



European Medicines Agency
Evaluation of Medicines for Human Use

London, 24 July 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
VELCADE

International Nonproprietary Name (INN): *bortezomib*

On 24 July 2008, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Velcade. The Marketing Authorisation Holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted a new indication as follows:

“Velcade in combination with melphalan and prednisone is indicated for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant.”

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Velcade will be as follows***:

“Velcade in combination with melphalan and prednisone is indicated for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant.”

VELCADE is indicated as mono-therapy for the treatment of progressive multiple myeloma in patients who have received at least 1 prior therapy and who have already undergone or are unsuitable for bone marrow transplantation.”

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

*** The text in bold represents the new or the amended indication.