26 May 2016
EMA/CHMP/327595/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Bortezomib Hospira

bortezomib

On 26 May 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Bortezomib Hospira, intended for the treatment of multiple myeloma and mantle cell lymphoma. The applicant for this medicinal product is Hospira UK Limited.

Bortezomib Hospira will be available as a 3.5 mg powder for solution for injection. The active substance of Bortezomib Hospira is bortezomib, an antineoplastic agent (ATC code: L01XX32). Bortezomib is a cytotoxic chemical entity that inhibits the proteolytic activity of the proteasome, a proteolytic complex that is involved in the breakdown of cellular proteins.

Bortezomib Hospira is a generic of Velcade, which has been authorised in the EU since 26 April 2004. Studies have demonstrated the satisfactory quality of Bortezomib Hospira. Since Bortezomib Hospira is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Velcade was not required.

A question and answer document on generic medicines can be found here.

The full indication is:

“Bortezomib Hospira as monotherapy or in combination with pegylated liposomal doxorubicin or dexamethasone is indicated for the treatment of adult patients with progressive multiple myeloma who have received at least 1 prior therapy and who have already undergone or are unsuitable for haematopoietic stem cell transplantation.

Bortezomib Hospira in combination with melphalan and prednisone is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

Bortezomib Hospira in combination with dexamethasone, or with dexamethasone and thalidomide, is indicated for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Bortezomib Hospira in combination with rituximab, cyclophosphamide, doxorubicin and prednisone is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation."

It is proposed that Bortezomib Hospira must be initiated and administered under the supervision of a physician qualified and experienced in the use of chemotherapeutic agents. Bortezomib Hospira must be reconstituted by a healthcare professional.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.