

Thalomid[®] capsules
Consumer Medicine Information

Severe life-threatening birth defects:

Thalidomide has caused severe birth defects when taken during pregnancy. Thalidomide should never be used by women who are pregnant or who could become pregnant whilst taking the drug or could become pregnant within 4 weeks after stopping the drug. Even a single dose can cause severe birth defects.

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Thalomid.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Thalomid against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

WHAT THALOMID IS USED FOR

Thalomid contains an active substance called 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.

Treatment of Multiple Myeloma

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.

Treatment of Skin Symptoms associated with Severe Erythema Nodosum Leprosum (ENL)

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.

Your doctor, however, may have prescribed Thalomid for another purpose.

If you have any questions about how Thalomid works or why this medicine has been prescribed for you please ask your doctor.

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

BEFORE YOU TAKE THALOMID

When you must not take it

Do not take Thalomid if you have an allergy 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.

If you think you may be allergic to Thalomid, ask your doctor for advice.

Do not give this medicine to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

Do not take this medicine if you are pregnant, or think you may be pregnant, or are planning to become pregnant.

Thalomid causes birth defects and foetal death, and may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are able to become pregnant but unable to follow the pregnancy prevention measures (outlined in the *i-access*[®] program).

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 pregnancy prevention measures (outlined in the *i-access*[®] program).

If any of these apply to you, tell your doctor before you take Thalomid.

Before you start to take it

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.

Take special care with Thalomid

Talk to your doctor before taking this medicine in the following situations:

1. For all patients taking Thalomid

Check with your doctor before taking this medicine if:

- You are at high risk of a blood clot developing in your veins (deep vein thrombosis) or in your lungs (pulmonary embolism).

- You do not understand the contraception advice given to you by your doctor or if you do not feel able to follow this advice.
- You have nerve damage, such as numbness, tingling or pain in your hands and feet.
- You have a history of seizures.
- You have had surgery in the previous 7 days or have wounds which are healing.

2. **For women** taking Thalomid

Even if your periods have stopped, it is essential to ask your doctor if there is any risk that you could become pregnant.

Do not take this medicine if you are pregnant. In addition, you should not become pregnant while taking this medicine but, if you do, **stop taking Thalomid** and inform your doctor immediately.

If you are a woman of childbearing potential, you should use reliable means of contraception. This means that you must use at least one highly effective method of contraception (including intrauterine devices, hormonal methods [after discussion with your doctor], tubal ligation, or partner's vasectomy) and preferably one additional effective method (including diaphragm, cervical cap, or latex condom by your partner). Your contraceptive methods should be discussed with your doctor before starting your treatment.

These birth control methods must be used 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.

3. **For men** taking Thalomid

Thalidomide passes into semen. Therefore, do not have unprotected sexual intercourse. You should use barrier methods of contraception (e.g. condoms) if your partner is of childbearing potential and for 4 weeks after treatment has stopped. You must not donate semen during treatment or for 4 weeks after stopping treatment.

Donating Blood

You must not donate blood during Thalomid treatment and for 4 weeks after stopping treatment.

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

Pregnancy

Thalidomide causes severe birth defects or death to an unborn baby.

- As little as one capsule taken by a pregnant woman can cause a baby to have serious birth defects.
- These defects can include shortened arms or legs, malformed hands or feet, eye or ear defects, and problems with internal organs.

If you are pregnant, you must not take Thalomid. In addition, you must not become pregnant while taking this medicine. If you do become pregnant during treatment, **stop taking Thalomid** and inform your doctor immediately.

You must use reliable means of contraception if you are a woman who is able to become pregnant (see previous section, "Take special care with Thalomid").

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.

For men taking Thalomid who have a female partner who is able to become pregnant, please see previous section “Take special care with Thalomid”. If your partner becomes pregnant whilst you are taking this medicine, you should inform your doctor immediately.

Use in other cases

You should tell your doctor if you have or have had any problems with your kidney or liver.

Taking other medicines

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

Some medicines and Thalomid may interfere with each other. These include:

- medicines that cause drowsiness, such as sleeping pills
- medicines used to treat depression or anxiety
- medicines used to treat heart problems and high blood pressure
- 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.

HOW TO TAKE THALOMID

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet. You should check with your doctor if you are not sure.

How much to take

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 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 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.

How to take it

Swallow the capsules whole with a full glass of water.

Do not crush or chew the capsule.

When to take it

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 take Thalomid

If you forget to take Thalomid at your regular 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.

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

If you take too much Thalomid (overdose):

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Thalomid. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

If you have any further questions on the use of Thalomid, ask your doctor or pharmacist.

WHILE YOU ARE TAKING THALOMID

Thalomid is available under a restricted distribution program called the *i-access*[®] program. Only physicians and pharmacists registered with this program can prescribe and dispense this medicine. In addition, this medicine will only be given to patients who are registered and meet all the conditions of the program.

Things you must do

Tell any other doctors, dentists, and pharmacists 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 this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

Do not drive or operate machinery until you know how Thalomid affects you.

This medicine may cause drowsiness or dizziness in some people.

Do not drink alcohol while you are taking this medicine.

This is because alcohol can make you sleepy and this medicine can make you even sleepier.

Do not stop taking Thalomid 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 similar symptoms or 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 your doctor.

SIDE EFFECTS

Like all medicines, Thalomid can have side effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by the following list of possible side effects; you may not experience any of them.

Stop taking Thalomid and see a doctor straight away or go to Accident and Emergency at your nearest hospital if you notice the following serious side effects:

- **Sudden signs of allergy** 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.
- **Severe skin reactions** 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.
- **Blurred vision; severe headache; weakness or numbness in the face, arm or leg; trouble speaking or understanding; loss of balance.**
This may be due to a stroke which could be a result of blood clots in the blood vessels of your brain.
- **Sudden pain in your chest or difficulty in breathing.**
This may be due to blood clots in the artery leading to your lungs. These can happen during treatment, or after treatment has stopped.
- **Pain or swelling in your legs, especially in your lower leg or calves.**
This may be due to blood clots in the veins of your leg. These can happen during treatment, or after treatment has stopped.
- **Feeling short of breath or getting tired easily after light physical activity, and swollen ankles and feet.**
This could be due to heart failure, a condition where the heart muscle cannot pump blood strongly enough to supply blood throughout the body.

The above list includes very serious side effects. You may need urgent medical attention. Most of these side effects are uncommon.

Tell your doctor straight away if you notice any of the following serious side effects:

- **Numbness, tingling, abnormal co-ordination or pain in your hands and feet.**
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 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.

- **Frequent infections, 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.**

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

- **Chest pain and dry cough**

This may be due to a chest infection e.g. pneumonia, or other lung problems.

- **Seizures, fits or convulsions.**

The above list includes serious side effects that may require medical attention.

Tell your doctor or pharmacist if you notice any of the following side effects and they worry you:

- Constipation, indigestion, feeling sick (nausea), being sick (vomiting), stomach pain, dry mouth
- Rash, dry skin
- Fainting, dizziness, sleepiness, tiredness, shaking (tremor), headache, blurred vision, difficulty in co-ordinating 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.

The above list mainly includes the more common side effects of your medicine.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING THALOMID

How to store Thalomid

- Keep Thalomid out of the reach and sight of children.
- 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.
- 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.

Disposal

If your doctor tells you to stop treatment with Thalomid or it has passed its expiry date, return any medicine that is left over to your pharmacist. Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

PRODUCT DESCRIPTION

What Thalomid looks like

Thalomid is available as 50 mg or 100 mg capsules in blister packs containing 28 capsules.

Thalomid 50 mg capsules

White, opaque capsule shells imprinted with “Celgene 50mg” with a “Do not get pregnant” symbol in black ink (SW-9008/SW-9009). The capsule shell contains gelatin and titanium dioxide (E171).

Thalomid 100 mg capsules

Tan, opaque capsule shells imprinted with “Celgene 100mg” with a “Do not get pregnant” symbol in black ink (SW-9008/SW-9009). The capsule shell contains gelatin, titanium dioxide (E171) and colourants black iron oxide and yellow iron oxide.

What Thalomid contains

- The active substance is thalidomide.
- Other ingredients are pregelatinised starch and magnesium stearate.
- The capsule shell ingredients are listed above in the section “What Thalomid looks like”.

This medicine does not contain any lactose.

Supplier

Thalomid is supplied in Australia by:

Celgene Pty Limited
Level 7, 607 St Kilda Road,
Melbourne, VIC 3004.
Telephone: 1800 CELGENE (1800 235 4363)

Australian Registration Number:

Thalomid (thalidomide) 50 mg capsules - AUST R 156729
Thalomid (thalidomide) 100 mg capsules - AUST R 156902

This leaflet was updated in December 2011.