



Thalidomide (Thalomid®)

Pronounce: tha-LID-oh-mide

Classification: Immunomodulatory Agent

About Thalidomide (Thalomid®)

Thalidomide is a type of "immunomodulatory agent", meaning it works by affecting the immune system. It appears to work in several ways, including inhibiting the formation of blood vessels, which tumors use to get nutrients needed to survive and grow. This is known as anti-angiogenesis. It also interferes with chemicals necessary for the growth of tumors and can cause cell death.

How to Take Thalidomide

Thalidomide is taken by mouth, in capsule form, once a day. Capsules should be swallowed whole with water; do not break, crush or chew this medication. It may be given in combination with other medications. Thalidomide is best taken before bedtime because it can cause sleepiness and in some cases anxiety and confusion. It should be taken at least one hour after your last evening meal.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

If you miss a dose and it has been less than 12 hours since your regular dose time, take it as soon as you remember. If it has been more than 12 hours, skip the dose. Do not take two doses at once to make up for a missed dose.

This medication can cause you to feel extremely drowsy. Exercise caution before driving or operating heavy machinery.

Thalidomide REMS Program

In order to receive thalidomide, patients will need to participate in a program called REMS (Risk Evaluation and Mitigation Strategy). This program educates healthcare professionals and patients about the dangers of thalidomide exposure to a fetus. This exposure can cause serious birth defects and patients taking the medication will need to use two reliable forms of birth control. This includes men taking thalidomide because it is present in sperm. The REMS program limits who can prescribe and dispense the medication. Patients will also need to complete a survey and safety agreement before starting the drug and every month they are taking it. Important safety reminders:

- Women should not become pregnant for 4 weeks before therapy, during therapy, and for 4 weeks after therapy is stopped.
- Women must agree to use 2 forms of reliable birth control or total abstinence during this time.
- A negative pregnancy test 10 to 14 days prior to treatment, within 24 hours prior to treatment, weekly during the first 4 weeks, and every 4 weeks thereafter is required for women of childbearing potential
- Men should not father a child for 4 weeks before therapy, during therapy, or for 4 weeks after therapy is stopped.

- Men must use a condom during any sexual contact during this time, even if they have had a vasectomy with women of childbearing potential and for up to 28 days after stopping treatment.
- Any pregnancy (in women taking the medication OR partners of men who take the medication) should be reported to your oncology team right away.
- Treatment must be stopped immediately for a missed period, abnormal pregnancy test, or abnormal menstrual bleeding; refer to a reproductive toxicity specialist if pregnancy occurs during treatment
- Do not donate blood or sperm during therapy and for at least 1 month after stopping therapy.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw it in the trash.

Where do I get this medication?

Certain cancer medications are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced by your pharmaceutical insurance coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Depending on your diagnosis and fund availability, co-pay assistance from private foundations may be available. Patient assistance may be available to qualifying individuals, depending on your prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients may also be available. Your care team can help you find these resources if they are available.

Possible Side Effects of Thalidomide

There are a number of things you can do to manage the side effects of thalidomide. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Blood Clots

Thalidomide can increase the risk of blood clots (DVT or PE). Symptoms can include swelling, redness or pain in an extremity, or shortness of breath. If you experience symptoms of these problems, you should contact your healthcare provider immediately or go to an emergency room.

Fatigue

[Fatigue](#) is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect. It is best to take the medication at bedtime to reduce

tiredness during the day. Avoid alcohol or other sedating medications while taking thalidomide.

Low Calcium Levels

Calcium is important for bone health. While receiving treatment, your calcium levels can drop, putting you at a higher risk for loss in bone mineral density, which may lead to osteopenia or osteoporosis. Your calcium level will be monitored with blood draws. Your care team may recommend you take calcium and vitamin D supplements to prevent bone loss, but do not take any supplements unless directed to do so.

Constipation

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for [suggestions to relieve the constipation](#).

Fluid Retention / Swelling

Some patients may develop fluid retention, which can cause swelling in the feet and/or ankles or face or gain weight. Fluid can also build up in the lungs and cause you to feel short of breath. Notify your healthcare team if you have any swelling, unexpected weight gain, or shortness of breath.

Peripheral Neuropathy (Numbness or Tingling in the Hands and/or Feet)

[Peripheral neuropathy](#) is a toxicity that affects the nerves. It causes a numbness or tingling feeling in the hands and feet, often in the pattern of a stocking or glove. This can get progressively worse with additional doses of the medication. In some people, the symptoms slowly resolve after the medication is stopped, but for some, it never goes away completely. You should let your healthcare provider know if you experience numbness or tingling in the hands and feet, as they may need to adjust the doses of your medication.

Shortness of Breath

Notify your care team right away if you develop any new or worsening symptoms, including shortness of breath, trouble breathing, cough, or fever.

Skin Changes

Some patients may develop a rash, very dry or itchy skin. Some rashes can be a very serious reaction and all skin changes should be reported to your care team. Use an alcohol-free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your doctor or nurse can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Your care team can give you more tips on [caring for your skin](#).

Low White Blood Cell Count (Leukopenia or Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your [WBC count can drop](#), putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- [Washing hands](#), both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever, or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.

- Shower or bathe daily and perform frequent [mouth care](#).
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your doctor or nurse before scheduling dental appointments or procedures.
- Ask your doctor or nurse before you, or someone you live with has any vaccinations.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the [count is low](#) you are at a higher risk of bleeding. Let your doctor or nurse know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin®, Aleve®, Advil®, etc. as these can all increase the risk of bleeding. Unless your healthcare team tells you otherwise, you may take acetaminophen (Tylenol).
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

Allergic Reactions

Severe allergic or skin reactions can occur with this medication. Call your healthcare provider or go to the emergency room if you experience symptoms of an allergic reaction, including swelling of the lips, mouth, tongue, or throat, or have difficulty breathing. Notify your care team if you develop any skin rash.

Important but Less Common Side Effects

- **Orthostatic Hypotension:** Some people may experience dizziness when standing up from a sitting position. Sit for a minute before getting up from a lying position.
- **Heart Problems:** Some people may develop a slow heartbeat (bradycardia), heart attack, or heart disease. Notify your healthcare provider if you have sudden weight gain, swelling in the ankles or legs, you feel abnormal heartbeats, or if you feel dizzy or faint. If you develop chest pain or pressure, pain in the left arm, back, or jaw, sweating, shortness of breath, clammy skin, nausea, dizziness or lightheadedness, call 911 or go to the nearest emergency room.
- **Skin Reactions:** Serious skin reactions can occur. If you develop a skin rash or peeling of your skin, notify your healthcare provider right away.
- **Seizures:** Seizures have been reported while taking this medication. Notify your oncology provider if you have a seizure.
- **Tumor Lysis Syndrome:** If there are a large number of tumor cells in your body prior to treatment, you are at risk for tumor lysis syndrome. This happens when the tumor cells die too quickly and their waste overwhelms the body. You may be given medication (allopurinol) and IV fluids to help prevent this. If you experience nausea, vomiting, diarrhea, or become lethargic (drowsy, sluggish), notify your oncology team right away. TLS can affect your kidney function. Your provider will monitor your kidney function with blood work. Notify your provider if you have little or no urine output.
- **Progressive Multifocal Leukoencephalopathy (PML):** Progressive Multifocal Leukoencephalopathy (PML) is a rare but very serious brain infection that has been reported with this medication. The signs of PML may develop over several weeks or months. They may include changes in mood or usual behavior, confusion, thinking problems, loss of memory, changes in vision, speech, or walking, and decreased strength or new weakness on one side of the body. If you develop any of these signs, call your oncology care team right away.

Reproductive Concerns

As discussed above, exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Thalidomide may cause severe birth defects or embryo-fetal death if taken during pregnancy. Thalidomide cannot be used in women who are pregnant or may become pregnant during therapy as even a single dose may cause severe birth defects. Effective birth control is necessary during treatment and for four weeks after treatment is completed, even if your menstrual cycle stops or you believe you are not producing sperm. You should not breastfeed while taking thalidomide.

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