



European Medicines Agency
Press office

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EMA PRESS RELEASE

EMA recommends new contraindication for Velcade (bortezomib)

The European Medicines Agency (EMA) has recommended that Velcade (bortezomib) should not be used in patients with certain severe pulmonary or heart problems (acute diffuse infiltrative pulmonary and pericardial disease).

Velcade is used to treat progressive multiple myeloma in patients who have failed to respond to at least one other treatment and who have already undergone or are unsuitable for bone marrow transplantation.

As part of the continuous monitoring of medicines the EMA reviewed all available information on the safety of Velcade. The EMA's Committee for Medicinal Products for Human Use (CHMP) concluded during its March 2008 meeting that the benefits of Velcade are greater than its risks, except in patients with acute diffuse infiltrative pulmonary and pericardial disease. The CHMP therefore recommended contraindicating the use of Velcade for these patients.

In addition, the Committee recommended strengthening the existing warnings on pulmonary disorders by advising doctors to perform chest X-rays and consider individual benefit-risk profiles, before starting patients on treatment with Velcade. Finally, the CHMP also recommended that new information on cardiac and pulmonary side effects observed during the post-marketing phase be included in the product information.

The new recommendations will be sent to the European Commission for adoption of a decision.

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Notes:

1. More information about the EMA recommendation is available in a [question-and-answer document](#).
2. More information about Velcade, including the currently approved information to prescribers and patients can be found in the European Public Assessment Report: <http://www.emea.europa.eu/humandocs/Humans/EPAR/velcade/velcade.htm>
3. This press release, together with other information on the work of the EMA, can be found on the EMA website: www.emea.europa.eu

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