Thalomid® capsules

thalidomide

New Zealand Consumer Medicine Information

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.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Thalomid is available only with a doctor's prescription.

BEFORE YOU TAKE THALOMID

When you must not take it:

Do not take this medicine if you are pregnant, or think that 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 this medicine 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 'Before you start to take it' below).

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

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.

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.

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 is available only under a special distribution program called the *i-access*® program. 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.
- **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.

Tell your doctor immediately if your partner becomes pregnant whilst you are taking this medicine.

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

3. For all 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.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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.

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/or high blood pressure
- medicines that can induce bleeding, such as aspirin
- 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.

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 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.

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 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 take too much Thalomid (overdose):

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON / 0800 764 766) 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

Things you must do:

Female patients:

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

All patients:

- **Tell any other doctors, dentists, and pharmacists who are treating 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.**
- **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.

Things you must 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.**
- **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 (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 similar symptoms or the same condition as you.**
- **Do not take this medicine to treat any other complaints unless your doctor tells you to.**
- **Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

  In that case, return it to your pharmacist.

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.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Thalomid.

Like all medicines, Thalomid can have side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following 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 as soon as possible if you notice any of the following:

- **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.
- **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.**

  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.**
- **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.**

  These may be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML).

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

If any of the following happens, stop taking Thalomid and see a doctor immediately or go to Accident and Emergency at your nearest hospital:

- **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.

  These could be due to rare but severe skin reactions such as Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis and Drug Reaction with Eosinophilia and Systemic Symptoms.
- **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 a heart attack or 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 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.
- **Vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.**

  These could be signs of bleeding in your gut.
- **Abdominal pain, dark urine, fever, joint pain, loss of appetite, nausea and vomiting, yellowing of the skin and/or eyes.**

  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.

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

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

Storage

Keep Thalomid out of the reach and sight of children.

Store your medicine in a cool, dry place where the temperature stays below 25°C.

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.

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 wallet-style 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).

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).

Ingredients

Thalomid capsules contain an active ingredient called thalidomide.

The other ingredients are:

- pregelatinised starch, and
- magnesium stearate.

The capsule shell contains gelatine and titanium dioxide (E171), and for 100mg capsules, also contains the colourants black iron oxide (E172) and yellow iron oxide (E172).

The printing ink contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, purified water, strong ammonia solution, potassium hydroxide, and black iron oxide (E172).

This medicine does not contain any lactose.

Distributor

The sponsor in New Zealand is:

Celgene Limited

PO Box 3035,

Wellington

Telephone: 0800 526 529.

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