



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 and 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 to learn more.

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What is lenalidomide?

Lenalidomide is an immunomodulatory drug (IMiD). This means it works by modifying the immune system. Lenalidomide, which is related to thalidomide (Thalomid®), was first approved in Australia in 2007 as a treatment for myeloma that had progressed on another therapy.

The cost of lenalidomide is subsidised by the Australian 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 received or are unable to receive a stem cell transplant. In February 2017, lenalidomide also became available through the PBS for newly diagnosed patients who are not eligible for an autologous stem cell transplant (without trying thalidomide first).

How does lenalidomide work?

Although the exact mechanism of lenalidomide is not yet 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;
- encouraging the immune system to attack and destroy myeloma cells;
- inhibiting growth of new blood vessels, which makes tumour growth more difficult;
- altering production and activity of cytokines involved in the growth and survival mechanisms of certain cancer cells; and
- affecting the genes that direct the cells' growth and activity.

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 (i.e., a 28-day cycle). Treatment is normally continued until the myeloma progresses. The usual starting dose of lenalidomide is 25mg once a day, and 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 a person's myeloma, side-effects and response to treatment.

Lenalidomide capsules should be swallowed whole with water at least 1 hour before, or 2 hours after eating (i.e., not at mealtimes) and should be taken at approximately the same time each day.

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What is the appropriate length of lenalidomide treatment?

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 factors including response to therapy, side-effects, whether treatment plan includes high-dose chemotherapy and stem cell transplantation, and a person's preference. Your doctor will discuss the length of treatment that is appropriate for you. Treatment with lenalidomide usually continues until there are signs that the myeloma has started to progress.

What are the possible side-effects of lenalidomide?

As with any medical treatment, lenalidomide may cause side-effects, and some of the more common or serious ones are listed below. Your treating doctor may vary your dose of lenalidomide to help manage side-effects.

Skin reactions: Lenalidomide can sometimes cause patches of dry skin, itchiness or rash. This can occur within the first few weeks of starting treatment. Rarely, some rashes are signs 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.

Low blood counts: Blood counts are usually checked regularly for the first 12 weeks of therapy, and monthly thereafter. Treatment may be interrupted based on the results of the blood tests. Lenalidomide may cause a decrease in the production of white blood cells (neutropenia), platelets (thrombocytopenia), or red blood cells (anaemia).

Blood clots: Lenalidomide can increase the risk of blood clots developing in the large, deep veins of the leg, known as deep vein thrombosis (DVT). If a piece of the clot breaks off, it may travel to the lungs and block blood flow to the lungs; a condition called pulmonary embolism. 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 while you are taking lenalidomide.

Muscle cramps. This common side-effect of lenalidomide generally can be managed and it may help to try:

- massage or stretching exercises
- to remain active
- isotonic sports drinks.

Gastrointestinal side-effects (constipation or diarrhoea). People taking lenalidomide with dexamethasone may experience gastrointestinal symptoms including constipation and diarrhoea. The risk of severe constipation is low. Mild constipation may be helped by:

- exercising regularly
- drinking plenty of water
- maintaining a high-fibre diet.

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People experiencing diarrhoea should inform their treating doctor as soon as possible, so it can be treated. Some simple methods to help reduce the symptoms of diarrhoea include:

- keeping your fluid intake up (but avoid caffeinated and carbonated drinks)
- eating small, frequent meals
- avoiding dairy products and spicy foods.

Other side-effects: fatigue, loss of energy, and breathlessness.

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 foetal death. Lenalidomide is related to thalidomide, a medication known to cause serious birth defects.

***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 further reduce the risk of exposing unborn babies to lenalidomide:

- The supply of lenalidomide is only available through *i-access*.
- 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.

Does lenalidomide cause second cancers?

There have been 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 each of these studies, patients also had 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 regimen.

Overall, experts believe that, given the available evidence, the benefits of lenalidomide treatment far outweigh any potential risk of developing second cancers.

The Leukaemia Foundation publishes the following information booklets:
Myeloma; Leukaemias, Lymphoma, Myeloma, MDS, MPN and Related Blood Disorders; and Living with Leukaemia, Lymphoma, Myeloma, MDS, MPN and Related Disorders.

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 or visit www.leukaemia.org.au