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EPAR summary for the public

Bortezomib Hospira

bortezomib

This is a summary of the European public assessment report (EPAR) for Bortezomib Hospira. 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 Hospira.

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

What is Bortezomib Hospira and what is it used for?

Bortezomib Hospira 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 Hospira 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 Hospira 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 Hospira is used in combination with dexamethasone, or with dexamethasone plus thalidomide.

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

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Bortezomib Hospira is a 'generic medicine'. This means that Bortezomib Hospira 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 Hospira contains the active substance bortezomib.

How is Bortezomib Hospira used?

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 chemotherapy.

Bortezomib Hospira 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 Hospira must not be given by other routes.

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

Doses of Bortezomib Hospira are given with rest periods between doses, in treatment cycles of three to six weeks depending on whether Bortezomib Hospira is given alone or in combination with other medicines. If a patient develops severe side effects, 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 Hospira see the summary of product characteristics (also part of the EPAR).

How does Bortezomib Hospira work?

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

How has Bortezomib Hospira been studied?

The company provided data from the published literature on bortezomib. No additional studies were needed as Bortezomib Hospira 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 Hospira?

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

Why is Bortezomib Hospira approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Bortezomib Hospira 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 Hospira be approved for use in the EU.

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

The company that markets Bortezomib Hospira will supply educational material to healthcare professionals on making up and giving the injection, calculating the dose, and prescribing and giving the correct treatment for patients receiving blood stem-cell transplantation.

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

Other information about Bortezomib Hospira

The European Commission granted a marketing authorisation valid throughout the European Union for Bortezomib Hospira on 22 July 2016.

The full EPAR for Bortezomib Hospira 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 Hospira, 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 07-2016.