



My treatment with REVLIMID[®] (lenalidomide)

**along with bortezomib and dexamethasone in newly diagnosed
multiple myeloma**

Contents

	Page
Your dosing calendar	1
Notes	3
What is multiple myeloma?	4
Why have I been prescribed REVLIMID®, bortezomib and dexamethasone?	9
Before starting treatment	12
Dosing regimen	13
While on my treatment	16
What side effects should I watch out for?	17
Achieving the best from my treatment	24
Safety and support - <i>i-access</i> ® program	27
Where can I find more information?	33
Additional information	35
Glossary	40

Note: Terms shown in **blue** throughout this booklet are explained in the glossary on page 40.

Dosing calendar

Initial therapy

In the calendar below, your doctor or nurse will mark up the days on which you will need to take your medication.

R = REVLIMID® (lenalidomide) [dose: _____] V = Velcade® (bortezomib) [dose: _____]
D = dexamethasone [dose: _____] I am on a _____ -day treatment cycle.

Day 1		Day 2		Day 3		Day 4	
R	D	R	D	R	D	R	D
V		V		V		V	
Day 5		Day 6		Day 7		Day 8	
R	D	R	D	R	D	R	D
V		V		V		V	
Day 9		Day 10		Day 11		Day 12	
R	D	R	D	R	D	R	D
V		V		V		V	
Day 13		Day 14		Day 15		Day 16	
R	D	R	D	R	D	R	D
V		V		V		V	
Day 17		Day 18		Day 19		Day 20	
R	D	R	D	R	D	R	D
V		V		V		V	
Day 21		Day 22		Day 23		Day 24	
R	D	R	D	R	D	R	D
V		V		V		V	
Day 25		Day 26		Day 27		Day 28	
R	D	R	D	R	D	R	D
V		V		V		V	

I will receive Velcade® (bortezomib) treatment at: _____

Dosing calendar

Ongoing therapy

In the calendar below, your doctor or nurse will mark up the days on which you will need to take your medication.

R = REVLIMID® (lenalidomide) [dose: _____]

Day 1	Day 2	Day 3	Day 4
R	R	R	R
Day 5	Day 6	Day 7	Day 8
R	R	R	R
Day 9	Day 10	Day 11	Day 12
R	R	R	R
Day 13	Day 14	Day 15	Day 16
R	R	R	R
Day 17	Day 18	Day 19	Day 20
R	R	R	R
Day 21	Day 22	Day 23	Day 24
R	R	R	R
Day 25	Day 26	Day 27	Day 28
R	R	R	R

Dexamethasone may or may not be needed as continuing treatment after your initial treatment. If dexamethasone is prescribed, then you will need to take it on the following days: _____

Notes

My doctor's name is:

Contact details:

My nurse's name is:

Contact details:

**Important
information about
my REVLIMID®
treatment:**

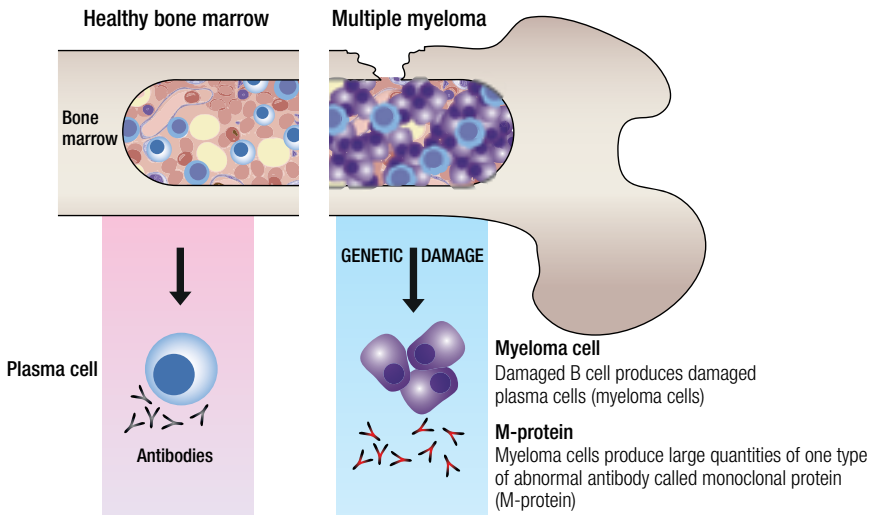
What is multiple myeloma?

Multiple myeloma is a **cancer** of the **plasma cells** in the blood. Plasma cells are **white blood cells** that originate and collect in the **bone marrow** – the soft, spongy, inner core of the bones. Plasma cells produce **antibodies**, which help the **immune system** recognise and fight infections.

Multiple myeloma occurs when genetically damaged plasma cells – called **myeloma cells** – are produced. The myeloma cells collect in the bone marrow, where they continue to divide and multiply in an uncontrolled way. The condition is called ‘multiple’ myeloma because it typically affects multiple sites in the body.

While there is no cure for multiple myeloma, symptoms can be decreased, and in some cases, symptoms can be controlled for a period of time, if they are well managed with continuing treatment and/or monitoring.

Multiple myeloma is a cancer of the cells that make antibodies, the proteins that help your body recognise and fight infections

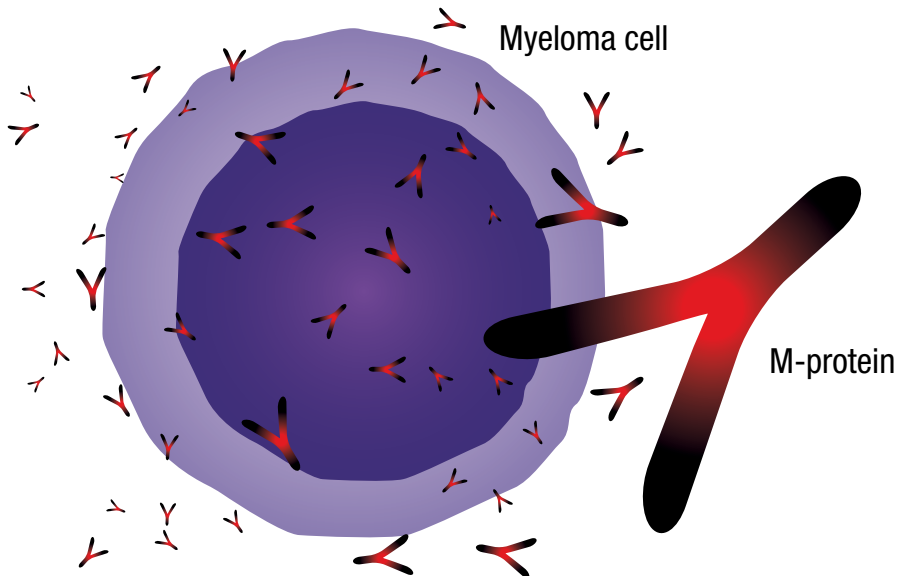


What is M-protein?

Myeloma cells produce an abnormal type of antibody called **M-protein** (also known as paraprotein).

Unlike normal antibodies, M-proteins cannot fight infection. As myeloma cells continue to divide and multiply, the cells 'crowd out' normal healthy plasma cells and reduce the body's ability to fight infections. As a result, people who have multiple myeloma are at an increased risk of infections, some of which can be serious (e.g. pneumonia).

Myeloma cells can also cause damage to the bones (leading to development of bone pain and/or fractures) and the kidneys.



Myeloma cell producing abnormal antibody, also known as M-protein

Who is affected by multiple myeloma?

Multiple myeloma becomes more common as people age. It is most often diagnosed in people aged 65–70 years. However, recent studies indicate that the number of people with multiple myeloma is increasing, and that it is occurring more often in younger people. Multiple myeloma occurs slightly more often in men than in women. To date, no cause for multiple myeloma has been identified. However, there are certain factors that may put some people at a higher risk of developing the disease. These include exposure to chemicals, pollutants, radiation or other environmental risk factors.

What are the symptoms of multiple myeloma?

One of the difficulties in diagnosing multiple myeloma is that its symptoms are varied and may be confused with those of other diseases. Some people may have no symptoms at all and the disease may be discovered only through routine physical examination. Early symptoms associated with multiple myeloma include:



Bone pain



Unexplained bone fractures



Unexplained weight loss



Frequent infections



Tiredness



Abnormal kidney function

How is multiple myeloma diagnosed?

In order to diagnose multiple myeloma, several tests and investigations are needed. The initial evaluation to confirm a diagnosis of multiple myeloma includes blood and urine tests as well as tests on bone and bone marrow.

Other tests may include X-rays, **magnetic resonance imaging (MRI)**, **computed tomography (CT)** and **positron emission tomography (PET)** scans. Having all of the appropriate multiple myeloma tests done is very important, because the results will help your doctor to assess the extent of the disease and to plan and monitor treatment.

Treatment for multiple myeloma

Treatments for multiple myeloma can be very effective at slowing its progress, controlling the symptoms, and improving quality of life, but they are not able to cure it. Multiple myeloma tends to follow a relapsing disease course.

With the help of therapy, most people achieve **remission** (a decrease in or low level of symptoms). However, at some point, symptoms can return and the disease is likely to eventually **relapse**.

What is an autologous stem cell transplant?

An autologous **stem cell** transplant (ASCT) is a procedure whereby healthy cells are taken from your own body and transplanted back following chemotherapy. Chemotherapy kills myeloma cells as well as good, healthy cells. This allows for use of high-dose chemotherapy to destroy myeloma cells, without depleting the healthy cells.

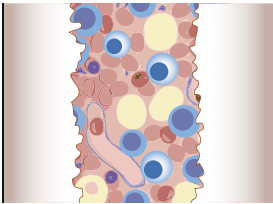
Your doctor will discuss if you are suitable for ASCT.

What is residual disease?

Residual disease is the name given to small numbers of myeloma cells that remain in the bone marrow even when a person is in remission. Residual disease is a major cause of relapse in multiple myeloma.

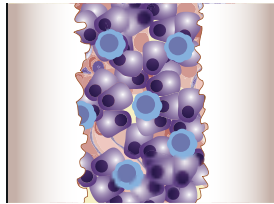
Some studies have shown that continuing to take multiple myeloma medication even when in remission can delay relapse by controlling the residual disease.

Healthy bone marrow



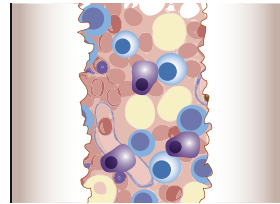
- Plasma cells function normally
- No M-protein

Bone marrow in multiple myeloma



- Myeloma cells crowd out healthy plasma cells
- Significant M-protein produced

Residual disease



- Some myeloma cells remain
- Contributes to relapse

Why have I been prescribed REVLIMID[®], bortezomib and dexamethasone?

Introduction to your medication

Your doctor has given you this booklet to help you navigate through your new treatment plan, which consists of a combination of three medicines, REVLIMID[®], Velcade[®] (bortezomib) and dexamethasone. The combination of these three drugs is often called RVD or VRd.

This three drug combination is given at the start of your treatment for multiple myeloma and can be given to previously untreated, newly diagnosed patients who may or may not receive a stem cell transplant later. This combination is administered for at least 24 weeks to give you a strong start to your fight against myeloma (further details on what comes after this treatment on page 13).

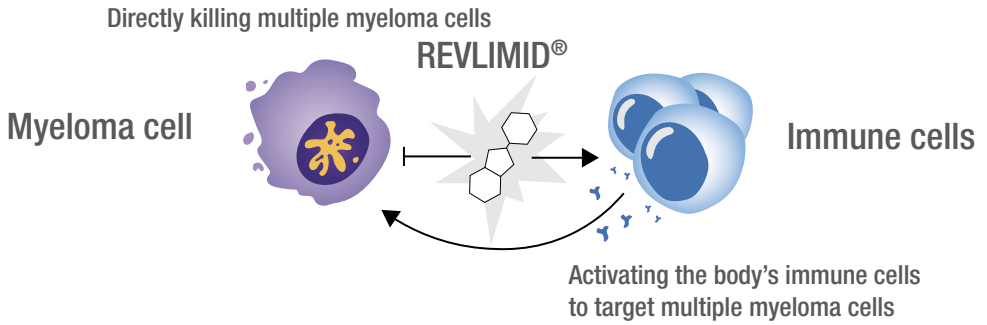
In the following sections we will explain how each of these drugs help your body fight against multiple myeloma.

REVLIMID[®]

REVLIMID[®] is the brand name of a medication called **lenalidomide**.

REVLIMID[®] belongs to a group of medicines called **immunomodulating agents** that work by acting on the cells involved in the body's immune system. REVLIMID[®] contains an active substance called lenalidomide.

REVLIMID[®] works in multiple ways within the bone marrow to stop or slow the growth of cancerous myeloma cells. One of the ways it works is by stimulating your own immune system to fight myeloma. It also works directly to kill the myeloma cells.

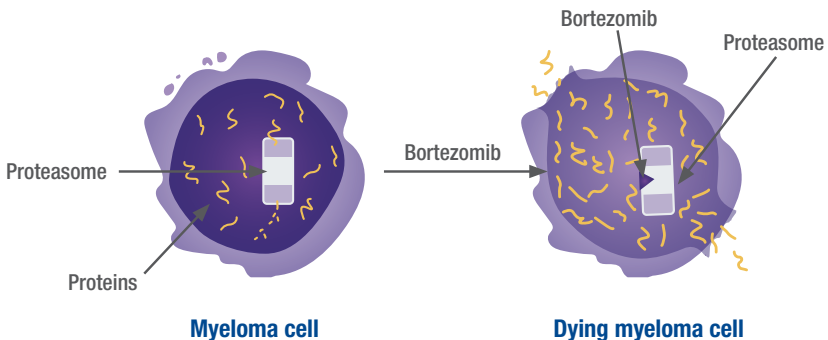


Bortezomib, also known as Velcade[®]

Bortezomib is a chemotherapy medicine that kills myeloma cells. Bortezomib will be given to you as an injection by a doctor or nurse experienced in its administration. Ask your doctor, nurse or pharmacist if you have any additional questions about bortezomib.

How does bortezomib kill myeloma cells?

- Cells have tiny structures inside them called proteasomes that act like garbage disposals, digesting proteins that are damaged or not needed within cells
- Myeloma cells are more dependent on proteasomes than normal cells
- Bortezomib stops proteasomes from digesting proteins within cells
- The build-up of unwanted proteins within cells can lead to cell death



For more information, please access the Bortezomib CMI

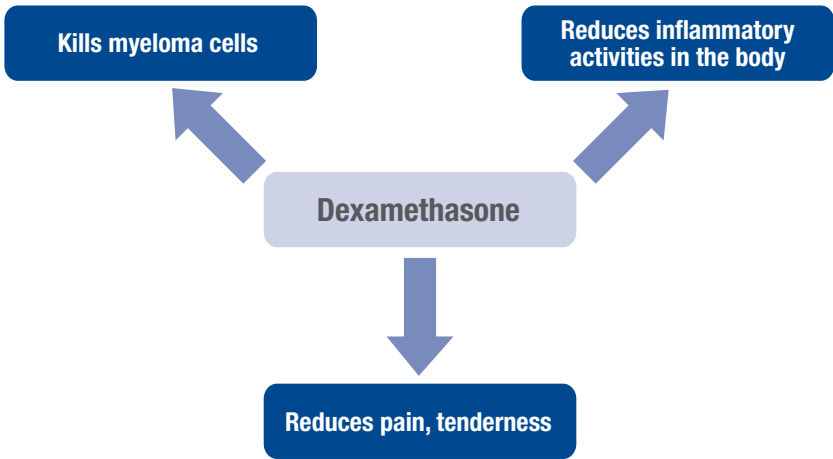
Dexamethasone

Dexamethasone belongs to a group of medicines called corticosteroids, which are synthetic versions of a naturally occurring hormone called cortisol.

It is used to prevent or reduce the symptoms of inflammation (such as swelling, redness, pain, tenderness or itching) in any part of the body.

It works by acting on the immune system and blocking the production of substances that trigger allergic and inflammatory actions.

Ask your doctor, nurse or pharmacist if you have any additional questions about dexamethasone.



To manage your multiple myeloma, it is important that you stay on your treatment plan provided by your doctor and take your combination treatment exactly as instructed.

Before starting treatment

How do I take REVLIMID®?

Your doctor will tell you how much REVLIMID® to take and for how long you will need to take it.



REVLIMID® comes in the form of gelatin capsules, which are taken orally (swallowed whole) with water once a day. Do not break, chew, crush or open the capsules



REVLIMID® should be taken on an empty stomach at least 1 hour before, or 2 hours after food



It does not matter what time of day you take REVLIMID®, but it is recommended that you take it at the same time each day

How do I take bortezomib?

Bortezomib is administered by your nurse or doctor by injection.

When bortezomib is given with REVLIMID®, it is administered on days 1, 4, 8 and 11 followed by a 10 day break from the treatment.

Therefore, one cycle of treatment with bortezomib may consist of a total of 4 doses given over 3 weeks.

How do I take dexamethasone?

Your doctor will tell you how many tablets you will need to take and how often to take them.

Dosing regimen

Example dosing chart

If you have any doubt about your dosing regimen, please contact your doctor or pharmacist immediately to clarify the right dosage for you

The tables below indicate the dosing that some myeloma patients on REVLIMID[®], bortezomib and dexamethasone treatment receive. Your doctor will prescribe the most suitable dose for your condition.

Initial therapy (up to 24 weeks)

	REVLIMID [®]	Bortezomib	Dexamethasone
Unless otherwise specified by your doctor	25 mg once daily on days 1–21 of 28-day cycles	1.3 mg/m ² on days 1, 4, 8 and 11 of 28-day cycles*	20 mg, once daily, on days 1–4 and 9–12 of 28-day cycles

OR you may be started on

	REVLIMID [®]	Bortezomib	Dexamethasone
Unless otherwise specified by your doctor	25 mg once daily on days 1–14 of 21-day cycles	1.3 mg/m ² on days 1, 4, 8 and 11 of 21-day cycles*	20 mg once daily on days 1, 2, 4, 5, 8, 9, 11 and 12 of 21-day cycles

*This dose will be calculated and administered to you by a doctor or nurse who is experienced at giving bortezomib.

Following the above, based on your physical condition, your doctor may proceed with:

Stem cell transplantation approach

This approach comprises of a combination of autologous stem cell transplantation (see page 8 for description) followed by continuous REVLIMID[®] maintenance therapy taken over cycles of 28 days:

- REVLIMID[®]: 10 mg, oral, once daily, on days 1–28

The dose may be modulated based on your tolerance. Your doctor will monitor your tolerance and advise how long you need to continue this treatment for.

Following the previous page, based on your physical condition, your doctor may alternatively proceed with:

Continued therapy approach

This approach comprises of a combination of two oral therapies. REVLIMID® and dexamethasone taken over cycles of 28 days:

- REVLIMID®: 25 mg, oral, once daily, on days 1–21
- Dexamethasone: 40 mg, oral, once daily, on days 1, 8, 15 and 22

Your doctor will monitor you closely and confirm if the above dosing is correct for you. They will also advise you how long you need to continue these cycles for.

What if I miss a dose of the above treatments?

If you forget to take your dose:

REVLIMID®	Dexamethasone
<ul style="list-style-type: none">• If it is less than 12 hours before your next dose, skip the dose you missed and take the next dose when you are meant to• Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally	<ul style="list-style-type: none">• Take the missed dose as soon as possible, then go back to your regular dosing schedule• If you do not remember until the next day, skip the missed dose and take the next dose as planned

- *Do not take a double dose to make up for the dose you missed*
- *If you are not sure what to do, ask your doctor or pharmacist*

Storing and handling my treatment



Never give REVLIMID® to another person



Keep your capsules in the original packaging until it is time to take them



Store your capsules in a known location to avoid misplacing or losing them



Store REVLIMID® in a cool and dry location (below 25°C)



Store dexamethasone in a cool and dry location (below 30°C)



Return any unused capsules to your pharmacist at the end of your treatment



Keep your capsules out of reach of children

While on my treatment

What tests will I need while I am taking this treatment?

Regular monitoring and follow-up will be an important part of your treatment. This allows your doctor to assess how well your treatment is working and also to check for evidence of potential side effects. Two of the most common tests are the **full blood count** (FBC) and M-protein tests.

Full blood count

An FBC is used to measure how many different types of cells are in your bloodstream. Your doctor can use FBCs to help diagnose multiple myeloma; however, the diagnosis cannot be made from an FBC alone.

Decisions to interrupt and/or reduce your dose of REVLIMID® will be based on the results of these blood tests, as well as the severity of any other symptoms or side effects you may be experiencing.

M-protein tests

Doctors generally classify multiple myeloma according to symptoms and the extent to which the disease has progressed. In multiple myeloma, one of the ways of determining the activity of the disease is through M-protein tests.

M-protein is the abnormal type of antibody produced by myeloma cells. The levels of M-protein in the blood or urine are a measure of how active the disease is in the body. An abnormal increase in M-protein level is commonly known as an **M-spike**.

In rare cases of multiple myeloma, known as non-secretory myeloma, the myeloma cells produce little or no M-protein. Although this can make it more difficult to diagnose and monitor multiple myeloma, there are highly sensitive tests available, such as serum-free light chain (SFLC) testing, which can help diagnose and monitor the condition.

What side effects should I watch out for?

Like all medicines, REVLIMID[®], bortezomib and dexamethasone can have side effects. Some of these effects may be serious; however, there may be ways to reduce the discomfort of these effects. You may need medical treatment if you get some of the side effects.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with REVLIMID[®], bortezomib and dexamethasone.

Potential side effects

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

REVLIMID®

Tell your doctor if you notice any of the following and they worry you:

Mouth or stomach symptoms

Diarrhoea, constipation, feeling sick (also called nausea), vomiting, stomach pain, indigestion, dehydration, dry mouth, sore mouth: mouth ulcers: difficulty in speaking, toothache, increase or decrease in weight, increase or decrease in appetite, loss of taste.

Skin symptoms

Itchiness, rash, redness of the skin, dry skin, bruising, excessive sweating.

Weakness symptoms

Dizziness, fainting, headache, shaking or tremors, unusual weakness, night sweats, reduced sense of touch.

Mood-related symptoms

Difficulty sleeping, depression, anxiety, feeling of confusion.

Pain and swelling symptoms

Back pain, muscle spasms, muscle and/or joint pain, swollen joints, bone pain, muscular weakness, pain in the extremities, feeling tired, fall, swelling of hands, ankles or feet.

Tell your doctor immediately if you notice any of the following:

Respiratory symptoms

Heart palpitations or fast heart beat, chest pains, dizziness or fainting, shortness of breath, weakness, or reduced ability to exercise.

Bleeding symptoms

Bleeding (including nosebleeds) or bruising more easily than normal.

Tiredness symptoms

Tiredness, headaches, shortness of breath, dizziness and looking pale.

Numbness symptoms

Numbness, tingling, pins and needles or weakness of the arms and legs.

Thirst symptoms

Passing large amounts of urine, excessive thirst, and having a dry mouth and skin.

Tenderness symptoms

Tender swollen lymph nodes, low-grade fever, pain, or rash.

Convulsion symptoms

Abnormal eye movements, convulsions, mood changes or irregular heart rhythms.

Vision related symptoms

Blurred vision or difficulty seeing.

See a doctor immediately or go to Emergency at your nearest hospital if you notice any of the following:

Allergy symptoms

Shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, mouth, tongue or other parts of the body; rash, itching or hives on the skin.

Symptoms with increased severity

Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals; painful red area on the skin that spreads quickly; peeling of the skin; high temperature, chills and muscle ache at the same time.

Other symptoms

Blurred vision; severe headache; weakness or numbness in the face, arm or leg; trouble speaking or understanding; loss of balance.

Chest pain, severe weakness, rapid or irregular heartbeat, and/or sudden, severe shortness of breath and coughing up pink, foamy mucus; fever; severe chills; decreased urination; rapid pulse; rapid breathing; confusion; nausea; vomiting; diarrhoea; pain or burning when you urinate; hacking cough; phlegm; sore mouth or throat; flu-like symptoms; feeling of tension in the nose, cheeks and behind your eyes; or mouth ulcers.

Pain or swelling in your legs, especially in your lower leg or calves.

Abdominal pain, dark urine, fever, joint pain, loss of appetite, nausea and vomiting, yellowing of the skin and/or eyes.

Potential side effects

Bortezomib

Tell your doctor if you notice any of the following:

Tiredness, generally feeling unwell, weakness, headache, hair loss.

Feeling sick (nausea) or vomiting, diarrhoea, constipation, loss of appetite, and/or weight, fear of gaining weight, belching after eating, stomach pain, bad taste in mouth.

Sensitivity, numbness, tingling or burning sensation, pins and needles, unpleasant sensations, blurred vision.

Bleeding or bruising more easily than normal, anaemia (a condition in which there is a decreased number of red blood cells).

Frequent infections (with symptoms such as fever, severe chills, sore throat or mouth ulcers), herpes virus or hepatitis infections or pneumonia.

Aching muscles, painful swollen joints, muscle tenderness or weakness not caused by exercise pain in your limbs, back pain, bone pain, muscle cramps.

Trouble sleeping, sweating, anxiety, mood swings, confusion or depression.

Swelling (around the eyes or in the ankles, wrists, arms, legs or face).

Cough, difficulty in breathing, dizziness, dehydration, chest pain, low or high blood pressure.

Rash, itching, redness of the skin or redness and pain at injection site, or any allergic reaction.

Potential side effects

Dexamethasone

Tell your doctor if you notice any of the following:

An increased seriousness or frequency of infections, bleeding or bruising more easily than normal.

Skin thinning, itchy rash, unusual bleeding or bruising under the skin, poor wound healing, increased sweating, red or purple streaks on skin, acne or extra hair growth.

Cataracts, eyes sticking out too far, decreased or blurred vision.

Mood changes, anxiety or nervousness, trouble sleeping, restlessness.

Headache, nausea or vomiting, dizziness, indigestion, stomach pain or discomfort, diarrhoea or constipation, increased or reduced appetite , bloating or rounding of the face or water retention.

Cramps or weakness in the muscles of the arms and legs, irregular heart beat, irregular menstrual periods.

Tell your doctor immediately or go to Emergency at your nearest hospital if you notice any of the following symptoms with your bortezomib or dexamethasone treatment:

Severe stomach or intestinal pain, rash, itching or hives on the skin.

Sudden changes in your vision.

Shortness of breath, wheezing or difficulty breathing.

Bleeding or bruising more easily than normal.

Major psychiatric or personality changes, fits.

Symptoms such as severe dizziness, fainting, weakness, chest pain or irregular heartbeat.

Swelling of the face, lips, mouth, tongue or throat that may cause difficulty in swallowing or breathing.

Achieving the best from my treatment

There are many things you can do to help achieve your treatment goals and continue getting the most out of life.



Continue taking your treatment until your doctor tells you to stop.



Remain on the lookout for new or old symptoms, as well as signs of any side effects.



Tell your doctor immediately about any changes to your condition or how you feel.



Ensure you always have a supply of your medication and remember to take it every day – if you sometimes forget, try setting a reminder or putting a note somewhere that you will see it.



Look after your health by eating a nutritious diet, doing regular gentle exercise, getting enough rest and reducing stress.



Communicate regularly with your doctor and healthcare team and never be afraid to ask questions about your illness or its treatment.



Seek support from relevant associations and patient groups (some suggested sources are listed on page 33 of this booklet).

You should never skip doses, change or stop your treatment without first talking to your doctor.

Other important considerations

REVLIMID®

Some important considerations for REVLIMID® treatment are described in detail in the following section on Safety and Support (from pages 28–32).

Please ask your doctor or pharmacist if you have any questions.

Bortezomib

- **Check with your doctor immediately** if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or experience painful or difficult urination.
 - Avoid people who have infections.
- **Be careful** when using a toothbrush, toothpick or dental floss.
 - Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.
- **Be careful** not to cut yourself when using sharp objects such as a razor or nail cutters.

Dexamethasone

- **Do not stop** taking dexamethasone or lower the dosage without checking with your doctor.
- **Do not have any immunisations** while you are taking dexamethasone without your doctor's approval.
 - Dexamethasone may reduce the effectiveness of live vaccines.
- **Avoid close contact** with anyone who has a contagious disease such as chicken pox or measles.
 - Exposure to such diseases while you are taking dexamethasone can put you at greater risk of developing these diseases if you have not had them before.
- **Tell any other doctors, dentists and pharmacists** who are treating you that you are taking dexamethasone, especially if you are being started on any new medicines.
- **Tell your doctor immediately** if you are diabetic and if you notice any change in your blood or urine sugar readings.

While you are receiving REVLIMID[®], bortezomib and dexamethasone, tell your other doctors, dentist or pharmacist if:

- *You are on other treatments, including, vitamins, herbal supplements or over the counter medicines*
 - *You are about to start on any new medicines*
 - *You plan to have surgery*
 - *You become pregnant or your partner becomes pregnant*
- *Keep all of your doctor's appointments so that your progress can be checked.*

Safety and support - *i-access*[®] program

REVLIMID[®] belongs to a group of drugs known as immunomodulatory drugs, or IMiDs. The following information is important for anyone receiving an IMiD for their treatment. If an IMiD is taken during pregnancy, it may cause birth defects or death to an unborn baby. To avoid exposure to unborn babies, IMiDs are available only under the *i-access*[®] program.

The *i-access*[®] program ensures that use and distribution of REVLIMID[®] is closely monitored and well controlled, and ensures that patients are fully informed about their treatment and – most importantly – that they take all necessary steps to avoid foetal exposure to REVLIMID[®].

Patients receiving REVLIMID[®] have the ability to nominate a local pharmacy to replenish their stock through the *i-access*[®] program.

Only patients who are formally enrolled in the *i-access*[®] program and agree to comply with all of the requirements of this program can receive REVLIMID[®]. For a full list of requirements and further information, please refer to the *i-access*[®] resource kit and Product Information.

i-access[®]

What are the requirements for patients enrolled in the *i-access*[®] program?

Special *i-access*[®] program requirements for women who are able to become pregnant*

Important: Do NOT become pregnant:

- During the 4 weeks before starting IMiD treatment
- While taking an IMiD
- During any interruption in IMiD treatment
- During the 4-week period following the conclusion of your IMiD treatment

Before starting treatment:

- You must sign an *i-access*[®] patient consent, agreeing not to become pregnant while taking an IMiD
- You must use at least one highly effective and, preferably, one additional effective form of birth control (contraception)[†] during the 4-week period before starting an IMiD
- You must have one negative medically supervised pregnancy test** confirmed by your doctor:
 - Either at the time of consultation, or in the 3 days prior to the visit to the doctor
 - The pregnancy test must be medically supervised and not a pregnancy test from a pharmacy

*Includes: women who are menstruating, amenorrhoeic due to previous medical treatment, < 50 years of age and/or peri-menopausal; women who have not been in natural menopause for ≥12 consecutive months. [†]Highly effective forms of birth control include intra-uterine device (IUD) (copper IUDs are not recommended), hormonal methods[†] (birth-control pills, injections, implants, ring), tubal sterilisation or partner's vasectomy (confirmed by 2 negative semen analyses). Additional effective forms of birth control include diaphragm, cervical cap or latex/polyurethane condom by her male partner. [†]For some IMiDs, progesterone only pills are recommended. Combined oral contraceptives are not recommended. Please ask your doctor which birth control method you should use. **Medically supervised means a test that has been conducted or overseen by a Healthcare Professional (HCP). Your HCP should refer to the relevant Product Information (Australia) or Data Sheet (New Zealand) for details of what type of pregnancy tests you should have. A test which is done at home without medical supervision is NOT acceptable.

During treatment:

- You must continue to use at least one highly effective and, preferably, one additional effective form of birth control (contraception)
- You must also undergo regular medically supervised pregnancy tests, regardless of whether continuous abstinence is practised:
 - Every 4 weeks during treatment

And

- The pregnancy tests should be performed on the day of the visit to the doctor or in the 3 days prior to the visit
- You must not breastfeed or donate blood[^]
- Never share, break, chew or open your IMiD capsules

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant or have sexual intercourse without using an effective means of birth control (contraception):

- Stop taking your IMiD immediately, tell your doctor straight away and have a pregnancy test

[^]In Australia, patients with myeloma are permanently excluded from donating blood.

For 4 weeks after treatment:

- You must continue to use at least one highly effective and, preferably, one additional effective form of birth control (contraception)
- You must continue the medically supervised pregnancy tests every 4 weeks, ensuring that a pregnancy test is conducted 4 weeks after stopping treatment
- You must not breastfeed or donate blood[^]

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant or have sexual intercourse without using an effective means of birth control (contraception):

- Tell your doctor immediately and have a pregnancy test
- If you experience any side effects, you should tell your doctor or pharmacist
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible

[^]In Australia, patients with myeloma are permanently excluded from donating blood.

***i-access*[®] program requirements for women who are NOT able to become pregnant**

Before starting treatment:

- You must sign an *i-access*[®] patient consent, indicating that you do not have the ability to have children
- This means that you are at least 50 years old and have been naturally postmenopausal for at least 12 months
- OR have premature ovarian failure confirmed by a specialist gynaecologist**
- OR have had your uterus removed ([hysterectomy](#))
- OR have had both ovaries removed
- OR have XY genotype
- OR have Turner Syndrome
- OR have uterine agenesis

During treatment and during treatment interruptions:

- You must not donate blood[^]
- Never share your IMiD capsules

For 4 weeks after treatment:

- You must not donate blood[^]
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible

Note: If you experience any side effects you should tell your doctor or pharmacist.

*Medically supervised means a test that has been conducted or overseen by a HCP. Your HCP should refer to the relevant Product Information (Australia) or Data Sheet (New Zealand) for details of what type of pregnancy tests you should have. A test which is done at home without medical supervision is NOT acceptable.

[^]In Australia, patients with myeloma are permanently excluded from donating blood.

i-access[®] program requirements for men

Before starting treatment:

- IMiDs are present in semen. You must therefore sign an *i-access*[®] patient consent agreeing to use a latex/polyurethane* condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy)

During treatment and during treatment interruptions:

- You must use a latex/polyurethane condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy)
- You must tell your doctor immediately if you have sexual intercourse with a woman without using a latex/polyurethane condom, or if you think for any reason that your partner may be pregnant
- You must not donate blood[^] or sperm
- Never share, break, chew or open your IMiD capsules

For 4 weeks after treatment:

- You must continue to use a latex/polyurethane condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy)
- You must tell your doctor if you have sexual intercourse with a woman without using a latex/polyurethane condom, or if you think for any reason that your partner may be pregnant
- You must not donate blood[^] or sperm
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible

Note: If you experience any side effects you should tell your doctor or pharmacist.

*If allergic to latex and polyurethane, any female sexual partner must use at least one highly effective and, preferably, one additional effective method of contraception. Please discuss with your doctor.

[^]In Australia, patients with myeloma are permanently excluded from donating blood

Where can I find more information?

Never be afraid to ask your doctor if you have any questions or concerns regarding your illness and/or its treatment, or if you simply want to know where you can go for more information; they will always be your most reliable source of information and advice.

For tips or advice about how to prevent or minimise treatment-related side effects, speak to your doctor or other members of your healthcare team who are involved in your treatment (e.g. nurse or pharmacist).

Further information about REVLIMID[®] and/or the *i-access*[®] program can be obtained by calling Celgene, a Bristol Myers Squibb Company's Customer Service on 1800 235 4363 and follow the auto-prompt.

Useful contacts

Myeloma Australia

Supports and provides information to those affected by myeloma, while advocating for availability of best treatment and supporting research.

The support line is manned by specialist myeloma nurse supporting patients diagnosed with myeloma.

Support line: 1800 MYELOMA (1800 693 566)

Web: www.myeloma.org.au

Leukaemia Foundation

Can provide support from qualified health professionals, transport to most metropolitan treatment centres, accommodation for regional patients receiving treatment in metropolitan centres, as well as practical support.

Tel: 1800 620 420 | Web: www.leukaemia.org.au

Cancer Council of Australia

Provides a wide range of information and support programs for people affected by cancer, including myeloma

Helpline: 13 11 20

Web: www.cancer.org.au

Cancer Institute NSW

Provides a wide range of information and support programs for people affected by cancer

Tel: (02) 8374 5600

Web: www.cancerinstitute.org.au

National Prescribing Service (NPS)

Provides a wide range of information and support programs for people affected by cancer

Tel: 1300 MEDICINE (1300 633 424)

Web: www.nps.org.au

Lab Tests Online

A public resource on clinical lab testing from the laboratory professionals who do the testing

Web: www.labtestsonline.org.au

Additional Information

Information for friends, family members and carers

This section of the booklet is designed to be read by family members, friends and carers of people being treated with REVLIMID[®], bortezomib and dexamethasone.

This section contains some general information about ways in which you can help support your family member, friend or person you are caring for, during their treatment. Learning about the disease and treatment will help you understand what they may be experiencing.

There are many ways for you to be supportive, such as helping out with the housework, giving medication reminders, or providing a shoulder to lean on. Remember, it's also important to look after yourself during this challenging time – staying healthy and making time for yourself will help you to be better able to provide support.

What are some practical ways in which I can help?



Understand their condition

Reading about multiple myeloma and its treatment will help you to better understand what your family member/friend is experiencing. Attending medical appointments with them is also a great support, as well as an opportunity to ask questions.

Visit the following websites to learn more:

- www.myeloma.org.au
- www.leukaemia.org.au



Learn about their medications

Become familiar with what each medication does, when it must be taken, and when prescriptions need renewing (using a diary can help). If they don't always remember to take their medication, you can discuss strategies to remind them, such as setting an alarm or leaving a note somewhere they'll see it every day.



Be aware of side effects

A very important way for you to help is by keeping an eye out for any side effects they may experience. If the patient experiences side effects, ensure they contact their doctor or medical team immediately.



Help with everyday jobs

Helping with tasks like cooking, shopping, gardening, housework, managing paperwork, such as paying bills, babysitting or driving them to appointments can make a big difference. You don't have to do it alone – you could coordinate a schedule or roster with other family members and friends who are eager to help.



Just be there for them

Don't underestimate the importance of simple things to show you care, like listening to what's on their mind and staying in touch. If they're feeling well enough, a great way to be supportive and help take their mind off their condition is to organise some 'normal' activities to do together, like seeing a movie, going out for dinner, or getting outside for some fresh air and exercise.

What are some tips for looking after my own wellbeing?

Caring for someone with multiple myeloma is challenging, and it can be easy to neglect your own wellbeing. But if you're not at your best, it will be difficult to provide the best care for someone else. So it's very important to make time for your needs – including your physical health, emotional wellbeing and social life. Below are some tips that may help.



Tips for physical health

- Try to eat 3 healthy, well-balanced meals per day
- Keep hydrated by drinking plenty of fluids
- Cut down on fatty foods, sugar, caffeine and alcohol
- Ensure you are getting adequate sleep
- Get regular, gentle exercise
- Take time to relax daily
- Don't forget to look after your own health.
- See your healthcare professional when needed



Tips for emotional wellbeing

- Be aware of signs of emotional distress (e.g. anxiety, depression, anger and stress), and seek professional help if required
- Do some exercise, deep breathing or relaxation techniques to relieve tension and clear your mind

- Find a regular hobby or take a class you're interested in
- Don't feel guilty about wanting or needing time away from your duties as a caregiver
- Take short breaks and arrange for alternate care, so you can feel secure and comfortable during your time away
- Talk to close friends or family about your feelings, or any changes in your mood they may have noticed
- Join a support group or online chat room with other caregivers who are in a similar situation (see page 33 for organisations that can help)
- Seek professional help if you're finding it difficult to cope



Tips for maintaining social relationships

- Reassure your family and friends that although you may not see them as often as you'd like, you do need and appreciate their support
- Share your experiences as a caregiver with them so they can try to understand what it's like for you, but also ask them about what's happening in their lives
- Accept invitations to social events, or invite people over to visit you at home
- Call or make plans to see people with whom you have lost touch
- Join a club or group activity

Glossary

Anaemia: A condition in which the number of red blood cells is below normal, resulting in fatigue or weakness

Antibodies: Proteins that fight infection

Bone marrow: The soft, sponge-like tissue in the centre of large bones that produces white blood cells, red blood cells and platelets

Cancer: A term for any disease in which damaged or abnormal cells divide and multiply uncontrollably

CT (computed tomography): An imaging technique that uses a computer to generate three-dimensional X-ray pictures

Full blood count (FBC): A test that measures the number and types of cells circulating in the blood

Gastrointestinal: Related to the digestive system

Hysterectomy: A surgical procedure in which the uterus is removed

Immune system: The complex group of organs and cells that defends the body against infection and disease

Immunomodulating agent: A substance that stimulates the immune system to help the body fight cancer.

Lenalidomide: The active ingredient in REVLIMID®; it works in multiple ways within the bone marrow to stop or slow the growth of cancerous myeloma cells

Maintenance therapy: An additional therapy that is given to improve the success of a primary cancer treatment, such as stem-cell transplantation

M-protein: A type of antibody made by myeloma cells; your doctor may test the level of M-protein in your blood and/or urine to monitor your disease and assess how well you are responding to treatment

M-spike: An abnormal increase in M-protein level

MRI (magnetic resonance imaging): An imaging technique that uses magnetic energy to provide detailed images of bone and soft tissue

Myeloma cells: Damaged plasma cells that are made in the bone marrow

PET (positron emission tomography): An imaging technique that uses radioactive glucose (sugar) to highlight cancer cells

Plasma cells: Special white blood cells that make antibodies

Platelets: The smallest cells in the blood, essential for blood clotting; also called thrombocytes

Relapse: The return of the disease or disease progression

Remission: Reduction or low level of symptoms

Residual disease: The term used for small numbers of cancer cells that remain in the bone marrow during treatment or after treatment when a patient is in remission

Stem cell: A cell that can develop into a wide variety of different cell types; stem cells can be found in bone marrow, where they develop into different types of blood cells

White blood cells: Cells that help the body to fight infection and disease



WARNING: Revlimid (lenalidomide) is structurally related to ‘thalidomide’, which is known to cause severe life-threatening human birth defects (deformed babies) and death to an unborn baby if taken during pregnancy. If Revlimid is taken during pregnancy, it may cause birth defects or death to an unborn baby. Do not take Revlimid if you are pregnant or think that you are pregnant.

Note: This booklet does not contain everything there is to know about multiple myeloma or its treatment, and is not intended to take the place of professional medical advice. Your primary source of information should always be your doctor and other healthcare providers who are involved in your care. You should follow your doctor’s instructions at all times and contact your doctor if you have any questions about your condition or its treatment.

For more information about Revlimid,
please refer to the Revlimid Consumer Medicine
Information (CMI) leaflet, which is available at:
<http://www.guildlink.com.au/gc/ws/celgene/cmi.cfm?product=cjcrevli>

Celgene Pty Ltd. ABN 42 118 998 771. Level 15, 60 City Road, Southbank VIC 3006, Australia.
Tel 1800 CELGENE (1800 235 4363)

www.celgene.com.au ®Registered Trademark. 2003-AU-2100024. BB-CEL4964. Date Prepared: May 2021.