19 September 2019
EMA/CHMP/496127/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Bortezomib Fresenius Kabi

bortezomib

On 19 September 2019, 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 Fresenius Kabi, intended for the treatment of multiple myeloma and mantle cell lymphoma. The applicant for this medicinal product is Fresenius Kabi Deutschland GmbH.

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

Bortezomib Fresenius Kabi is a generic of Velcade, which has been authorised in the EU since 26 April 2004. Since Bortezomib Fresenius Kabi 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 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 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 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.
>
> Bortezomib in combination with rituximab, cyclophosphamide, doxorubicin and prednisone is

[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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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 Fresenius Kabi be prescribed by physicians qualified and experienced in the use of chemotherapeutic agents.

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.