

## Patient Medication Information

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **THALOMID**®

#### Thalidomide Capsules

This Patient Medication Information is written for the person who will be taking **THALOMID**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or you want more information about **THALOMID**, talk to a healthcare professional.

**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**.

#### Serious warnings and precautions box

**THALOMID** should only be prescribed by a healthcare professional experienced in the use of anti-cancer drugs and who is registered with RevAid.

Serious side effects with the use of **THALOMID** include:

- birth defects, 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
- liver problems which may lead to death.
- severe allergic reaction called anaphylaxis

**THALOMID** is only available under a controlled distribution program called RevAid.

#### What **THALOMID** is used for:

**THALOMID** is used to treat adults 65 years or older who have Multiple Myeloma that has not yet been treated. **THALOMID** is used in combination with the medications melphalan and prednisone.

#### How **THALOMID** works:

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

#### The ingredients in **THALOMID** are:

Medicinal ingredients: thalidomide

Non-medicinal ingredients: black ink, black iron oxide (100 mg capsule), gelatin, magnesium stearate, pregelatinized corn starch, titanium dioxide, yellow iron oxide (100 mg capsule),

#### **THALOMID** comes in the following dosage form:

Capsules: 50 mg and 100 mg

**Do not use THALOMID if:**

- you are pregnant, could become pregnant or you get pregnant while taking THALOMID. Even a single dose (1 capsule of any strength of THALOMID) taken by a pregnant woman can cause severe birth defects.
- you are breastfeeding
- you are a male patient and are unable to follow or comply with the birth control measures of the RevAid Program
- you are allergic to thalidomide, lenalidomide or pomalidomide or any of the other ingredients in THALOMID

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take THALOMID. Talk about any health conditions or problems you may have, including if you:**

- have or have had blood problems such as blood clots
- have liver problems
- have had a seizure
- take medications to stimulate your bone marrow to make red blood cells, or other medications that make you feel sleepy
- are taking hormone replacement therapy or hormonal birth control. This is because there is a risk for blood clots when taking THALOMID. This risk is increased if you are also taking hormone replacement therapy or hormonal birth control.
- have peripheral neuropathy (feel numbness, tingling or pain or a burning feeling in your feet or hands)
- smoke, have high blood pressure or high cholesterol levels
- have HIV
- have had previous hepatitis B or C virus infection (a viral infection of the liver)
- have had an organ transplant
- are over the age of 75 years

**Other warnings you should know about:**

**Second cancers:** Cases of Acute Myeloid Leukemia and Myelodysplastic Syndrome (blood cancers) have been seen in patients taking THALOMID in combination with the medications melphalan and prednisone. Talk to your healthcare professional if you are concerned about an increased risk of getting other cancers.

**Birth defects and birth control:**

THALOMID can cause **severe birth defects or death to an unborn baby and any method of birth control can fail.** In order to take this medicine, you **MUST** meet the following conditions:

**Females who can get pregnant, even if you have a history of infertility or your period has stopped:**

- Talk to your healthcare professional about birth control options that are right for you while you are taking THALOMID.
- You must use at least two effective methods of birth control at the same time every time you have heterosexual sexual contact. Any type of birth control can fail. This is why it is important to use two methods at the same time.
- Use two effective methods of birth control:

- for at least 4 weeks before starting THALOMID treatment,
- during THALOMID treatment,
- during interruptions of THALOMID treatment, and
- 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; and
  - the second within 24 hours of starting treatment.
- Pregnancy tests will be repeated during treatment:
  - once weekly for the first 4 weeks, and
  - once every 4 weeks (or once every 2 weeks if your period is irregular) for the rest of your treatment including if your treatment is stopped temporarily
 The results of these tests must be negative.
- You must have a final pregnancy test 4 weeks after stopping THALOMID.
- **If you get pregnant while taking THALOMID, contact your healthcare professional right away and stop taking THALOMID.**
- **If you miss your period or have unusual period bleeding, contact your healthcare professional. You will need a pregnancy test.**

#### **Males:**

- THALOMID is present in the sperm of males who take this medicine.
- 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, and
  - 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 an unborn baby is exposed to your sperm, and
  - you must use a condom.
- **If you think your female partner has become pregnant while you are taking THALOMID, contact your healthcare professional right away.**

#### **All Patients:**

- Do not give blood while you are taking 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.

**Orthostatic hypotension:** THALOMID may cause dizziness and low blood pressure on standing. When getting up from lying down, sit upright for a few minutes first.

**Driving and operating machines:** THALOMID causes drowsiness and sleepiness. Do not drive or operate machinery until you know how THALOMID affects you.

**Alcohol:** Alcohol may increase drowsiness and sleepiness caused by THALOMID.

**Tests and Check-ups:** Your healthcare professional will do blood tests regularly. The results of these tests will tell them how THALOMID is affecting your blood and liver. If you have HIV you will need to have your viral load measured regularly. Before starting THALOMID, your healthcare professional will give you a check up and will do an exam of your nervous system. While you are taking THALOMID, they will also check you regularly for signs of peripheral neuropathy.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with THALOMID:**

- medicines that may increase drowsiness including those to treat anxiety, psychosis, insomnia, allergies and pain (including antihistamines, anxiolytics, hypnotics, antipsychotics, opiates, barbiturates and sleeping pills)
- hormone replacement therapy and hormonal birth control
- medicines that increase the risk of peripheral neuropathy including vincristine and bortezomib
- steroids, which may be used to treat pain
- medicines that slow heart rate including beta blockers and anticholinesterase drugs
- medicines that increase the production of red blood cells

**How to take THALOMID:**

- Take THALOMID exactly as your healthcare professional has told you.
- Take capsules once per day before going to bed. This will make you less likely to feel sleepy at other times.
- Take capsules at about the same time each day. Swallow capsules whole with water.
- Do not break, chew, or open your capsules.
- Keep your THALOMID capsules in the package until you are ready to take them.
- 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. If you touch the powder inside the capsule, wash the area with soap and water.
- If you are being assisted with your medication, females who could become pregnant, or who plan to become pregnant must wear gloves when handling THALOMID.

**Usual dose:**

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

If you have side effects, your healthcare professional may lower your dose, stop your treatment for a period of time or stop your treatment permanently.

### Overdose:

If you take too much THALOMID you may feel drowsy and experience sleepiness. You may also notice tingling and numbness in your hands and feet.

If you think you, or a person you are caring for, have taken too much THALOMID, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

### Missed Dose:

If you miss a dose of THALOMID and:

- it is less than 12 hours since you should have taken your dose, take the dose right away.
- it is more than 12 hours have passed since you should have taken your dose, do not take the dose. Take your next dose at the normal time on the following day. Do not take 2 doses at the same time.

### Possible side effects from using THALOMID:

These are not all the possible side effects you may have when taking THALOMID. If you experience any side effects not listed here, tell your healthcare professional.

- Sleepiness or feeling tired
- Feeling shaky
- Swelling of your hands and feet
- Vomiting, dry mouth, nausea, diarrhea, upper abdominal pain
- Feeling weak, fever, feeling generally unwell, swelling
- Back pain
- Depression, confusion
- Problems related to sexual function (unable to engage in sexual intercourse)
- Dryness of the skin
- Low blood pressure

### Serious side effects and what to do about them

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Neutropenia (low white blood cells): infections, fatigue, fever, aches and pain, flu-like symptoms		√	
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness		√	
Common			
Constipation	√		

<b>Rash</b>			√
<b>Peripheral neuropathy:</b> numbness, tingling, abnormal coordination or pain or pain or a burning sensation in the feet or hands. Can be severe, painful and disabling, may be temporary or permanent		√	
<b>Dizziness</b>	√		
<b>Uncommon</b>			
<b>Pulmonary embolism</b> (PE, blood clot in the lung)) <b>and deep vein thrombosis</b> (DVT, blood clot in a deep vein of the arm or leg): breathing problems, chest pain, arm or leg swelling			√
<b>Sepsis</b> (severe blood infection) and <b>Septic shock:</b> fever, chills and severe shaking, and possibly complicated by low blood pressure and confusion		√	
<b>Myocardial Infarction</b> (heart attack): chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick or vomiting			√
<b>Ischemic stroke</b> (poor blood flow to part of the brain due to a blood clot in an artery in the brain): having difficulty in seeing or speaking, which is temporary			√
<b>Thrombocytopenia</b> (low blood platelets): bleeding or bruising in the absence of injury		√	
<b>Bradycardia</b> (abnormally slow heartbeat, which can be irregular or regular)		√	
<b>Pneumonia</b> (infection in the lungs): chest pain when you breath or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath			√

<b>Herpes zoster virus</b> (shingles): a painful skin rash of fluid-filled blisters, blisters appear along a strip of skin, itching		√	
<b>Syncope</b> (fainting): unconsciousness		√	
<b>Confusional state</b> : memory and thinking problems		√	
<b>Kidney disease</b> : nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain, loss of appetite, drowsiness, confusion, coma			√
<b>Rare</b>			
<b>Severe allergic reaction</b> (anaphylactic reaction and/or angioedema): sudden swelling of the face, lips, tongue; throat problems, breathing or swallowing; severe rash or itching; fainting; very rapid heartbeat			√
<b>Bleeding in the stomach or bowels</b> : bloody or black tarry stools			√
<b>Ataxia</b> : abnormal coordination, unsteady, difficulty walking,	√		
<b>AV Block</b> (problem with the electrical signaling in the heart that causes the heart to beat more slowly than normal): chest pain, fatigue, shortness of breath, palpitations, rapid breathing, nausea, dizziness, fainting	√		
<b>Lung disease</b> : shortness of breath, wheezing, cough and chest tightness, fatigue, getting lung infections more often			√
<b>Heart failure</b> (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention,		√	

lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			
<b>Mouth infection:</b> sores in the mouth on lips or gums, bad breath, pain teeth, gum or jaw, sore, swollen or bleeding gums		√	
<b>Very Rare</b>			
<b>Liver problems including Hepatitis</b> (inflammation of the liver) and <b>Reactivation of hepatitis B and C virus</b> (a previous viral infection of the liver becomes active again): 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			√
<b>Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug reaction with eosinophilia and systemic symptoms (DRESS)</b> (severe skin reactions/rash): red rash across face and body, peeling skin or blistered skin, flat red rash, fever, body aches, flu-like symptoms, high fever, swollen glands			√
<b>Tumour lysis syndrome</b> (the sudden, rapid death of cancer cells due to the treatment): nausea, shortness of breath, irregular heartbeat, heart rhythm disturbances, lack of urination, clouding of urine, muscle spasms or twitching, tiredness and/or joint pain, severe muscle weakness, and seizures			√
<b>Unknown</b>			
<b>Progressive Multifocal Leukoencephalopathy</b> (a rare brain infection): vision changes, difficulty speaking, weakness in limbs, change in the way you walk			√



or balance, persistent numbness, decreased or loss of sensation, memory loss or confusion			
<b>Seizures (fits):</b> muscle twitching, changes in emotions, confusion, uncontrollable shaking with or without loss of consciousness			√
<b>Myelodysplastic syndrome (MDS) and Acute Myeloid Leukemia (AML)</b> (types of blood cancer): shortness of breath, fatigue, pale skin, bruising or bleeding, infections, fever, night sweats, feeling cold, headache, loss of appetite	√		
<b>Organ transplant rejection:</b> flu-like symptoms (fever, chill, body ache, nausea, cough, shortness of breath, feeling unwell or tired), pain at the area of the transplant, less urine, sudden weight gain		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting ([canada.ca/drug-device-reporting](http://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

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

### If you want more information about THALOMID:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Drug Product Database website

(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.bms.com/ca/en](http://www.bms.com/ca/en), or by calling 1-888-RevAid1 (1-888-738-2431).

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