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MYELOMA
EURONET



Bortezomib (Velcade®)

Information for
myeloma patients,
their families and
friends



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Myeloma Euronet, the European Network of Myeloma Patient Groups, is an international non-profit association (Association Internationale sans but lucratif, AISBL) registered in Belgium
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Disclaimer

The information in this brochure is not meant to replace the advice of your medical team. They are the best people to ask if you have questions about your individual situation.

**Bortezomib
(Velcade®)**

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Introduction

This brochure is written for patients with multiple myeloma and their families and friends. It provides information on Bortezomib, a drug to treat multiple myeloma. While Bortezomib is the name of the active substance, the drug is mostly referred to under its product name, Velcade®, which is why this name is used throughout this brochure.

This brochure reviews what Velcade is, how it works, when it is used in multiple myeloma, what to expect from treatment and what potential side-effects may occur.

Some of the more technical or unusual words appear in bold the first time they are used and are explained in the “Medical terms explained” section at the back of the brochure.

Aims of this brochure

- To help you understand more about Velcade treatment
- To answer some of the more common questions around Velcade
- To help you make informed decisions about the treatment options available

Myeloma UK, the only organisation dealing exclusively with myeloma and its related disorders in the UK, provides a range of specific English-language information materials which cover all aspects of the treatment and management of myeloma.

For example, if you would like a more general overview of what multiple myeloma is, how it is diagnosed, the most commonly used treatments and many of the things you may have to cope with in living with myeloma, you can order free copies of the brochures “Myeloma – Your Essential Guide” and “Living with Myeloma – Your Essential Guide” from Myeloma UK. You can either call their Myeloma Infoline (see below) or visit their Web site at www.myeloma.org.uk.

If you would like to talk to someone about any aspect of multiple myeloma, its treatment and management, call the Myeloma Infoline. Your call will be answered by Myeloma Information Nurse Specialists who are supported by medical and scientific advisors. The Myeloma Infoline is open Monday to Friday, 9.00 hrs to 17.00 hrs GMT, and is free to phone from anywhere in the UK. From inside the UK, call 0800 980 3332, from outside the UK, call +44 131 557 3332 (charged at normal rate).

What is Velcade and how does it work?

Velcade is the first in a new class of anti-cancer drugs called proteasome inhibitors.

Proteasome inhibitors have a unique mechanism of action and work differently from standard **chemotherapy**. This is very important as they can therefore be used alongside chemotherapy or instead of it when it stops working.

The proteasome, which is found in all cells, works by breaking down the many different proteins that control the life-cycle of cells. Velcade works by temporarily blocking the function of the proteasome, resulting in a build-up of proteins which confuses the cell and causes it to die.

However, unlike the healthy cells which can recover within less than 72 hours, myeloma cells are between 100-1000 times more sensitive to Velcade and therefore cannot recover. The quick recovery of normal healthy cells can also prevent certain side-effects such as hair-loss occurring.

Proteasome with proteins enter at the top and waste proteins (peptides) leave at the bottom.



Velcade acts like a cone to block the proteasome causing protein build-up.

Figure 1 – Proteasomes

How does Velcade affect multiple myeloma?

By blocking the proteasome, Velcade can affect the growth and survival of myeloma cells through multiple mechanisms of action.

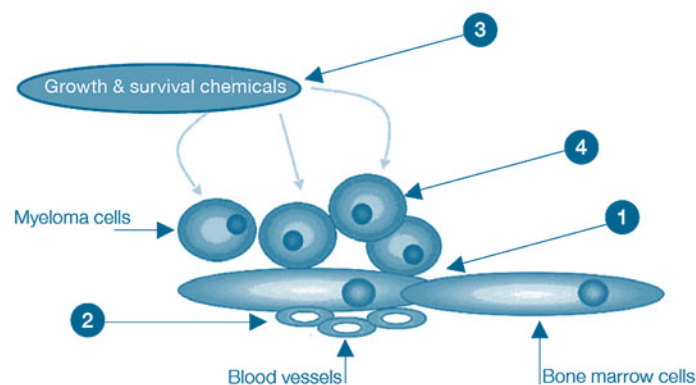


Figure 2 – The different ways Velcade can affect multiple myeloma

These include:

- 1 Preventing the myeloma cells from sticking to bone marrow cells
- 2 Inhibiting the growth of new blood vessels which supply the myeloma cells with oxygen and nutrition
- 3 Altering the production of chemicals crucial for the growth and survival of myeloma cells
- 4 Velcade may also have a direct killing (cytotoxic) effect on the myeloma cells.

How is Velcade used in multiple myeloma?

The introduction of Velcade as a treatment for multiple myeloma has been arguably one of the most important treatment breakthroughs in the last 40-50 years.

When it was first made available in 2004 outside of **clinical studies**, it was used in patients who had **relapsing** or **refractory disease** and who had received at least two previous treatments.

In 2005, its use was extended to include patients whose multiple myeloma had relapsed or had become refractory after having had just one prior treatment.

Its use in both these groups of patients was initially as monotherapy, i.e. on its own. However, it is now almost always used in combination with the steroid dexamethasone, as it has been shown that when Velcade and dexamethasone are given together they produce a greater effect than when each is given on its own.

In September 2008, Velcade was approved in combination with melphalan and prednisone (MP) for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant.

Clinical trials are underway to investigate the potential of Velcade at various stages of disease and in combination with both other standard and new treatments to enhance treatment effects or reverse resistance.

Even though Velcade is an approved multiple myeloma treatment option in Europe, having access to this treatment is still an issue in several European countries. For current information about the availability of Velcade in the UK contact the Myeloma Infoline (see page 24 for details) or visit the Myeloma UK Web site at www.myeloma.org.uk.

In case of drug access problems in other European countries, you can check the links section on the multi-lingual Myeloma Euronet Web site at www.myeloma-euronet.org to see if there is a patient support organisation in your country that might be able to help.

What follows, is a brief summary of the use and activity of Velcade at the various different stages of multiple myeloma.

Patients who have received one or two prior treatments

As already mentioned, Velcade has been shown to be effective in patients who have relapsed or refractory disease after having received at least two prior treatments. The pivotal study in this group of patients showed an overall response rate to Velcade of 43% lasting on average for one year.

Studies comparing Velcade with high-dose dexamethasone in patients who have received at least one prior treatment (sometimes referred to as “second-line” patients) have shown Velcade to be more effective.

In patients receiving Velcade:

- More than 40% of patients responded
- Responses were not as good when it was used later in the disease
- A higher number of patients achieved a complete response
- Responses lasted longer
- Overall survival was better

These results therefore suggest a benefit from using Velcade as early in the disease as possible.

Combination with dexamethasone

Velcade may be given with the steroid dexamethasone either at the start of treatment or, if there is no response to Velcade alone, after the first two or three cycles.

In patients who don't respond to Velcade alone, adding dexamethasone has produced a response in a further 20% of patients. The improved response included patients who had previously not responded to dexamethasone alone.

The combined, improved effectiveness of Velcade and dexamethasone means that current standard practice is usually to prescribe both together from the start.

Newly-diagnosed patients and combination therapy

The approval for treating newly-diagnosed patients with Velcade (often referred to as “first-line,” “frontline” or “upfront” treatment) was based on results from an international clinical study called VISTA (Velcade as Initial Standard Therapy in multiple myeloma: Assessment with melphalan and prednisone).

More than 680 newly diagnosed, untreated multiple myeloma patients from 22 countries in Europe, Asia, and North and South America participated in this study, which was conducted between December 2004 and September 2006.

The myeloma patients, who were not candidates for high-dose chemotherapy with bone marrow transplant, were randomly assigned to one of two groups: 344 patients received Velcade, in addition to melphalan and prednisone, while the control group of 338 received melphalan plus prednisone alone.

The study demonstrated that adding Velcade to MP

- extends the length of time before the disease progresses
- extends the length of time a patient remains disease-free following treatment
- improves complete response rates
- improves overall survival

Other promising studies are under way to investigate the role of Velcade in patients with multiple myeloma, particularly in combination with other treatments, including, but not limited to, dexamethasone, doxorubicin, lenalidomide and thalidomide in various combinations.

How is Velcade given?

Treatment with Velcade should take place in a specialised medical unit, under the supervision of a physician who is experienced in the use of this kind of medicinal product.

Velcade is given as a quick injection into a vein (intravenously) lasting only three to five seconds. If you have not previously been treated for multiple myeloma, Velcade will be given to you in combination with melphalan and prednisone.

Before each dose of Velcade, blood tests may be taken and the results of these examined before the injection can be given. Hydration with intravenous fluids may also be given before Velcade is administered as this helps to protect and flush the vein. This means that it may take up to half a day to receive the Velcade treatment.

Velcade is given in a 21-day cycle. It is injected twice weekly for two weeks (days 1, 4, 8 and 11) followed by a 10-day rest period (days 12 to 21).

Usually this means it is given on a Monday and Thursday or on a Tuesday and Friday.

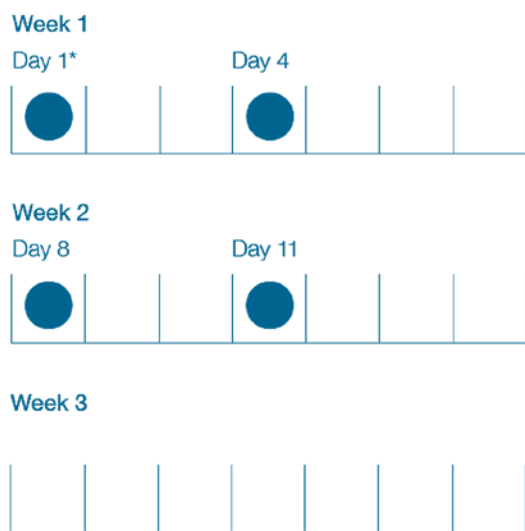


Figure 3 – One Velcade cycle

When Velcade is given with melphalan and prednisone, the treatment consists of a total of 9 cycles (54 weeks). In cycles 1-4, Velcade is administered two times per week (days 1, 4, 8, 11, 22, 25, 29 and 32). In cycles 5-9, Velcade is given once weekly (days 1, 8, 22 and 29). Melphalan and prednisone can be administered orally (can be swallowed) and are given on days 1, 2, 3 and 4 of the first week, for nine 6-week treatment cycles.

Your doctor will decide the total number of cycles that you need. It all depends on your response to the treatment and how well you tolerate potential treatment **side-effects**.

What is the best dose?

Height and weight are used to calculate the exact dose for each patient. The starting dose for Velcade is normally 1.3 milligrams per square meter body surface area.

The dose may be reduced or the drug withdrawn temporarily during treatment if certain side-effects are experienced. There is evidence that, where necessary, using a lower dose of Velcade is still effective in treating multiple myeloma, whilst producing less side-effects.

The injection will take 3 to 5 seconds, and the injection syringe will then be rinsed through with a small quantity of sterile, sodium chloride (salt) solution.

Is Velcade best given alone or in combination?

As stated above, there is evidence that better outcomes can be achieved when Velcade is given in combination with other multiple myeloma treatments. The decision to give Velcade on its own or as part of a combination will be based on the individual disease and clinical factors together with doctor and patient preference.

For how long is Velcade given?

The ideal length of Velcade treatment will vary from patient to patient and in which combination it is given. If there is no response within two or three cycles (when given with dexamethasone), Velcade treatment would normally be stopped and other options discussed.

What are the potential side-effects?

In general, the side-effects of Velcade are mild to moderate, however this can vary considerably from patient to patient. It is important to highlight side-effects promptly to nurses and doctors as they can usually be easily treated or managed.

Often the best way to reduce side-effects is to lower the dose of Velcade. There is evidence that a lower dose of Velcade is still effective but produces fewer side-effects. However, if side-effects remain troublesome, it may be necessary to stop treatment altogether and consider other options.

The most common side-effects include gastrointestinal effects, reduced levels of blood cells, fatigue, fever and shivering fits, headache, and a nerve disorder called peripheral neuropathy. Several common side-effects are explained in more detail below.

Gastrointestinal effects

Velcade has been shown to cause diarrhoea, constipation, nausea and vomiting. Whilst usually mild to moderate and easily manageable, these side-effects can become problematic in some cases. It is important to ensure good fluid intake and maintain a balanced diet. Your doctor may prescribe specific medication, which can help control your symptoms.

Thrombocytopenia

Thrombocytopenia means that you have a low-level of **platelets** in your blood. Platelets are blood cells that help the blood to clot. If the platelet count drops too far, it can cause bleeding.

Whilst being treated with Velcade, your platelet count may drop during the dosing days (days 1, 4, 8 and 11) but should rise again during the treatment break (days 12 to 21).

If your platelet count gets too low your doctor may give you a platelet transfusion.

Your blood count will be monitored regularly, but you should watch out for signs of bleeding such as easy bruising and nose bleeds – tell your doctor straightaway if this happens.

Fatigue

Fatigue can occur quite commonly whilst receiving Velcade. The fatigue may be a result of **anaemia** (a low red blood cell count), which can be managed with blood transfusions or a growth hormone called **erythropoietin (EPO)**. Fatigue can also be managed through proper rest, nutrition, hydration and regular gentle exercise.

Low blood pressure

If you have a history of hypotension (low blood pressure), or are on drugs to help lower your blood pressure, you may need your medication altered whilst having Velcade treatment. Ensuring a good fluid intake can help prevent hypotension whilst being treated with Velcade.

Peripheral neuropathy

Peripheral neuropathy means that the nerves in the hands, feet, arms or legs are damaged. This can cause numbness, tingling, increased sensitivity and pain.

Neuropathy can be caused not just by Velcade but also by other myeloma treatments, such as thalidomide and vincristine, as well as by the disease itself. These can all contribute to any peripheral neuropathy symptoms caused by Velcade.

Symptoms such as numbness, tingling and pain should be reported to your doctor or medical team as soon as possible. The best way to manage peripheral neuropathy is to reduce the dose of Velcade.

In the majority of cases symptoms will improve or disappear after the dose of Velcade is reduced. This is why it is important to tell your doctor about any symptoms promptly.

Velcade may need to be temporarily stopped or, in more severe cases, discontinued and other options discussed.

Pain and discomfort can be alleviated by gentle massage, taking warm baths, using heat / cold packs and paying attention to posture. Nerve-related pain often requires specific pain-killing drugs which can be prescribed and monitored by your doctor.

Other interventions which have been reported to help symptoms of neuropathy included nutritional supplements such as vitamin B, folic acid and various amino acid supplements. However, these are not established treatments and should be discussed with your doctor.

A series of English-language Infosheets on Diet and Nutrition, Fatigue and Peripheral Neuropathy can be ordered through Myeloma UK (see page 24 for details).

Questions for your doctor / medical team

It can be helpful to write down your questions and give a copy to your doctor at the start of your consultation. Consider asking a trusted person to go along with you to the appointment.

You might want to carry a piece of paper with you so you can make a note of questions as they occur to you.

Some questions you may need answered include:

- Would Velcade help me?
- What are the aims of treatment with Velcade?
- Are there any alternative treatments?
- Is Velcade appropriate for me to take at this stage of my disease?
- How experienced are you and your team in using Velcade?

- How long might I be on Velcade?
- What side-effects might I expect?
- What should I do if I experience any side-effects?
- Which side-effects should I report urgently and to whom?
- Is Velcade being given to me as part of a clinical study?
- What options are available if Velcade does not help or stops working?

When discussing treatment options, also ask about specific instructions for using drugs; contraindications; what to do in case of intolerance; other treatment options; clinical trials; the option to sit and wait to see what happens; additional treatment or care options (e.g., psycho-oncological care).

Make sure you have received answers to all of your questions and ask for a copy of your medical results.

Don't forget to take notes or ask the person who is with you to do that for you. Always ask if there is something that you don't understand. You have the right to medical information that is explained to you in a way you can understand.

If there wasn't enough time, ask for a second appointment to follow this up. Ask for any supplementary information they may have on the things you have discussed.

Always consider getting a second opinion if you are not satisfied and tell your doctor about it. Professional doctors will not have an issue with this.

Be realistic and don't let anyone push you towards a certain treatment. Take your time and make sure you take an informed decision that really suits your needs.

Medical terms explained

Anaemia: A below-normal number of red blood cells in the blood. This reduces the ability of the blood to supply oxygen to the body, causing fatigue and weakness.

Chemotherapy: The treatment of cancer with drugs that kill all rapidly dividing cells. Chemotherapy can be injected into a vein (intravenous or IV) or swallowed as tablets (orally).

Clinical study: A research study of new treatment that involves patients. Each study is designed to find better ways to prevent, detect, diagnose, or treat disease and to answer scientific questions.

Erythropoietin (EPO): A hormone produced by the kidneys. Myeloma patients with damaged kidneys don't produce enough erythropoietin and can become anaemic. Injections with synthetic erythropoietin can be helpful. Blood transfusion is another alternative, especially in an emergency.

Platelets: Platelets are a type of blood cell which is integral to the normal clotting mechanism of blood.

Refractory disease: Refractory disease is disease that has failed to respond to previous treatments.

Relapse: Relapsing disease is disease that has responded to prior treatment but is showing signs of returning.

Side-effects: Problems that occur when treatment affects healthy cells. Common side-effects of standard cancer treatments are fatigue, nausea, vomiting, decreased blood cell counts, hair loss and mouth sores. New treatments being tested may have these or other unknown side-effects.

About Myeloma Euronet

Myeloma Euronet, a non-profit network organization of multiple myeloma patient groups, is a European initiative dedicated to raising the awareness of multiple myeloma, an increasingly common form of bone marrow cancer.

Myeloma Euronet provides information on the diagnosis, treatment and care of persons living with multiple myeloma and supports its member organisations in the fulfilment of their mission.

Myeloma Euronet also advocates, independently and in collaboration with organisations with similar objectives, on behalf of those affected by multiple myeloma.

The goals of Myeloma Euronet are to:

- Advocate the cause of myeloma among EU health care policy makers and share best practice in shaping appropriate policies at the European level
- Raise European awareness of multiple myeloma amongst relevant stakeholders and the public
- Provide information on appropriate diagnosis, treatment, care and support for myeloma patients and their families
- Build partnerships among members of Myeloma Euronet in order to share experience and expertise
- Encourage the growth of new multiple myeloma patient groups throughout Europe, especially in cities and countries where they are not now found

Myeloma Euronet was launched at the 10th Congress of the European Hematology Association (EHA) in Stockholm on 3 June 2005. It is an international non-profit association (Association Internationale sans but lucratif, AISBL) registered in Belgium:

rue de Dampremy, 67/32

B-6000 Charleroi

Belgium Registration number: 883.729.287

Myeloma Euronet's Secretariat is located in Berlin, Germany.

Myeloma Euronet has members in 20 European countries and is a member of the European Cancer Patient Coalition (ECPC), the European Cancer Organisation (ECCO) and the European Organisation for Rare Diseases (Eurordis). More information about Myeloma Euronet can be found on our multi-lingual, award-winning Web site at www.myeloma-euronet.org. This Web site is available in the following languages: Arabic (in part), Czech, English, French, German, Greek, Italian, Polish, Portuguese, Romanian, Russian, Spanish and Turkish.

The Web site also provides a wealth of information about myeloma as well as useful links to other support organisations, a list of events, a quiz, surveys, and many other useful resources.

We need your help!

Myeloma Euronet relies heavily on voluntary donations and fundraising to support our much needed projects and services. If you would like to support us in our efforts, we would be very grateful if you could make a donation by using the bank information given below or let us know if there is any other way for you to help us.

This could be, e.g. by helping us translate our Web site into more languages, assisting us in our fundraising efforts, covering the design and/or printing of information materials on multiple myeloma, providing a travel grant for one of our members to attend a Myeloma conference or Infoday, etc. If you have an idea for a fundraising event, or have any questions, please don't hesitate to get in touch – we'd love to hear from you!

Donate by bank transfer

Our bank information is:

Account number: 1937013520

Bank code: 370 501 98

Sparkasse KoelnBonn

Germany

International Bank Account Number:

DE74 3705 0198 1937 0135 20

SWIFT-BIC.: COLSDE33

Donate by post

If you would like to donate by post, send your donation to:

Myeloma Euronet Secretariat

c/o Robert Schaefer

Brunnenstrasse 178/179

D-10119 Berlin | Germany

You can send a cheque or postal order payable to 'Myeloma Euronet' for the amount you wish to donate.

Thank you for your support!

Myeloma patient organisations in Europe

Austria

Myelom- und Lymphomhilfe Österreich
Josef Mayburgerkai 54
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selbsthilfe@myelom.at | www.myelom.at

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Croatia

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Dansk Myelomatose Forening
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AF3M
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Germany

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Portugal

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заболеваниями»
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Slovenská myelómová spoločnosť – klub pacientov
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851 07 Bratislava
klub.pacientov@myelom.sk | www.myelom.sk

Slovenia

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modic.kristina@gmail.com

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AEAL - Asociación de afectados por Linfomas, Mielomas y Leucemias
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28006 Madrid
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From outside the UK: +44 131 557 3332 (charged at normal rate)
myelomauk@myeloma.org.uk
www.myeloma.org.uk

If you are aware of myeloma patient organisations in other European countries, please let us know.



MYELOMA
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**Myeloma Euronet – The voice of
myeloma patients in Europe**