European Medicines Agency

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QUESTIONS AND ANSWERS ON THE ADDITION OF A CONTRAINDICATION FOR VELCADE (*bortezomib*)

As part of its continuous monitoring of medicines, the European Medicines Agency (EMEA) has reviewed the available information on the safety of Velcade (bortezomib), in particular the medicine's pulmonary and cardiovascular side effects (affecting the lungs, the heart and the blood vessels).
The EMEA's Committee for Medicinal Products for Human Use (CHMP) has concluded that Velcade's benefits continue to outweigh its risks. However, it recommended that patients with 'acute diffuse infiltrative pulmonary disease' (a severe lung problem) and pericardial disease (affecting the sac that surrounds the heart) should not be prescribed Velcade.

What is Velcade?

Velcade is a powder that is made up into a solution for injection. It is used to treat progressive multiple myeloma (a cancer of the plasma cells in the bone marrow) in patients who have failed to respond to at least one other treatment and who already have had, or cannot undergo, bone marrow transplantation.
The active substance in Velcade, bortezomib, is a proteasome inhibitor. It blocks the proteasome, which is a system within the cells that breaks down proteins when they are no longer needed. When the proteins in the cancer cells, such as the proteins that control the growth of the cells are not broken down, the cells are affected and they eventually die.
Velcade has been authorised in the European Union since April 2004, and is marketed in most Member States.

What is the issue with the safety of Velcade?

The CHMP has been monitoring the safety of Velcade since it was first authorised. Following cases of lung side effects in patients taking Velcade, the European product information was updated in July 2006 to include a warning on lung disorders.
As part of the follow-up to this update, the Committee requested that the company that makes Velcade provide all available information on the safety of Velcade, particularly its lung- and heart-related side effects, both from post-marketing surveillance and from recent clinical studies. The review of this information was finalised at the CHMP meeting of 17-19 March 2008.

What are the conclusions of the CHMP?

The CHMP concluded that Velcade's benefits in patients with acute diffuse infiltrative pulmonary and pericardial diseases do not outweigh its risks. It therefore recommended a change to the product information to include a contraindication to the use of Velcade in patients with these diseases.
The Committee also recommended that the existing warnings on lung disorders be strengthened and that heart and lung side effects be included in the product information.

What is the advice to patients and prescribers?

- Doctors should prescribe Velcade according to the updated product information.
- They should carry out a chest X-ray before treatment with Velcade. This will give a baseline to assess the patients, should they develop new or increased shortness of breath or cough during treatment.
- Patients who are taking Velcade and have any questions or concerns should talk to their doctor or pharmacist.

A European Commission decision on this opinion will be issued in due course.

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