

THALOMID[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using THALOMID?

THALOMID contains the active ingredient thalidomide. THALOMID is used to treat multiple myeloma, a cancer of the bone marrow. THALOMID is also used for the treatment of the skin symptoms associated with moderate to severe erythema nodosum leprosum (ENL) which can occur if you have leprosy.

For more information, see Section [1. Why am I using THALOMID?](#) in the full CMI.

2. What should I know before I use THALOMID?

Do not use if you have ever had an allergic reaction to THALOMID or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use THALOMID?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with THALOMID and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use THALOMID?

- Your doctor will choose the dose for you, monitor your progress and may adjust your dose. Your doctor will tell you how much THALOMID to take and for how long you will need to take it.
- Swallow the capsules whole with a full glass of water. Do not crush or chew the capsule.

More instructions can be found in Section [4. How do I use THALOMID?](#) in the full CMI.

5. What should I know while using THALOMID?

Things you should do	<p>Remind any doctor, dentist, pharmacist, or nurse you visit that you are using THALOMID.</p> <p>Tell your doctor immediately if you suspect that you are pregnant. You should also stop taking THALOMID in this case.</p> <p>Your doctor may do some tests (blood tests, nerve function tests, etc.) from time to time to make sure the medicine is working and to prevent unwanted side effects</p>
Things you should not do	<p>Do not stop taking THALOMID (unless you suspect that you are pregnant) or change the dose without first checking with your doctor.</p> <p>Do not become pregnant or breastfeed whilst taking THALOMID.</p>

	<p>Do not donate semen during treatment or for 4 weeks after stopping treatment.</p> <p>Do not have sexual intercourse without using effective means of contraception.</p> <p>Do not donate blood during treatment or for 4 weeks after stopping treatment.</p>
Driving or using machines	<p>Be careful before you drive or use any machines or tools until you know how THALOMID affects you. THALOMID may cause dizziness in some people</p>

For more information, see Section [5. What should I know while using THALOMID?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, THALOMID can have side effects. Sometimes they may be serious, most of the time they are not. You may need medical attention if you get some of the side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING: Thalidomide has caused severe life-threatening human birth defects (deformed babies) and death to an unborn baby when taken during pregnancy. If THALOMID is taken during pregnancy, it may cause birth defects or death to an unborn baby. Do not take THALOMID if you are pregnant, think that you are pregnant or planning to become pregnant.

THALOMID[®] (tha-lo-mid)

Active ingredient(s): *thalidomide* (tha lid' oh mide)

Consumer Medicine Information (CMI)

This leaflet provides important information about using THALOMID. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using THALOMID.**

Where to find information in this leaflet:

- [1. Why am I using THALOMID?](#)
- [2. What should I know before I use THALOMID?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use THALOMID?](#)
- [5. What should I know while using THALOMID?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using THALOMID?

THALOMID contains the active ingredient thalidomide. THALOMID belongs to a group of medicines known as immuno-modulating agents that work 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.

THALOMID is used to treat multiple myeloma, a cancer of the bone marrow. It is used in combination with other medicines, melphalan and prednisone, for the treatment of newly diagnosed multiple myeloma in patients aged over 65 years or patients who cannot receive high dose chemotherapy. It is also used in combination with dexamethasone at the start of high dose chemotherapy treatment or a bone marrow transplant. To find out more about these medicines, please ask your doctor.

THALOMID may also be used for the treatment of multiple myeloma after other treatments have failed.

THALOMID is also used for the treatment of the skin symptoms associated with moderate to severe erythema nodosum leprosum (ENL) which can occur if you have leprosy. Thalidomide can also help to stop the skin symptoms returning.

Ask your doctor if you have any questions about how THALOMID works or why this medicine has been prescribed for you.

2. What should I know before I use THALOMID

Warnings

Do not use THALOMID if:

- you are allergic to thalidomide, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
Shortness of breath, wheezing or difficulty breathing
Swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
- you are under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.
- you are pregnant, or think you may be pregnant, or are planning to become pregnant. THALOMID causes birth defects (deformed babies) and death to an unborn baby and may affect your developing baby if you take it during pregnancy.
- Do not take THALOMID if you are able to become pregnant but unable to follow the required pregnancy prevention measures (outlined in the i-access[®] program - see section 'Before you start to take it' below).
- Do not breastfeed if you are taking this medicine. It is not known if thalidomide is passed into breast milk. However, as thalidomide is known to cause birth

defects, do not breastfeed while you are receiving THALOMID.

- Do not take this medicine if you are a male patient who is unable to follow the required pregnancy prevention measures (outlined in the i-access program - see section below)
- Always check the ingredients to make sure you can use this medicine.
- Follow your doctor's instructions carefully.
- You will have been given specific instructions by your doctor particularly on the effects of thalidomide on unborn babies.
- If you have not fully understood these instructions, please ask your doctor again before taking thalidomide.
- Your doctor will have enrolled you in the i-access program to ensure that thalidomide is used safely.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant, intend to become pregnant, or are able to become pregnant, even if you think this is unlikely e.g. if your periods have stopped.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The i-access program

Thalidomide can cause severe and life-threatening human birth defects (deformed babies) and death to an unborn baby if taken during pregnancy.

To avoid exposure to unborn babies, THALOMID has restricted availability under a Pregnancy Prevention Program (i-access). This program is designed to ensure that THALOMID is always prescribed and taken in the recommended way. Importantly, only patients who are enrolled in this program and therefore have agreed to fully comply with all the requirements of this program can receive THALOMID.

Some of the requirements of the i-access program are outlined in the following sections. Your doctor will discuss all the details with you.

1. For women taking THALOMID

Before starting this treatment, ask your doctor if you are able to become pregnant, even if you think this is unlikely e.g. if your periods have stopped.

If you are able to become pregnant:

- Your doctor will make sure that you have pregnancy tests before treatment, every 4 weeks during treatment, and 4 weeks after stopping treatment.
- **Use reliable means of contraception for at least 4 weeks before starting THALOMID treatment, during treatment and treatment interruption, and for at least 4 weeks after THALOMID treatment has stopped.**

Your doctor will tell you what method of contraception to use.

Effective methods of contraception include the following:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e., desogestrel)

Combined oral contraceptive pills are not recommended as they can increase the risk of blood clots blocking blood vessels in patients with MM being treated with this medicine.

You must stop taking THALOMID and inform your doctor straight away if:

- You miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- You have heterosexual intercourse without using reliable means of contraception.

2. For men taking THALOMID

If your partner is able to become pregnant, use barrier methods of contraception (e.g. condoms) during THALOMID treatment, during treatment interruption, and for 4 weeks after treatment has stopped.

If your partner becomes pregnant whilst you are taking this medicine, tell your doctor immediately.

Do not donate semen during treatment or for 4 weeks after stopping treatment.

3. For all other patients taking THALOMID

Do not donate blood during THALOMID treatment and for 4 weeks after stopping treatment.

Discuss with your doctor if you have or have had any of the following medical conditions:

- Heart attack, blood clots, high blood pressure or high cholesterol
- Diabetes
- Frequent infections
- Hepatitis B virus infection
- Numbness, tingling or pain in your hands and feet
- Severe skin rash
- Seizures
- Thyroid problems
- You have had surgery in the previous 7 days or have wounds which are healing
- Kidney or liver problems.

If you have not told your doctor about any of the above, tell him/her before you start taking THALOMID.

It is important to note that a small number of patients with multiple myeloma may develop additional types of cancer (regardless of their type of therapy). At this stage it cannot be excluded that this risk may be slightly increased with THALOMID treatment. Therefore, your doctor will carefully evaluate the benefit and risk when you are prescribed THALOMID.

If you are not sure if any of the above applies to you, talk to your doctor before taking this medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with THALOMID and affect how it works.

These include:

- medicines that cause drowsiness, such as sleeping pills
- medicines used to treat depression or anxiety
- medicines used to treat heart problems and/or high blood pressure
- hormonal contraceptives
- medicines used to treat anaemia
- hormone replacement therapy
- medicines used in the treatment of cancer such as vincristine
- medicines used in the treatment of AIDS such as zalcitabine and didanosine

These medicines may be affected by THALOMID or may affect how it works. You may need to take different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking THALOMID.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect THALOMID.

4. How do I use THALOMID?

- THALOMID capsules should be swallowed whole with a full glass of water.
- Do not crush or chew the capsule

How much to take / use

- Your doctor will choose the dose for you, monitor your progress and may adjust your dose. Your doctor will tell you how much THALOMID to take and for how long you will need to take it.
- For the treatment of newly diagnosed multiple myeloma, the usual dose is 200 mg a day, taken in treatment cycles lasting 4 to 6 weeks, in combination with the following medicines:
 - melphalan and prednisolone which are taken on Days 1 to 4 of each 6-week cycle.
 - dexamethasone which is taken on Days 1 to 4, 9 to 12 and 17 to 20 of each 4-week cycle.
- For newly diagnosed multiple myeloma patients above 75 years of age taking THALOMID in combination with melphalan and prednisone, the thalidomide recommended starting dose is 100 mg per day.

- For the treatment of multiple myeloma after failure of other treatments, doses of THALOMID from 200 mg a day up to 400 mg a day may be given.
- For the treatment of erythema nodosum leprosum, THALOMID may be given in doses of 100 to 400 mg a day.
- Follow the instructions provided and use THALOMID until your doctor tells you to stop.

When to take / use THALOMID

Take this medicine by mouth, at least one hour after food.

If you have to take multiple capsules, take them as a single dose before going to bed.

This will make you feel less sleepy at other times.

If you forget to use THALOMID

THALOMID should be used regularly at the same time each day. If you miss your dose at the usual time and

- less than 12 hours have passed, take your capsule immediately. Take your next capsule at the usual time.
- more than 12 hours have passed, do not take your capsule. Take your next capsule at the usual time the next day.

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.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much THALOMID

If you think that you have used too much THALOMID you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using THALOMID

Things you should do

Female patients

- Tell your doctor immediately if you suspect that you are pregnant or suspect that you may be pregnant. You should also stop taking THALOMID in this case.

All patients

- Tell any other doctors, dentists, pharmacists, or nurses who treat you that you are taking THALOMID.

- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking THALOMID.
- Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (blood tests, nerve function tests, etc.) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Call your doctor straight away if you:

- you suspect that you are pregnant. You should also stop taking THALOMID in this case.
- Remind any doctor, dentist or pharmacist you visit that you are using THALOMID

Things you should not do

Female patients

- **Do not become pregnant or breastfeed whilst taking THALOMID.**
- **Do not have sexual intercourse without using effective means of contraception described to you by your doctor.**

Male patients

- **Do not donate semen during treatment or treatment interruption, or for 4 weeks after stopping treatment.**

- **Do not have sexual intercourse without using effective means of contraception described to you by your doctor.**

All patients

- **Do not donate blood during treatment or treatment interruption, or for 4 weeks after stopping treatment.**
- In Australia, patients with some types of cancer are permanently excluded from donating blood.
- Do not stop taking THALOMID (unless you suspect that you are pregnant) or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take this medicine to treat any other complaints unless your doctor tells you to.

Things to be careful of

- **If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**
- Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to you doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how THALOMID affects you.

THALOMID may cause drowsiness or dizziness in some people

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may can make you sleepy and this medicine can make you even more sleepy.

Looking after your medicine

- Store your medicine in a cool, dry place where the temperature stays below 25°C
- Keep this medicine in the original package in order to protect it from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills

Keep it where children cannot reach it.

When to discard your medicine

Do not use THALOMID after the expiry date, which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Do not use any pack that is damaged or shows signs of tampering. In that case, return it to your pharmacist.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<p data-bbox="204 432 746 481">Sudden signs of allergy</p> <ul data-bbox="204 510 746 965" style="list-style-type: none">• such as rash, itching or hives on the skin; swelling of the face, lips or tongue or other parts of the body; and/ or shortness of breath, wheezing or trouble breathing. <p data-bbox="204 987 699 1037">Severe skin reactions</p> <ul data-bbox="204 1066 746 1980" style="list-style-type: none">• including painful red patches on the skin; blisters; bleeding in the lips, eyes, mouth and nose; and peeling of the skin. You may have a high temperature, chills and muscle ache at the same time. These could be due to rare but severe skin reactions such as Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis and Drug Reaction	<p data-bbox="817 432 1375 819">Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>with Eosinophilia and Systemic Symptoms.</p> <p>Blurred vision; severe headache; weakness or numbness in the face, arm, or leg; trouble speaking or understanding; loss of balance.</p> <p>This may be due to a stroke which could be a result of blood clots in the blood vessels of your brain.</p> <p>Sudden pain in your chest or difficulty in breathing.</p> <p>This may be due to a heart attack or blood clots in the artery leading to your lungs. These can happen during treatment, or after treatment has stopped.</p> <p>Pain or swelling in your legs, especially in your lower leg or calves.</p>	

Serious side effects	What to do
<p>This may be due to blood clots in the veins of your leg. These can happen during treatment, or after treatment has stopped.</p> <p>Feeling short of breath or getting tired easily after light physical activity, and swollen ankles and feet.</p> <p>This could be due to high blood pressure in the lungs or heart failure, a condition where the heart muscle cannot pump blood strongly enough to supply blood throughout the body.</p> <p>Vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.</p> <p>These could be signs of bleeding in your gut.</p>	

Serious side effects	What to do
<p>Abdominal pain, dark urine, fever, joint pain, loss of appetite, nausea and vomiting, yellowing of the skin and/or eyes.</p> <p>These are symptoms of liver failure which, in some cases, may be due to Hepatitis B virus infection. Some cases of Hepatitis B virus infection may not result in symptoms initially.</p> <p>Numbness, tingling, abnormal co-ordination or pain in your hands and feet.</p> <p>This may be due to nerve damage. It may become very severe, painful and disabling. If you experience such symptoms, speak to your doctor immediately, who may reduce the dose or discontinue the treatment. This side effect usually happens after you have been taking THALOMID for several months but</p>	

Serious side effects	What to do
<p>can happen sooner than this. It can also happen some time after treatment has stopped. It may not go away or may go away slowly.</p> <p>Signs of frequent infections such as fever, severe chills, sore throat, or mouth ulcers; bleeding or bruising more easily than normal; and tiredness, headaches, shortness of breath, dizziness and looking pale.</p> <p>This may be due to low numbers of blood cells in your body. Your doctor may monitor your blood cell numbers during treatment with THALOMID.</p> <p>Chest pain and dry cough</p> <p>This may be due to a chest infection e.g. pneumonia, or other lung problems.</p>	

Serious side effects	What to do
<p>Seizures, fits or convulsions.</p> <p>Blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion.</p> <p>These may be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML).</p>	

Other side effects

Other side effects	What to do
<p>Very Common side effects:</p> <ul style="list-style-type: none"> • Constipation, indigestion, feeling sick 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Other side effects	What to do
<p>(nausea), being sick (vomiting), stomach pain, dry mouth</p> <ul style="list-style-type: none"> ● Rash, dry skin ● Fainting, dizziness, sleepiness, tiredness, shaking (tremor), headache, blurred vision, difficulty in coordinating movement, loss of balance ● Swelling of the hands and feet, feeling generally unwell, weakness, feeling the cold ● Depression, confusion, mood changes, anxiety ● Low blood pressure; a spinning feeling in your head, making it difficult to stand up and move normally ● Slow heart rate ● Muscle cramps ● Decreased sexual drive, abnormal periods. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What THALOMID contains

Active ingredient (main ingredient)	Thalidomide
Other ingredients (inactive ingredients)	Pregelatinised starch and magnesium stearate.

	<p>The 50 mg capsule shell contains gelatin and titanium dioxide (E171).</p> <p>The 100 mg capsule shell contains gelatin, titanium dioxide (E171) and colourants black iron oxide and yellow iron oxide.</p>
Potential allergens	Does not contain lactose

Do not take this medicine if you are allergic to any of these ingredients.

What THALOMID looks like

THALOMID is available as 50 mg (AUST R 156729) and 100 mg (AUST R 156902) capsules in blister packs containing 28 capsules.

THALOMID 50 mg capsules

White, opaque capsule shells imprinted with "BMS" and "50mg" on the body, with a "Do not get pregnant" symbol in black ink (SW-9008/SW-9009) on the cap. The capsule shell contains gelatin and titanium dioxide (E171).

THALOMID 100 mg capsules

Tan, opaque capsule shells imprinted with "BMS" and "100mg" on the body, with a "Do not get pregnant" symbol in black ink (SW-9008/ SW-9009) on the cap.

The capsule shell contains gelatin, titanium dioxide (E171) and colourants black iron oxide and yellow iron oxide.

Who distributes THALOMID

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave

Victoria 3170, Australia

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

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