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Velcade (*bortezomib*)

An overview of Velcade and why it is authorised in the EU

What is Velcade and what is it used for?

Velcade is a cancer medicine that is generally used in combination with other medicines to treat multiple myeloma, a blood cancer, in:

- adults whose disease is getting worse after at least one other treatment and who have already had blood stem-cell transplantation or cannot have it. In these patients, Velcade is used either on its own or with pegylated liposomal doxorubicin or dexamethasone;
- previously untreated adults who cannot have high-dose chemotherapy with blood stem-cell transplantation. In these patients, Velcade is used in combination with melphalan and prednisone;
- previously untreated adults who are going to receive high-dose chemotherapy followed by a blood stem-cell transplantation. In these patients, Velcade is used in combination with dexamethasone, or with dexamethasone plus thalidomide.

Velcade is also used to treat mantle cell lymphoma, another blood cancer. It is used in adults who have not received any treatment for their cancer and who cannot have blood stem-cell transplantation. In these patients Velcade is used with rituximab, cyclophosphamide, doxorubicin and prednisone.

Velcade contains the active substance bortezomib.

How is Velcade used?

Velcade can only be obtained with a prescription. Treatment should only be started under the supervision of a doctor who has experience in the use of cancer chemotherapy. Velcade is available as an injection containing 1 or 3.5 mg.

Velcade is given by injection into a vein. Velcade 3.5 mg can also be given by injection under the skin in the thigh or the belly. Velcade must not be given in other way. It is given in treatment cycles of 3 to 6 weeks depending on whether Velcade is given alone or in combination with other medicines. The dose depends on the patient's height and weight.

If the patient develops severe side effects, the doctor may reduce the dose, delay the treatment or stop it altogether.

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For more information about using Velcade, see the package leaflet or contact your doctor or pharmacist.

How does Velcade work?

The active substance in Velcade, bortezomib, is a proteasome inhibitor. It blocks the proteasome, which is a system in cells that breaks down proteins that are no longer needed. Blocking the proteasome system results in a build-up of unwanted proteins that causes the cells to die. Proteasome inhibitors have a bigger effect on cancer cells than on normal cells.

What benefits of Velcade have been shown in studies?

In multiple myeloma, 10 main studies, involving over 4,300 adults, found Velcade given alone or in combination with other medicines to be effective in several patient groups. The main measures of effectiveness were the number of patients whose disease responded to treatment and how long the patients lived without their disease getting worse.

In mantle cell lymphoma, a main study involved 487 previously untreated adults who were not suitable for blood stem-cell transplantation. Patients treated with Velcade together with rituximab, cyclophosphamide, doxorubicin and prednisone lived for 24.7 months without their disease getting worse compared with 14.4 months for patients treated with the same combination but using another medicine, vincristine, in place of Velcade.

What are the risks associated with Velcade?

The most common side effects with Velcade (which may affect more than 1 in 10 people) are nausea (feeling sick), diarrhoea, constipation, vomiting, tiredness, weakness, fever, thrombocytopenia (low blood platelet count which can lead to easy bruising and bleeding), anaemia (low red blood cell count), neutropenia (low levels of a type of white blood cell that fights infection), nerve damage in arms and legs, headache, paraesthesia (numbness and tingling), decreased appetite, difficulty breathing, rash, shingles, and muscle and bone pain.

The most serious side effects include heart failure, tumour lysis syndrome (complications due to sudden breakdown of cancer cells), pulmonary hypertension (high blood pressure in the arteries of the lungs), posterior reversible encephalopathy syndrome (a brain disorder), acute diffuse infiltrative pulmonary disease (a severe lung problem) and autonomic neuropathy (damage to nerves controlling organs such as the bladder, eyes, gut, heart and blood vessels).

Velcade must not be used in patients who are hypersensitive (allergic) to bortezomib, boron or to any of the other ingredients. It must not be given to patients with acute diffuse infiltrative pulmonary disease or pericardial disease (disease of the sac around the heart).

For the full list of side effects and restrictions of Velcade, see the package leaflet.

Why is Velcade authorised in the EU?

The European Medicines Agency decided that Velcade's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Velcade?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Velcade have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Velcade are continuously monitored. Side effects reported with Velcade are carefully evaluated and any necessary action taken to protect patients.

Other information about Velcade

Velcade received a marketing authorisation valid throughout the EU on 26 April 2004.

Further information on Velcade can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/velcade.

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