



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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Thalidomide is an immunomodulatory drug (IMiD). This means it works by acting on the cells involved in the body's immune system. The immune system is part of the body's defence which helps to fight illness and infection.

Thalidomide (Thalomid®) was approved in Australia in 2007 as a treatment for myeloma (also known as multiple myeloma) that had progressed on another therapy. In 2009, it was approved as a first-line treatment for people newly diagnosed with myeloma. Thalidomide is often combined with dexamethasone in the treatment of myeloma.

When can thalidomide be used?

Thalidomide can be used in combination with other medicines (i.e., melphalan and prednisone) for the treatment of newly diagnosed myeloma in people aged over 65 years or in those who cannot receive high dose chemotherapy. It also is used in combination with dexamethasone at the start of high dose chemotherapy treatment or a bone marrow transplant. As well, thalidomide may be used to treat myeloma after other treatments have failed.

How does thalidomide work?

Although the exact mechanism of thalidomide is not yet fully understood, it works in the following ways to help control myeloma cell production.

- 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 thalidomide can help improve the body's immune responses and inhibit inflammation. They also are able to improve the activity of certain very specialised white blood cells (T-cells and natural killer cells) that 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.
- Preventing the myeloma cells sticking to the bone marrow.

How is thalidomide taken?

Thalidomide comes as a capsule to be taken by mouth. Usually, thalidomide is taken once a day at bedtime and at least one hour after an evening meal. Take thalidomide exactly as directed. Do not take more or less of it, or take it more often than prescribed by your doctor.

As a guide, the doses most commonly used are within the range 50–200mg. Much higher doses (over 400mg) have been tried, but side-effects at these doses make thalidomide harder to tolerate, and evidence from clinical studies and practice suggests lower doses can be just as effective as higher doses for most people.

The length of your treatment depends on how your myeloma responds to thalidomide and whether the symptoms return when you stop taking the medication. Your doctor may need to interrupt your treatment or reduce the dose if you experience certain side-effects. Do not stop taking thalidomide without talking to your doctor.

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Special precautions

As with most chemotherapy drugs, one of the most serious side-effects associated with thalidomide is the potential for severe birth defects or foetal death. To avoid exposure to unborn babies, thalidomide is available only under the i-access® program – a special distribution program which ensures thalidomide is always prescribed and taken in the recommended way.

i-access program

The use of thalidomide is carefully controlled by the Australian Government's Therapeutic Goods Administration (TGA) and is only available under the i-access program.

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

- The supply of thalidomide is only available through this special i-access program.
- Only doctors registered with the i-access program can prescribe thalidomide.
- Only pharmacies registered with the i-access program can dispense thalidomide.
- In order to receive thalidomide, all patients must enroll on the i-access program and agree to fully comply with all requirements of the program.

Some of the requirements of the i-access program include:

- not becoming pregnant while taking thalidomide;
- not breastfeeding while taking this medication;
- females who are pregnant or plan to become pregnant must not take thalidomide;
- if you become pregnant while taking thalidomide, stop the medication immediately and contact your treating doctor; and
- female partners of men who are taking thalidomide must call their treating doctor immediately if they become pregnant.

Females who are able to become pregnant must:

- undergo regular, medically-supervised pregnancy tests prior to commencing and while on thalidomide treatment;
- use two different forms of effective birth control at the same time; and
- start contraception at least four weeks prior to starting thalidomide.

Thalidomide may be present in male semen, therefore, all males taking thalidomide 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 thalidomide and for at least four weeks following the end of treatment.

What are the possible side-effects of thalidomide treatment?

As with any medical treatment, thalidomide may cause side-effects. The side-effects listed below are among the more common or more serious ones that may be experienced. Your treating doctor may vary your dose of thalidomide to help manage any side-effects you experience.

Constipation

This can be a problem, particularly when higher doses are used. Constipation can be helped with a good fluid intake (three litres per day) and a high-fibre diet with plenty of fresh fruit and vegetables. It may be necessary to use laxatives. Consult a health professional (doctor, pharmacist or nurse) if you require advice on managing and treating constipation.

Skin reactions

Thalidomide can sometimes cause patches of dry skin, itchiness or a rash, especially within the first few weeks of starting treatment, but these conditions usually clear up by themselves. Sometimes the rash may need treatment with antihistamines and/or steroid creams, especially if it is itchy. If the rash continues and is troublesome, make sure you talk about this with your treating doctor who may reduce the dose of thalidomide or stop it temporarily.

Rarely, some rashes are a sign of a potentially more serious side-effect of thalidomide that causes 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 thalidomide should be stopped straight away as the condition can become much more serious.

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Blood clots

Thalidomide 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 (PE). Symptoms may include chest pain and/or shortness of breath. Tell your treating doctor straightaway if you experience any of these symptoms: skin redness; arms and/or leg swelling; shortness of breath; chest pain; rapid heartbeat and rapid breathing; or 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 while you are taking thalidomide.

Peripheral neuropathy

Peripheral neuropathy is a broad term that describes any changes to the nerves and their function in the body's extremities, most commonly the feet and legs. This means the nerves affected don't work properly. Thalidomide may cause nerve damage that can be severe and permanent. This damage may occur any time during or after your treatment. Your doctor will examine you regularly to see how thalidomide has affected your nervous system. If you experience any of the following symptoms, call your doctor immediately: numbness, tingling, pain, burning or abnormal coordination in the hands and feet. The Leukaemia Foundation has a fact sheet on peripheral neuropathy, available at: www.leukaemia.org.au.

Drowsiness

Thalidomide's first use was as a sedative, so drowsiness is a common and expected side-effect. It appears to lessen with continued administration at the same dose, but you may need a dose reduction if severe drowsiness occurs. Sleepiness and a 'hang-over' effect the next morning can be minimised by taking thalidomide in the evening before going to bed. The best time to take thalidomide will vary from patient to patient, but in general terms thalidomide should be taken 2-3 hours before bedtime. If you are affected by drowsiness you should not operate machinery or drive a car, and be careful doing any activities that require you being fully alert. Drowsiness also can make you feel fatigued or tired. Fatigue is a common symptom for many people with myeloma.

Dizziness

Dizziness can sometimes occur while taking thalidomide. People can experience dizziness, light-headedness and fainting when getting up too quickly from a lying position. To help avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up. If you are taking blood pressure, fluid or heart medication while on thalidomide your doctor will assess your experience of this symptom and adjustments to medication may be required.

Low blood counts

Thalidomide can uncommonly cause a decrease in the number of red and white blood cells and platelets in your blood. A low red blood cell count (anaemia) may cause fatigue. If you become anaemic you may need to have a blood transfusion or receive other treatments to help boost your red cell count. A low white blood cell count may make you more susceptible to infections. You may need to take extra precautions, such as avoiding crowded places and asking people who are unwell not to visit you. If your white cell count is very low, you may be given drugs to help treat this. A low platelet count (thrombocytopenia) increases your risk of bleeding. If your platelet count gets too low, your doctor may give you a platelet transfusion. Your blood counts will be monitored regularly throughout your treatment with thalidomide, to prevent these counts getting too low.

Many of these side-effects are manageable. Speak to your treating doctor if you experience any side-effects that concern you.

The Leukaemia Foundation publishes the guides: 'Understanding Myeloma. A guide for patients and families'; 'Understanding Autologous Transplants'; and 'Understanding Allogeneic Transplants'.

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