approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Bortezomib Accord has been shown to be comparable to Velcade. Therefore, the

CHMP's view was that, as for Velcade, the benefit outweighs the identified risk. The Committee recommended that Bortezomib Accord be approved for use in the EU.

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

A risk management plan has been developed to ensure that Bortezomib Accord is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Bortezomib Accord, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

## Other information about Bortezomib Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Bortezomib Accord on 20 July 2015.

The full EPAR and risk management plan summary for Bortezomib Accord can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Bortezomib Accord, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 07-2015.