



### About us

The Leukaemia Foundation is Australia's peak body for blood cancer, funding research and providing free services to support people with leukaemia, lymphoma, myeloma and related blood disorders.

We invest millions of dollars in the work of Australia's leading researchers to develop better treatments and cures and provide free services to support patients and their families.

We receive no ongoing government funding. We rely on the generosity of the community and corporate sector to further our Vision to Cure and Mission to Care.

### We can help you

Our range of free services supports thousands of Australians, from diagnosis, through treatment and beyond. To learn more, please call 1800 620 420 to speak with one of our Support Services team.

### You can help us

There are many ways that you can help us to improve the quality of life for people with blood cancer. From making a donation, to signing up for an event, from volunteering, or joining us as a corporate sponsor - please call 1800 500 088 or go to [www.leukaemia.org.au](http://www.leukaemia.org.au) to learn more.

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### What is Lenalidomide?

**Lenalidomide is an immunomodulatory drug (IMiD). This means that it works by modifying the immune system. Lenalidomide, which is related to thalidomide (Thalomid®) was approved in Australia in 2007 as a treatment for multiple myeloma which has progressed on another therapy. Lenalidomide is often combined with dexamethasone in the treatment of multiple myeloma. Lenalidomide is more potent than thalidomide in reducing myeloma cell production.**

In Australia the cost of lenalidomide is subsidised by the government under the Pharmaceutical Benefits Scheme (PBS) for patients with progressive myeloma after at least one other treatment (thalidomide must have been tried) and who have either received or are unable to receive a stem cell transplant.

#### How does lenalidomide work?

Although the exact mechanism of lenalidomide is yet to be fully understood, it has been shown to work in several ways to help control myeloma cell production by:

- Directly killing or stopping the growth of myeloma cells.
- Acting as an immunomodulatory agent, encouraging the immune system to attack and destroy myeloma cells. Immunomodulatory agents such as lenalidomide are able to induce immune responses and inhibit inflammation. They also enhance the activity of specialised white blood cells (T cells and natural killer cells) which help kill cancer cells.
- Inhibiting the growth of new blood vessels (angiogenesis). The restriction of blood vessel growth makes further tumour growth more difficult.
- Altering production and activity of cytokines, which are involved in the growth and survival mechanisms of certain cancer cells.
- Affecting the genes that direct the cells' growth and activity, particularly those associated with cytokines, apoptosis (cell death), and metabolism.

#### How is lenalidomide taken?

In Australia lenalidomide is available in four dosage strengths — 5mg, 10mg, 15mg and 25mg hard capsules. It is taken every day for 21 days with a seven day rest period (ie 28-day cycle). Treatment is normally continued until the myeloma progresses. The usual starting dose of lenalidomide is 25mg once a day. The minimum dose is 5mg daily. The dose of lenalidomide may vary from patient to patient for several reasons depending on the nature and stage of the person's myeloma, any side effects a person may have and how the myeloma is responding to treatment.

Lenalidomide capsules should be swallowed whole with water and can be taken either with or without food. Lenalidomide can be taken at any time of the day but should be taken at approximately the same time each day.

#### How long can lenalidomide be taken for?

Lenalidomide is most effective in controlling myeloma when it is given as a continuous and uninterrupted treatment. The length of treatment with lenalidomide is determined on an individual basis and may depend on a number of factors including:

- Response to therapy
- Side effects
- Whether treatment plan includes high-dose chemotherapy and stem cell transplant
- The person's preference

You and your doctor will discuss the length of treatment that is right for you.

Treatment with lenalidomide usually continues until there are signs that the myeloma has started to progress. At this point, the treating doctor will discuss treatment options with you.

Lenalidomide is approved for use in combination with dexamethasone. Your treating doctor will prescribe the dose of dexamethasone that is appropriate for you.

### **What are the possible side effects of lenalidomide treatment?**

As with any medical treatment, lenalidomide may cause a number of side effects. The side effects listed below are some of the more common or more serious ones that may be experienced. Your treating doctor may vary the dose of lenalidomide that you are on to help manage any side effects that you may experience.

- **Skin reactions**

Lenalidomide can sometimes cause patches of dry skin, itchiness or a rash. This can occur within the first few weeks of starting treatment but usually clears up by itself. Sometimes the rash may need treatment with anti-histamines and/or steroid creams, especially if it is itchy. If the rash continues and is troublesome, talk to your treating doctor about it and they may reduce the dose of lenalidomide or stop it temporarily.

Rarely, some rashes are a sign of a potentially more serious side effect of lenalidomide causing the skin to turn red, blister and peel — e.g. Stevens-Johnson syndrome or toxic epidermal necrolysis. If this happens, you should inform your doctor immediately and lenalidomide should be stopped straight away as the condition can become much more serious.

- **Low blood counts**

Blood counts are usually checked every two weeks for the first 12 weeks of therapy and at least monthly thereafter. Treatment may be interrupted based on the results of the blood tests and on general condition.

Lenalidomide may cause a decrease in the production of white blood cells (neutropenia), platelets (thrombocytopenia), or red blood cells (anaemia).

- **Low red blood cells (Anaemia)**

A low red blood cell count is known as anaemia. When your red cell count is low it is difficult for your body to move oxygen around and as such you may become tired or breathless more easily than normal. If you experience these symptoms you should inform your treating doctor. Your doctor may adjust your dose of lenalidomide and recommend a blood transfusion to help boost the red cell count.

- **Low white blood cells (Neutropenia)**

Neutropenia is a condition where your body does not have enough neutrophils, a type of white blood cell important in the body's fight against infection.

Contact your treating doctor if you have symptoms of an infection such as:

- A temperature of more than 38°C
- Dizziness or fainting
- Redness at a wound site
- Difficulty breathing
- A cough or sinus congestion

If your treating doctor tells you that you have neutropenia when you are taking lenalidomide you may need to take precautions, such as avoiding crowded places and asking family and friends not to visit if they have an infection such as a cough or cold.

If your neutrophil count is very low, medication may be given to help increase it — e.g. filgrastim — and your dose of lenalidomide may be adjusted.

- **Low platelets (Thrombocytopenia)**

A low platelet count is known as thrombocytopenia. Platelets help blood to clot if you injure yourself, therefore a low platelet count may increase your risk of bleeding. Your treating doctor may recommend a platelet infusion or change your dose of lenalidomide if your platelet count is low.

Contact your treating doctor if you have signs of thrombocytopenia such as:

- Multiple large bruises
- Blood in urine or stools
- Spontaneous nosebleeds
- Small red or purple spots on the body
- Bleeding that does not stop with pressure

- **Blood clots**

Lenalidomide can increase the risk of blood clots developing in the large, deep veins of the leg (known as Deep Vein Thrombosis or DVT) and this can produce symptoms of swelling, tenderness, pain and redness in the leg. If a piece of the clot breaks off, it may travel to the lungs and block blood flow to the lungs. This condition is called pulmonary embolism, symptoms of which may include chest pain and or shortness of breath.

Tell your treating doctor straight away if you experience any of the following symptoms:

- Skin redness
- Arm and/or leg swelling
- Shortness of breath
- Chest pain
- Rapid heartbeat and rapid breathing
- Coughing up blood

Your doctor may prescribe a medication to prevent DVTs such as aspirin, low-dose heparin or warfarin. Treatment with full-dose heparin and warfarin may be used to treat a DVT should one develop whilst you are taking lenalidomide.

### **Special precautions**

As with most chemotherapy drugs, one of the most serious side effects associated with lenalidomide is the potential for severe birth defects or fetal death. Lenalidomide is related to thalidomide, a medication which is known to cause serious birth defects. Although lenalidomide has not been tested in pregnant women, it has harmed unborn animals in animal testing. It is therefore recommended that:

- You do not become pregnant while taking lenalidomide.
- Females who are already pregnant, or who plan to become pregnant, must not take lenalidomide.
- If you become pregnant while taking lenalidomide, stop taking it immediately and contact your treating doctor.
- Female partners of men who take lenalidomide must call their treating doctor immediately if they become pregnant.

### ***i-access*® program**

The use of both thalidomide and lenalidomide is carefully controlled by the Federal Government's Therapeutic Goods Administration (TGA). Lenalidomide is only available under a program known as *i-access*®.

To help ensure your safety and to further reduce the risk of exposing unborn babies to lenalidomide:

- The supply of lenalidomide is only available through *i-access*.
- This program is carefully controlled by the TGA.
- Only doctors registered with the *i-access* program can prescribe lenalidomide.
- Only pharmacies registered with *i-access* program can dispense lenalidomide.
- In order to receive lenalidomide all patients must enroll on the *i-access* program.

Females who are able to become pregnant must undergo routine pregnancy tests prior to being prescribed lenalidomide. All females who are able to become pregnant must use two different forms of effective birth control at the same time while taking lenalidomide. In addition, they must start contraception at least four weeks prior to starting lenalidomide.

Lenalidomide may be present in male ejaculate, therefore all males taking lenalidomide must use a latex condom during sexual contact with a woman who is or could become pregnant, even if they have had a vasectomy. Males must not donate sperm while taking lenalidomide and for at least four weeks following the end of treatment.

### **Muscle cramps**

Muscle cramps are a common side effect of lenalidomide but can generally be managed. It may help you to try:

- Massage or stretching exercises
- Remaining active
- Isotonic sports drinks

### **Gastrointestinal side effects**

People taking lenalidomide with dexamethasone may experience gastrointestinal symptoms, including constipation and diarrhea.

The risk of severe constipation is low. Mild constipation may be helped by:

- Exercising regularly
- Drinking plenty of water
- Maintaining a high-fibre diet

People experiencing diarrhea should inform their treating doctor as soon as possible so it can be treated.

Some simple methods to help reduce the symptoms of diarrhea may be:

- Keeping up your fluid intake, but avoid caffeinated and carbonated drinks
- Eating small, frequent meals
- Avoiding dairy products and spicy foods

### **Other side effects**

Some other side effects may include fatigue, loss of energy and breathlessness. Many of these side effects are manageable. Speak to your treating doctor if you experience any side effects that concern you.

### **Does lenalidomide cause second cancers?**

There have been recent reports of a small number of myeloma patients developing a second new cancer. These observations were made in three clinical studies in newly diagnosed myeloma patients who received treatments which included lenalidomide.

In all of the studies, patients had also received melphalan as part of their treatment. There have been no second cancers in other studies with lenalidomide where melphalan was not part of the treatment.

Overall, experts believe that given the available evidence, the benefits of lenalidomide treatment far outweigh any potential risk of developing second cancers. However, if you have any concerns about the risk of developing a second cancer, you should discuss this with your treating doctor.

***The Leukaemia Foundation publishes the guides 'Understanding Leukaemias, Lymphomas, Myelomas and Related Blood Disorders' and 'Living with Leukaemias, Lymphomas, Myelomas and Related Blood Disorders: Information and Support'.***

It is not the intention of this fact sheet to recommend any particular form of treatment to you. You need to discuss your particular circumstances at all times with your treating doctor. For more information, Freecall 1800 620 420, email [info@leukaemia.org.au](mailto:info@leukaemia.org.au) or visit [www.leukaemia.org.au](http://www.leukaemia.org.au)