

FACTSHEET

MYELOMA PATIENTS EUROPE

BORTEZOMIB

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FACTSHEET

MYELOMA PATIENTS EUROPE

Myeloma Patients Europe (MPE) has developed a series of factsheets for patients and patient advocates, providing an overview of available treatment options for myeloma and covering some relevant topics related to the disease.

The factsheets cover important issues around the treatment, so that patients can feel safe and ask specific questions to their doctor.

For each of the available therapies, the following topics will be addressed:

- What is myeloma?
- What is the particular treatment?
- How does the treatment work?
- What are the benefits?
- What are the side effects?
- Who should not receive the treatment?
- How and when is the treatment given?

Access the following factsheets on:

- Amyloidosis
- Belantamab mafodotin
- Bortezomib
- Carfilzomib
- Daratumumab
- Elotuzumab
- Ixazomib
- Lenalidomide
- Panobinostat
- Pomalidomide
- Thalidomide
- Stem cell transplant

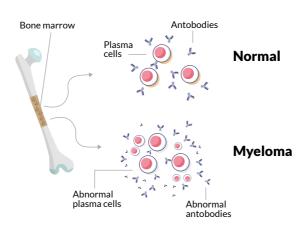
Myeloma treatment is constantly evolving and the factsheets will be updated regularly to reflect the latest developments.

What is myeloma?

Myeloma is a rare cancer of the bone marrow. It is due to the formation of abnormal plasma cells, also called myeloma cells, which divide uncontrollably. Usually, plasma cells help the body to fight infections by making antibodies that recognise and attack germs. Myeloma affects multiple places in the body (this is why it is sometimes referred to as 'multiple myeloma') where bone marrow is normally active, such as the bones of the spine, pelvis, rib cage and the areas around the shoulders and hips.

Myeloma causes pain, anaemia (low red blood cells), fatigue, fractures, recurring infections, bruising and high blood calcium (hypercalcaemia). These symptoms require treatment; if the disease responds to therapy, there could be periods of time where symptoms subside and may not require any treatment. This cycle of remission and recurrence (relapse) often occurs several times. Many patients, particularly in relapse setting, will be on treatment for a long period of time to ensure that their myeloma is kept at bay.

Treatment may involve taking a combination of drugs that have been found to be more effective than single drugs. Myeloma generally cannot be cured, but survival rates are increasing in myeloma, due to the availability of new treatment and many patients are able to enjoy a good quality of life. A number of other new treatments have recently been approved or are under consideration for use following relapse, or for refractory myeloma.



Myeloma

What is bortezomib (Velcade[®])?

Bortezomib is a cancer medicine approved in Europe in 2012 for the treatment of adult patients with myeloma in the following situations:

- Patients untreated previously who cannot receive high dose of chemotherapy with an autologous stem cell transplantation. In this case, bortezomib is used in combination with melphalan and prednisone (VMp).
- Patients untreated previously who are eligible for high-dose chemotherapy and autologous stem cell transplantation. In this case, bortezomib is used in combination with dexamethasone (Vd), or with dexamethasone plus thalidomide (VTd). Patients whose disease is getting worse after at least one other treatment and who have already had, or are unsuitable for, transplant of blood stem-cells. In this case, bortezomib is used alone or in combination with dexamethasone (Vd) or pegylated liposomal doxorubicin (a type of chemotherapy).

How does bortezomib work?

Bortezomib blocks a system within the cells called proteasomes. Proteasomes are large molecules found in cells of the body, and they are involved in the breakdown of damaged or unwanted proteins. Proteasome inhibitors temporarily block their function, stopping them from breaking down unwanted proteins. This causes proteins to build up to toxic levels, killing the myeloma cells. Myeloma cells rely more heavily on proteasomes than normal healthy cells; they are therefore much more sensitive to proteasome inhibitors.

What are the benefits of bortezomib?

Bortezomib has been evaluated in 10 main studies with 4,339 patients with myeloma, being used alone or in combination with other therapies. In many patients groups, these studies show an improved progression free survival, period of time during which the patient has no evidence of progressive disease and has no signs or symptoms of multiple myeloma.

What are the side effects of bortezomib?

The most common side effects during treatment with bortezomib (that are affecting more than 1 in 10 patients) are¹:

- peripheral neuropathy (nerve damage in the hands and feet) the most common
- vomiting
- nausea
- diarrhoea
- constipation
- fatigue (tiredness)
- pyrexia (fever)
- thrombocytopenia (low blood platelets count)
- anaemia (low red blood cell counts)
- neutropenia (low levels of neutrophils, a type of white blood cell)
- headache
- paraesthesia (sensations of pins and needles)
- decreased appetite
- dyspnoea (difficulty breathing)
- rash
- herpes zoster (shingles)
- myalgia (muscle pain)

The most serious adverse reactions include heart failure, tumour lysis syndrome (complications due to the quick and massive destruction of cancer cells), pulmonary hypertension (high blood pressure in the arteries of the lungs), posterior reversible encephalopathy syndrome (a reversible brain disorder), acute diffuse infiltrative pulmonary disease (a severe lung problem), and autonomic neuropathy (damage to nerves controlling organs).

Who should not receive bortezomib?

Bortezomib must not be used by patients with any of the following conditions: acute diffuse infiltrative pulmonary disease (a type of lung disease) or pericardial disease (disease affecting the sac that surrounds the heart).

How and when is bortezomib given?

Bortezomib can be injected into a vein (intravenous) or under the skin (subcutaneously). Intravenous bortezomib has fallen out of favour, therefore you will commonly see bortezomib 3.5 mg given subcutaneously into the abdomen or the thigh.

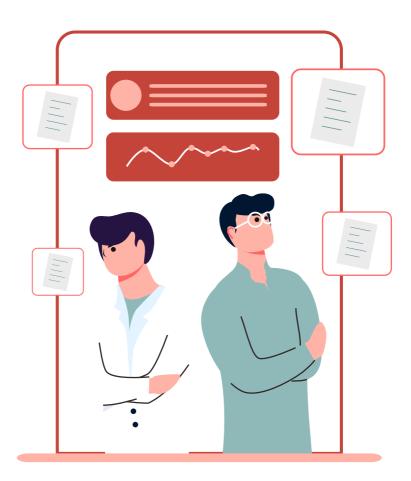
Bortezomib is given in treatment cycles of three to six weeks, depending on whether it is given alone or in combination with other myeloma medicines. In each cycle, there are at least 72 hours between one dose of bortezomib and the next one.

When severe side effects appear, the dose should be adjusted or the treatment could be suspended or delayed.



References

- European Medicines Agency. Velcade® (bortezomib) European public assessment report (EPAR) – http://www.ema.europa.eu/docs/en_GB/ document_library/EPAR_-_Summary_for_the_public/human/000539/ WC500048136.pdf - last updated 1/2015.
- 2. Manufacturer's product information: http://www.velcade.com/ Rajkumar SV, Kumar S. Multiple Myeloma: Diagnosis and Treatment. Mayo Clin Proc. 2016;91(1):101–19.





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MPE is a network of European myeloma patient organisations. It supports national patient organisations to improve treatment and access for patients in their countries and helps inform and raise awareness on a European level through its educational programmes. Please note, this information does not replace the information provided by your doctor. If there is anything that is not clear to you, please always ask your clinical team.



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