

PART III: CONSUMER INFORMATION

Pr^rTHALOMID[®]

Thalidomide Capsules House Standard

This leaflet is part III of a three-part "Product Monograph" published when THALOMID[®] (thalidomide capsules) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about THALOMID[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

THALOMID[®] can only be given to patients who are registered in and meet all conditions of the RevAid[®] program. RevAid[®] is a controlled distribution program of THALOMID[®].

What the medication is used for:

THALOMID[®] is used in combination with melphalan and prednisone in the treatment of patients with previously untreated Multiple Myeloma (MM) who are 65 years of age or older.

What THALOMID[®] does:

THALOMID[®] is thought to work in multiple ways to stop or slow the growth of cancer cells.

When it should not be used:

Do not take THALOMID[®] if:

- You are pregnant. Even a single dose (1 capsule of any strength of THALOMID[®]) taken by a pregnant woman can cause severe birth defects.
- You are at risk of becoming pregnant
- You become pregnant during THALOMID[®] treatment
- You are breastfeeding
- You are a male patient and are unable to follow or comply with the contraceptive measures of the RevAid Program
- You are allergic to thalidomide, lenalidomide or pomalidomide or any of the other ingredients in THALOMID[®].

What the medicinal ingredient is:

thalidomide

What the nonmedicinal ingredients are:

Each capsule contains pregelatinized starch and magnesium stearate in a gelatin capsule. The additional composition of the different capsule strengths is provided in the table below.

Summary of dosage forms				
Strength	Color	Imprint	Pack size	Non-medicinal ingredients
50 mg	White opaque	CELGENE / 50 mg Do Not Get Pregnant logo	28 capsules	titanium dioxide, black ink
100 mg	Tan opaque	CELGENE / 100 mg Do Not Get Pregnant logo	28 capsules	black iron oxide, yellow iron oxide, titanium dioxide, black ink
200 mg	Blue opaque	CELGENE / 200 mg Do Not Get Pregnant logo	28 capsules	FD&C Blue #2, titanium dioxide, white ink

What dosage forms it comes in:

THALOMID[®] is available as capsules. Each capsule contains 50 mg, 100 mg or 200 mg of thalidomide.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

THALOMID[®] should only be prescribed by a doctor experienced in the use of anti-cancer drugs and registered with the RevAid[®] controlled distribution program.

Serious side effects with the use of THALOMID[®] include:

- birth defects (deformed babies), or death of an unborn baby and spontaneous abortion
- peripheral neuropathy (damage to peripheral nerves resulting in numbness, tingling, loss of sensation and pain)
- blood clots in the veins and arteries
- In some cases, a higher risk of liver problems which may lead to death.

THALOMID[®] is only available under a controlled distribution program called RevAid[®].

BEFORE you use THALOMID[®] talk to your doctor or pharmacist if you:

- are pregnant or are planning to get pregnant
- are breastfeeding
- have blood problems
- have liver problems
- have or have had heart problems (fainting spell (syncope), slow heart beat)
- have had a seizure

- take other medications that make you feel sleepy
- feel numbness, tingling or pain or a burning feeling in your feet or hands
- have a history of hypersensitivity (an allergic reaction) to thalidomide, or any ingredient in THALOMID®. In rare cases, severe allergic reactions (anaphylactic reaction and/or angioedema) have been reported in patients taking THALOMID®. Talk to your doctor immediately if you have symptoms of allergic reactions.
- smoke, have high blood pressure or high cholesterol levels.
- have had previous hepatitis B or C virus infection (a viral infection of the liver).

THALOMID® may cause birth defects. In order to take this drug you must meet the following conditions:

1. Females who can get pregnant:

- Discuss contraception (birth control) with your health care provider.
- Use at least two effective methods of contraception at the same time.
- Use these two effective methods of contraception:
 - For at least 4 weeks before starting THALOMID® treatment
 - During interruptions of THALOMID® treatment
 - During THALOMID® treatment
 - For at least 4 weeks after stopping THALOMID® treatment
- You must have two negative pregnancy tests before starting treatment:
 - The first 7-14 days prior to starting treatment
 - The second within 24 hours of starting treatment.
- You must have negative pregnancy tests during treatment:
 - Once weekly for the first 4 weeks
 - Once every 4 weeks (or once every 2 weeks if your period is irregular) for the duration of treatment and during treatment interruption
- You must have a final pregnancy test 4 weeks after stopping THALOMID®.

2. Males:

- THALOMID® is present in the sperm of males who take this drug. Use a condom every time you have sexual intercourse with a woman who is pregnant or can get pregnant. This must be done even if you have undergone a successful vasectomy. The condom must be used while:
 - You are taking THALOMID®
 - During interruptions of treatment
 - For 4 weeks after stopping THALOMID®
- Do not donate sperm while taking THALOMID® and for 4 weeks after stopping THALOMID®.

- Inform your sexual partner who can get pregnant that:
 - You are taking THALOMID®
 - There is a risk of birth defects, stillbirths, and spontaneous abortions if a fetus is exposed to your sperm.
 - You must use a condom.

You should contact your doctor immediately if you think your female partner becomes pregnant while you are taking THALOMID®.

3. All Patients:

THALOMID® may cause birth defects and any method of birth control can fail. You should contact your doctor immediately if you think you or your female partner may be pregnant. You should also contact your doctor if you miss your period or experience unusual menstrual bleeding.

- Do not give blood while you take THALOMID® and for 4 weeks after stopping THALOMID®.
- Do not share THALOMID® with other people.

Do not take THALOMID® if you are not enrolled in or do not meet the requirements of the RevAid® controlled distribution program.

Second cancers, namely acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), which are types of blood cancer, have been reported in a small number of patients taking THALOMID® in combination with melphalan and prednisone. Patients should talk to their doctors if they have any concerns about their own increased risk of getting other cancers.

THALOMID® is not recommended for use in children under 19 years of age.

If you are older than 75 years of age there is a possibly greater risk for serious side effects of THALOMID®.

THALOMID® causes drowsiness and sleepiness. **Do not** drive or operate machinery until you know how THALOMID® affects you.

Alcohol may increase drowsiness and sleepiness caused by THALOMID®.

INTERACTIONS WITH THIS MEDICATION

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. It is possible that THALOMID® and other medicines may affect each other causing serious side effects, especially with sleeping pills, alcohol, antihistamines, hormone replacement therapy, hormonal contraceptives, steroids, drugs that increase the risk of peripheral neuropathy, drugs that increase the risk of bradycardia (slow heart rate), and drugs that increase the production of red blood cells.

The risk of having blood clots is increased if you take hormone replacement therapy or hormonal contraceptives

while taking THALOMID®.

Know the medicines you take. To help you keep track of what medicines you take, make a list of them to show your healthcare provider and pharmacist.

PROPER USE OF THIS MEDICATION

How do I take THALOMID®?

- Take THALOMID® exactly as prescribed by your healthcare professional.
- Keep the capsules in the package until you are ready to take them.
- Take the capsules as a single dose before going to bed. This will make you less likely to feel sleepy at other times.
- You should try to take it at about the same time each day.
- Take the capsule directly from the package and place it in your mouth. Do not put the capsule on the counter or onto a dish or other container before taking it.
- Swallow THALOMID® Capsules whole with water.
- Do not break, chew, or open your capsules.

It is important to remember that if you are being assisted with your medication, females who could become pregnant, or who plan to become pregnant can handle THALOMID® capsules if they are using latex gloves.

Will I have to go for tests during treatment with THALOMID®?

You will have regular blood tests during your treatment with THALOMID®. You should have your blood tested about once a month. Your healthcare provider may adjust your dose of THALOMID® or interrupt your treatment based on the results of your blood tests and on your general condition.

Dose:

Capsules should be taken once daily with water at bedtime.

- Patients older than 75 years of age: 100 mg once daily
- Patients 75 years of age or younger: 200 mg once daily

Overdose:

Taking more medication than prescribed in some cases is called an overdose, this is potentially harmful. If you take too much THALOMID® or overdose, call your healthcare provider or poison control centre right away (using the phone number provided on the first page of your local phone book).

Missed Dose:

There are two options if you miss a dose:

1. If less than 12 hours have passed since missing a dose, take the dose.
2. If more than 12 hours have passed since missing a dose at the normal time, do not take the dose. Take the next dose at the normal time on the following day. Do **not** take 2 doses at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, THALOMID® can have side effects.

The most common side effects are:

- Changes in your blood cell counts. Your doctor will monitor your blood cell counts during treatment with THALOMID®
- Constipation
- Sleepiness or feeling tired
- Unusual sensation of numbness, tingling, pins and needles, loss of sensation or pain
- Dizziness
- Feeling shaky
- Swelling of your hands and feet
- Nausea
- Rash

The less common side effects are:

- Heart failure, slow heart rate which can be irregular or regular
- Being sick (vomiting), dry mouth, feeling sick (nausea), diarrhea, upper abdominal pain
- Feeling weak, fever, feeling generally unwell, swelling
- Herpes zoster infection, chest infection (pneumonia), mouth infection (oral fungal infection)
- Recurrence (to become active again) of a previous hepatitis B or C infection, which can be fatal in some cases
- Changes of potassium level in your blood
- Back pain
- Abnormal coordination, unsteady, difficulty in walking, state of unconsciousness, memory and thinking ability disorder
- Depression, confusion
- Kidney disease (acute renal failure)
- Problems related to sexual function (unable to engage in sexual intercourse)
- Shortness of breath, sudden pain in your chest or difficulty in breathing (which may be a symptom of blood clots in the lungs called pulmonary embolism), lung disease
- Rash, dryness of the skin
- Pain or swelling in your legs which may be due to blood clots in the veins (thrombosis), low blood pressure

Peripheral Neuropathy

Tell your doctor if you notice any numbness, tingling,

abnormal co-ordination or pain in your hands and feet. This may be due to nerve damage (called peripheral neuropathy), which is a very common side effect. It may become very severe, painful and disabling. If you experience such symptoms, speak to your doctor, who may reduce the dose or stop your treatment. This side effect usually happens after you have been taking this medicine 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.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Common <ul style="list-style-type: none"> • constipation • rash • numbness, tingling, or pain or a burning sensation in the feet or hands • dizziness 	√	√	√
Un-common <ul style="list-style-type: none"> • breathing problems, chest pain, arm or leg swelling • severe blood infection (sepsis) accompanied by fever, chills and severe shaking, and possibly complicated by low blood pressure and confusion (septic shock) • Chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick or vomiting. This may be due to blood clots in the arteries (which may be symptoms of a heart attack/myocardial infarction). • Having difficulty in seeing or speaking, which is temporary. This may be due to a clot in an artery in the brain. • Bleeding or bruising in the absence of injury. 		√	√
Rare <ul style="list-style-type: none"> • Symptoms of severe allergic reactions (anaphylactic reaction and/or angioedema) such as sudden swelling of the face, lips, tongue; throat problems, breathing or swallowing; severe rash or itching; fainting; very rapid heartbeat • Bloody or black tarry stools 			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<p>Very Rare</p> <ul style="list-style-type: none"> Symptoms of inflammation of the liver (hepatitis /reactivation of hepatitis B and C virus) itchy skin, jaundice (yellowing of the skin or whites of eyes), fever, tiredness, joint/muscle pain, loss of appetite, nausea and vomiting, pain in the upper right abdomen, pale stools and dark urine Skin reactions (Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis) red rash across face and body, peeling skin or blistered skin, flat red rash, fever, body aches; (Drug reaction with eosinophilia and systemic symptoms) flu-like symptoms and a rash on the face then an extended rash with a high temperature and swollen glands 			√
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This is not a complete list of side effects. For any unexpected effects while taking THALOMID®, contact your doctor or pharmacist.

HOW TO STORE IT

Store THALOMID® at 15-30°C. Keep out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The information in this document is current as of the last revision date shown below. The most current information can be found at: www.revaid.ca or by contacting the sponsor, Celgene Inc., at: 1-888-RevAid1 (1-888-738-2431) or visiting www.celgenecanada.net.

This leaflet was prepared by Celgene Inc.

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