

Thalidomide Program

The drug thalidomide, brand name Thalomid®, was first used in the 1950s to prevent morning sickness in pregnant women. The drug was removed from the market when it was discovered to cause life-threatening birth defects.

But scientists continued to study the drug in the laboratory and now have a better understanding of how it works. They have discovered it has enormous potential to treat people with newly diagnosed with multiple myeloma, those who have not responded to other myeloma treatments, and those who have a recurrence of myeloma after an initial successful treatment. It may also be used to treat adults with various other solid and hematologic malignancies such as AVMs (arteriovenous malformations).

Protections and Safeguards

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.

- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called “THALOMID REMS,” Risk Evaluation and Mitigation Strategy. The program registers patients taking thalidomide and monitors the doctors that prescribe it and the pharmacists that dispense it. Only prescribers and pharmacies certified by the THALOMID REMS program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS program. Before you start taking this drug, you and your loved ones should read this important information.

Everyone who is prescribed thalidomide, including men and women who cannot become pregnant, must be registered with REMS.®

How Thalidomide Works

Thalidomide is not a traditional chemotherapy drug, but a form of immunotherapy. 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 myeloma cells. Thalidomide may also reduce the ability of bone marrow to make substances that promote the survival and growth of the cancerous cells. Thalidomide affects both myeloma cells and how your body supports their growth. Reducing the number of myeloma cells may allow normal blood cells to grow.

Response to thalidomide therapy takes time and varies from person to person. Your healthcare providers will discuss your individualized dosing/treatment plan with you. Usually, improvement is seen after about 2 months of treatment, but you may feel better anywhere from 2 weeks to 8 months after therapy has started.

Precautions You Must Take

- **This medicine can cause serious or life-threatening birth defects in unborn babies.** Do not take it if:
 - you are pregnant
 - you are breastfeeding
 - you are able to become pregnant
 - you are not using 2 methods of birth control (both men and women). Continue to use 2 methods of birth control for 4 weeks after treatment ends.
- **Males: You MUST use latex condoms every time he has sexual contact with a woman who can become pregnant, even if he has had a vasectomy.**
- **Females capable of becoming pregnant:** You must take a pregnancy test the day before starting treatment and **every week** during the first month of treatment. Your doctor must do the test; you cannot use a home pregnancy test. After the first month, you must have a pregnancy test **every 4 weeks**. If your periods are irregular, you will be tested every **2 weeks**.
- Do not donate blood or sperm while taking this drug or for 4 weeks after you have stopped taking the drug.

Side Effects

Work closely with your healthcare team so you can recognize and keep track of any side effects, whether you think they are related to your treatment or not. Tell your doctors and nurses immediately about any changes in your body that you notice.

For some of these side effects, your doctor may adjust or temporarily discontinue your treatment.

- **Drowsiness**
 - Take thalidomide at bedtime/late evening (at least 1 hour after eating) to reduce drowsiness the next day.
 - Don't drink alcohol or take medications (tranquilizers) that cause drowsiness, unless directed to do so by your doctor; and do not drive a car or operate machinery if feeling drowsy.
- **Peripheral Neuropathy:** Numbness, tingling, burning, and/or pain in hands or feet, or leg weakness, are common complaints. It usually starts in the tips of the toes or fingers and moves up the feet to the legs or from the hands up the arms. This potentially severe side effect may happen at any time while taking thalidomide – or even after you have stopped taking it. Tell your doctor and nurse if you experience any of these symptoms. Sometimes the nerve damage may improve slowly. For some people, it may go away after they stop taking the medication; for other people, it does not go away.
 - Walk and exercise as much as you can. Keeping active helps maintain the blood flow to your hands and feet. If you exercise in a gym, tell the instructor that you have peripheral neuropathy.
 - Protect your heads and feet, particularly when handling hot items or when weather is severe. Use oven mitts, gloves, socks, and shoes. Avoid tight fitting shoes and socks.

- Foot and hand massages may help relieve stiffness, improve circulation, and temporarily dull the pain. After the massage, remember to clean the lotions and creams off your hands and feet.
 - Have someone check the water temperature before you take a shower, wash dishes, etc. or use a thermometer or a part of your body that is not affected by PN.
 - Get rid of throw rugs and other obstacles that can increase your risk of falling or tripping.
 - Ask about balance training and/or physical or occupational therapy.
- **Rash:** You may get a rash within the first 2 weeks of starting thalidomide. Since a few of these rashes may be signs of a very serious illness, talk to your Roswell doctors and nurses if you get any type of rash while taking thalidomide.
 - **Constipation:** To help prevent constipation while taking thalidomide, eat a healthy diet high in fiber, exercise regularly, and drink at least eight glasses of water a day. If you become constipated, talk to your doctor or nurse about using a stool softener or mild laxative. Do not take any medications or products for constipation, prescription or over-the-counter, until your doctor/nurse gives permission.
 - **Orthostatic Hypotension:** You may have sudden dizziness after standing from a reclining or sitting position, a condition called orthostatic hypotension.
 - Sit upright for a few minutes before standing up from a lying or sitting position and then stand up slowly. Avoid quick position changes.
 - Be sure your doctors and nurses know about any medications you are taking before you start taking thalidomide - especially diuretics and heart or blood pressure medications.
 - **Low White Blood Count (Leukopenia, Neutropenia):** Thalidomide therapy may decrease your number of white blood cells (WBCs) and, as a result, you may have trouble fighting off infections. Your healthcare providers do blood tests periodically to monitor your white blood cell count and adjust your thalidomide accordingly.

Blood Clots

- There is an increased risk of blood clots, DVTs (blood clots in a deep vein – usually in the thigh or calf), and pulmonary emboli (blood clots in the lungs) with the use of thalidomide. The risk is higher if you are also taking chemotherapy, including dexamethasone.
- If the clot occurs in the large, deep veins of your leg (DVT), you may have **swelling, tenderness, pain, and redness in that leg or the groin area.**
- If a clot breaks off the wall of the blood vessels and travels to the lungs (pulmonary embolus or PE), it can block the blood flow to the lungs and cause **shortness of breath and sharp chest pain** that gets worse when you take a deep breath.
- Tell your doctors and nurses **immediately** if you have any of these symptoms. If you cannot reach your doctor, go to the emergency room

Less Common Side Effects (Thalomid® taken with dexamethasone)

- Swelling in feet, ankles, and legs (edema)
- Low calcium level in the blood (hypocalcemia)
- Low sodium level in the blood (hyponatremia)
- High sugar (glucose) in the blood (hyperglycemia)
- Confusion
- Insomnia/restlessness
- Shortness of breath
- Anxiety/agitation

Guidelines for Taking Thalidomide

- Always take your medicine as directed by your healthcare providers.
- Thalidomide is available in different dosage strengths: 50 mg, 100 mg, 150 mg, and 200 mg capsules. Each dose is a different color. Your doctor will determine what dose is right for you.
Note: As of 2024, there are no generic versions of this medication available in the U.S.



White: 50 mg



Tan: 100 mg



Blue & Tan: 150 mg



Blue: 200 mg

Each capsule has a “Do Not Get Pregnant” logo on it.

- Thalidomide should be taken by mouth, with water, before going to bed, at least 1 hour after your evening meal.
- If you miss a dose of thalidomide one day, **do not** “double up” the next dose, or try to “fit it in” the next day before your regular dose. Call your healthcare provider.

Storage and Handling

- Store the blister packs at room temperature and out of direct light.
- Keep the capsules in their packs until just before you take it.
- Keep this and all medications out of the reach of children.

Dexamethasone

Thalidomide may be given alone or with dexamethasone, a corticosteroid drug.

- The recommended dose of dexamethasone is 40 mg once a day.
- Dexamethasone is commonly taken on days 1-4, 9-12, and 17-20 in 28- day cycles. If you will be taking dexamethasone, your doctor will tell you when to take it.

Additional Steps You Can Take

- Even if your disease has stabilized or in remission, continue to see your doctor regularly for monitoring.
- Watch for new or old symptoms and report them to your doctor.
- Pay careful attention to your overall health – exercise, eat a nutritious diet, get enough rest, and strive to lower stress in your everyday life.
- Learn all you can about your condition.
- Keep communications open with your healthcare team at Roswell Park.
- Remember, there is hope. With existing treatments and new therapies on the way, more treatment options are becoming available.
- Seek support.

Resources and Support

- **Thalomid® REMS Patient Resources:** <https://www.thalomidrems.com/patient-resources.html>
- **CancerCare:** www.cancercare.org/
- **Roswell Park's 11 Day Power Play Cancer Resource Center:** www.roswellpark.org/cancer-care/support/resource-center Located on 1st Floor Main Hospital, Monday-Friday 9:00am – 4:00pm, **716-845-8659**, option #1.
- **National Cancer Institute:** www.cancer.gov Cancer Information Service Contact Center. English & Spanish Services available Mon – Fri., 9 a.m. to 9 p.m. ET Phone: **1-800-422-6237**
- **Institutional Insight Program (Multiple Myeloma Research Foundation):** www.multiplemyeloma.org Keeps patients and caregivers informed about multiple myeloma, new treatments, and research.
- **The International Myeloma Foundation:** <http://myeloma.org> Hosts a toll-free hotline—staffed by trained specialists—at **(800) 452-CURE (800-452-2873)** in the U.S. and Canada. The line is open Monday –Thursday, 9 a.m. - 4 p.m. Pacific Time and Fridays 9 a.m. – 2 p.m.
- **Leukemia & Lymphoma Society:** www.lls.org

Glossary

Anemia: Blood has a lower than normal number of oxygen-carrying red blood cells.

Antibodies: Protein molecules that bind to a foreign substance (antigen) and either destroy it or make it easier for other cells to destroy it.

Arsenic trioxide (Trisenox): A medication used to treat multiple myeloma and some leukemias.

Basophil: A type of white blood cell involved in inflammation and allergic reactions.

Biopsy: Removal of cells or tissues for examination under a microscope.

Bone marrow: The soft tissue in the center of most large bones. Bone marrow produces white blood cells, red blood cells, and platelets.

Bortezomib (Velcade): A type of targeted therapy used to treat multiple myeloma and mantle cell lymphoma.

Chemotherapy: The use of medications, often in combination, to stop the growth of cancer cells either by killing them or by stopping their reproduction.

Clinical trials: Research studies that evaluate the safety and effect of new treatments and other interventions.

Dexamethasone: A corticosteroid medication used alone or in combination with other drugs to treat multiple myeloma.

Eosinophil: A type of white blood cell involved in inflammation and allergic reactions.

Hypercalcemia: Abnormally high levels of calcium in the blood.

Hyperglycemia: Abnormally high sugar level in the blood. **Hypocalcemia:** Abnormally low levels of calcium in the blood. **Hyponatremia:** Abnormally low level of sodium in the blood.

Immune system: The group of organs and cells that defend the body against infection and disease.

Immunotherapy: medications that cause your own immune system to attack cancer cells. Also called biological therapy.

Leukopenia: Abnormally low levels of white blood cells.

Lymphocyte: A class of white blood cell, including T cells and B cells, which produces antibodies and other substances that fight disease and infection.

Metastasis: The spread of cancer from one part of the body to another.

Monocytes: A type of white blood cell that develops into a macrophage, a cell that surrounds and digests foreign substances.

M-proteins: The antibody made by myeloma cells. Multiple myeloma patients often have high amounts of M-proteins in blood and urine.

Myeloma cells: Cancerous plasma cells.

Natural killer cell: A type of lymphocyte that directly kills invading foreign cells.

Neoplasm: An abnormal growth of cells/tissue that may be benign or cancerous.

Neutrophil: A type of white blood cell that directly kills invading bacteria.

Peripheral neuropathy: Injury to the nerves that supply sensation to the arms and legs.

Plasma cells: A type of B-lymphocyte that produces antibodies.

Plasma cell neoplasms: Diseases in which white blood cells called plasma cells grow abnormally and may become cancerous. Multiple myeloma is the most common plasma cell neoplasm.

Platelets: Platelets are fragments of cells that circulate in the blood and help form clots to stop bleeding.

Pulmonary embolism (PE): A blood clot in an artery that prevents normal blood flow to the lungs.

Red Blood Cells (RBCs): The cells in the blood that carry oxygen to the body's tissues.

Remission: When there is no evidence of an illness.

Stem cells: The cells from which all other cells develop.

Thalidomide (Thalomid®): An immunomodulatory drug, or ImiD; a drug that appears to inhibit the growth and survival of myeloma cells and the growth of new blood vessels that feed tumors.

Thrombus: A blood clot that forms on the walls inside blood vessels.

White blood cells (WBCs): Cells that help the body fight infection and disease.