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Questions and answers

Recommendations to prevent administration errors with Velcade (bortezomib)

The European Medicines Agency is aware of three fatal cases of administration error that occurred with Velcade in the European Union, where the medicine was accidentally given intrathecally (into the space that surrounds the spinal cord) instead of intravenously (into a vein). The Agency's Committee for Medicinal Products for Human Use (CHMP) is reminding healthcare professionals that Velcade should only be given by injection into a vein and is recommending precautionary measures to prevent further administration errors from occurring.

What is Velcade?

Velcade is an anticancer medicine that contains the active substance bortezomib. It is available as a powder that is made up into a solution for injection into a vein.

Velcade is used to treat patients with multiple myeloma, a cancer of the plasma cells in the bone marrow.

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 26 April 2004 and is marketed in all Member States as well as Norway, Iceland and Liechtenstein.

What is the problem with the use of Velcade?

Velcade is currently only authorised to be given by injection into a vein. The Agency was informed that since its authorisation in 2004, three patients had died because Velcade was accidentally injected

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intrathecally (into the space that surrounds the spinal cord) instead of intravenously. All three cases involved patients who were also receiving intrathecal chemotherapy at the same time as Velcade.

What action is being taken?

To prevent further administration errors from occurring, the CHMP has agreed for a letter to be sent out to healthcare professionals reminding them that Velcade should only be given intravenously. In addition, healthcare professionals are advised to consider specific precautionary measures.

As for all medicines, the Agency will continue to monitor the safety of Velcade closely.

What are the recommendations for healthcare professionals?

Healthcare professionals are reminded that Velcade should only be given intravenously and are advised to consider the following precautionary measures:

- When possible, different connectors should be used for medicines to be administered via intrathecal or intravenous route.
- When possible, intrathecal chemotherapy should be administered at a different time than any other parenteral chemotherapy (chemotherapy given by injection or drip into a vein).
- Syringes should be clearly labelled with the name of the medicine and route of administration to be used.
- Procedures should be in place for double checking the labelling of syringes before administration.
- Intravenous and intrathecal injections should be handled only by suitably trained healthcare professionals.
- Healthcare professionals involved in administration or management of cancer chemotherapy should be trained and informed of the dangers of intrathecal administration of Velcade and of the recommended measures to prevent this from occurring.

The current European public assessment report for Velcade can be found on the Agency's website: http://www.ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.