

Thalidomide

Names	The generic drug name is thalidomide (tha-LI-doe-mide). The brand name is Thalomid®. There may be other brand names for this medication.
How is it Administered?	Thalidomide comes as a capsule. It is usually taken about an hour before you go to sleep. (If taken during the day, it may cause drowsiness.) You must swallow it whole. Store this medication in a cool, dry place – away from the light.
Why am I Taking Thalidomide?	<p>Thalidomide is used to treat multiple myeloma, a cancer that begins in the plasma cells in the bone marrow.</p> <p>Thalidomide must not be taken by women who are pregnant or who could become pregnant while taking this medication. Even a single dose taken during pregnancy can cause severe birth defects or death of the unborn baby.</p> <p>A program called STEPS® (System for Thalidomide Education and Prescribing Safety) registers patients taking thalidomide and monitors the doctors that prescribe it and the pharmacists that dispense it. This helps ensure that everyone is following the established safety guidelines. Everyone who is prescribed thalidomide, including men and women who cannot become pregnant, must be registered with STEPS.®</p>
How Does it Work?	<p>Thalidomide is not a traditional chemotherapy drug; it is a form of immunotherapy. Exactly how it works against cancer cells is not yet known. Clinical studies suggest that thalidomide may work in multiple ways and at multiple sites within the bone marrow to stop or slow the growth of cancer cells.</p> <p>Thalidomide is both an immunomodulatory agent and an anti-angiogenic agent.</p> <ul style="list-style-type: none">• An immunomodulatory agent helps your immune system to attack the cancer.• An anti-angiogenic agent interferes with the cancer's ability to build the new blood vessels it needs to grow. <p>Thalidomide may also reduce the ability of bone marrow to make substances (cytokines) that promote the growth of cancer cells.</p>

What Should I Tell My Doctor Before I Begin Treatment?

Tell your doctor if you:

- have had an allergic reaction to thalidomide or other medication
- are pregnant or breastfeeding, or may be pregnant
- have or have ever had a low white blood cell count (WBC), human immunodeficiency virus (HIV) or AIDS, or seizures
- are taking any medications. Some may interfere with your thalidomide therapy; others with hormone-based contraception such as birth control pills, IUDs, injections, and implants.

This drug may interact with other medications or cause harmful side effects. Tell your doctor and pharmacist about all prescription or over-the-counter medications, vitamins, herbal, or diet supplements that you are taking.

What Are Some Possible Side Effects?

- Severe, possibly life-threatening birth defects if thalidomide is taken during pregnancy
- Fatigue, drowsiness, confusion, weakness, moodiness
- Itchy, red rash
- Tingling, burning, numbness, pain in the hands, arms, feet, legs (peripheral neuropathy)
- Constipation
- Orthostatic hypotension (dizziness when you stand up)
- Low white blood cell (WBC) count (leukopenia and neutropenia), which can increase your risk for infection
- Swelling in feet, ankles, and legs

How Can I Manage These Side Effects?

- Follow the STEPs® program carefully to prevent pregnancy.
- Take your medication before you go to bed at night to help reduce daytime drowsiness. Do not take any other medications that make you sleepy.
- Avoid sun exposure and wear sunscreen with an SPF of at least 30 when you go outside. Avoid tanning beds. If you get a rash, do not put anything on it – keep the area clean and dry and call your doctor. You may need to stop thalidomide until the rash is evaluated to rule out a severe skin problem (Stevens-Johnson syndrome).
- Ask your doctor about medication, such as stool softeners or laxatives, to help prevent or lessen constipation. Drink 2-3 quarts of fluid a day unless your doctor limits your fluids and eat foods high in fiber. Avoid alcohol. Eating foods high in fiber may also help prevent constipation.
- If you have orthostatic hypotension: When getting up from bed, sit up slowly and put your feet on the floor – wait a few minutes before standing. If you are seated in a chair, stand up slowly. Avoid standing for long periods of

time. Raise the head of your bed. Compression stockings may help with circulation but crossing your legs may reduce circulation.

- If you have swelling in feet or ankles, try putting your feet up whenever you are sitting. Compression stockings may also help. Let your doctor know you are having this problem.

When Should I Call the Doctor?

Call your doctor immediately if you experience:

- any sign of infection: **fever of 100.4°F (38°C) or higher**, chills, cough, sore throat, pain or burning upon urination; redness or tenderness along a vein, at an IV site, or at any other wound or skin irritation
- any sign of an allergic reaction: itching, hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing, dizziness, or palpitations
- any sign of a blood clot: pain, tenderness, redness, warmth, or swelling in the arms or legs; shortness of breath; or chest pain.
- unusual bruising or bleeding: bleeding lasts more than 10-15 minutes or that causes dizziness; black or bloody stools; vomit that is bloody or that looks like coffee grounds; blood in your urine or phlegm /mucus, unusually heavy menstrual bleeding, spontaneous bleeding from your gums or nose, or superficial bleeding into the skin that appears as a rash of pinpoint-sized reddish-purple spots (petechiae)
- fainting, slow heartbeat, or seizures
- late or missed menstrual period

What Else Should I Know About Thalidomide?

- **Both men and women must take steps to prevent pregnancy. This medicine can cause serious or life-threatening birth defects in unborn babies.** You should not use this medicine if you are pregnant or breastfeeding, or if you may become pregnant during treatment. This medicine can cause birth defects if it is used by the father when his sexual partner becomes pregnant. If a pregnancy occurs while you are using thalidomide, stop taking the medicine and tell your doctor right away.
- Use **2 forms of effective birth control** to avoid pregnancy for 4 weeks before you start using thalidomide, all during your treatment, and for at least 4 weeks after your treatment ends. **This is very important whether you are a man or a woman.** The most effective forms of birth control for women includes birth control pills or implants, a diaphragm or cervical cap, an IUD, or tubal ligation. The most effective for men are vasectomy and condoms.
- Females who can get pregnant: Your doctor will do pregnancy tests before starting treatment and every month during treatment.

- Males: You must use a latex condom **every time** you have sexual intercourse with a woman who could get pregnant - **even if you have had a vasectomy.**
- Do not drink alcohol while you are using this medicine.
- You will need to see your doctor every month during your treatment to talk about your condition and any side effects you may be experiencing. At each visit, your doctor may give you a prescription for up to a 28-day supply of medication with no refills. You must have this prescription filled within 7 days.
- You will be asked to sign a consent and agreement form before starting thalidomide. This form tells you about the guidelines for safe use and the risks. Make sure you understand before signing the form. You will be asked to take part in a telephone survey and have your name placed on a patient registry list.
- If you miss a dose or forget to take your medicine, take it as soon as you can. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. **Do not use extra medicine to make up for a missed dose**
- Store the medicine at room temperature in a closed container, away from heat, moisture, and direct light.
- Thalidomide may make you drowsy. Do not drive a car, operate machinery, or do other activities that require you to be fully alert until you know how this medication affects you.
- Thalidomide will be present in your blood and body fluids. Anyone who may come into contact with these fluids should wear gloves or wash any exposed areas of skin with soap and water. **Do not donate blood or sperm while you are using thalidomide.**
- If you are taking thalidomide to treat multiple myeloma, there is a risk that you will develop a blood clot in your arms, legs or lungs. This risk is greater when thalidomide is used along with other chemotherapy medications such as dexamethasone.
- If you would like more information about thalidomide, talk to your doctor or pharmacist.