

Thalidomide (Thalomid)

About This Drug

Thalidomide is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Decrease in the number of white blood cells. This may raise your risk of infection.
- Nausea
- Constipation (not able to move bowels)
- Fever
- Tiredness and weakness
- Swelling of the hands, feet, or any other part of the body
- Decreased level of calcium in your blood
- Decreased appetite (decreased hunger)
- Muscle weakness (lack of muscle strength)
- Confusion or agitation
- Feeling nervous or worried (anxiety)
- Tremors (shaking in all or parts of the body)
- Weight loss or gain
- Effects on the nerves are called peripheral neuropathy. You may feel numbness, tingling, or pain in your hands and feet. It may be hard for you to button your clothes, open jars, or walk as usual. The effect on the nerves may get worse with more doses of the drug. These effects get better in some people after the drug is stopped but it does not get better in all people.
- Trouble breathing
- Dry skin
- A red skin rash which sometimes can peel
- Blood clots and events such as stroke and heart attack. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain.
- Feeling dizzy

Note: Each of the side effects above was reported in 20% or greater of patients treated with thalidomide. All possible side effects are not included. Your side effects may be different depending on

your cancer diagnosis, condition, or if you are receiving other drugs in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- This drug may increase your risk of a heart attack and stroke
- Extreme tiredness or feeling sleepy
- Severe peripheral neuropathy that may not go away
- Low blood pressure and feeling dizzy
- Decrease in heart rate and passing out
- A severe decrease in the number of white blood cells and platelets. This may raise your risk of infection and raise your risk of bleeding.
- Severe allergic skin reaction. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.
- Tumor lysis syndrome: This drug may act on the cancer cells very quickly. This may affect how your kidneys work and can be life-threatening.
- Possible increased amount of HIV in your blood if you are HIV positive.
- Allergic reactions, including anaphylaxis, are rare but may happen in some patients. Signs of allergic reaction to this drug may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this drug. You should get urgent medical treatment.**
- Seizure. Common symptoms of a seizure can include confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. There are other less common symptoms of seizures. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Use of an intrauterine device (IUD) or implant as a method of birth control may increase your risk of infection or bleeding during its use, insertion or removal.

Note: *Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.*

Important Information

- You will need to sign up for a special program called Thalomid REMS when you start taking this drug. Your nurse will help you get started.
- Two negative pregnancy tests are required in women of childbearing potential prior to starting treatment. Routine pregnancy tests are required during treatment.
- Let your doctor know right away if you think you may be pregnant and report any pregnancy at 1-888-423-5436.
- Men should not donate sperm during treatment, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping thalidomide because this drug is present in semen and may cause harm to a baby.



- Do not donate blood during your treatment, during any breaks (interruptions) in your treatment, and for 4 weeks after your treatment.
- This drug may impair your ability to drive or use machinery. Use caution and talk to your doctor and/or nurse about any precautions you may need to take.

How to Take Your Medication

- Take the medicine by mouth without food, preferably at bedtime or at least 1 hour after you eat your evening meal.
- Swallow whole with water, do not open or crush it.
- **Missed dose:** If you miss a dose, take it as soon as you think about it. If it is within 12 hours of your next dose, then skip the missed dose. Do not take 2 doses at the same time, instead, continue with your regular dosing schedule and contact your doctor.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- Pregnant women or women trying to get pregnant should not handle your medicine.
- If any of the capsules are broken, do not touch them with bare hands. Carefully throw away the capsules and wash your hands after handling.
- If you get any of the content of a broken capsules on your skin, you should wash the area of the skin well with soap and water right away. If the content of the broken capsule comes in contact with the inside of your eyes, nose, and mouth, flush well with water. Call your doctor if you get a skin reaction.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in original blister packs at room temperature until it is ready to be taken. Protect from light.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medication label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.



- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- If you are dizzy, get up slowly after sitting or lying.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Ask your doctor or nurse about medicines that are available to help stop or lessen constipation.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- To help with weight loss, drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages, milkshakes, and nutritional supplements) instead of water.
- To help with decreased appetite, eat small frequent meals and include a source of protein at every meal and snack, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- Moisturize your skin several times a day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.

Food and Drug Interactions

- There are no known interactions of thalidomide with food, however this medicine should be taken on empty stomach.
- Avoid drinking alcohol when taking thalidomide.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known drug interactions with thalidomide. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- There are known interactions of thalidomide with certain medicines that cause sedation such as opioids and antihistamines. Check with your doctor before starting any of these medicines.
- The use of estrogen-containing products and hormonal contraceptive while taking thalidomide may increase your risk of blood clots. Talk to your doctor if you have questions or concerns.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher



- Chills
- Easy bleeding or bruising
- Confusion or agitation
- Feeling dizzy or lightheaded
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back or it can be constant. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, especially on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or sudden bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**
- Wheezing and/or trouble breathing
- Your leg is swollen, red, warm and/or painful
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- No bowel movement in 3 days or when you feel uncomfortable
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- Dry skin that is bothersome
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Tiredness or weakness that interferes with your daily activities
- Numbness, tingling, or pain in your hands and feet
- New rash and/or itching or a rash that is not relieved by prescribed medicines
- Signs of low calcium such as numbness or tingling around your mouth or in your hands and/or feet, muscle stiffness, twitching, spasms, or cramps
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If you have any of these symptoms, call 911.**
- Signs of tumor lysis: confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Even one dose taken by a pregnant woman can cause these very harmful effects, including death of the unborn baby. Stop taking thalidomide and call your doctor right away if you have unprotected sex, miss



your menstrual period and/or have any unusual menstrual bleeding, have stopped taking your birth control or think for any reason that you may be pregnant.

- Women of childbearing potential should abstain continuously from heterosexual sexual intercourse or use 2 effective methods of birth control, one of which, must be a highly effective method of birth control, 4 weeks before treatment starts, during your cancer treatment and during any breaks (interruptions), and for at least 4 weeks after stopping treatment. A highly effective method of birth control other than tubal ligation includes hormonal (birth control pills, injections, patch and/or implants), IUD, and a partner's vasectomy.
- Men with female partners of childbearing potential should always use a latex or synthetic condom during your cancer treatment, during any breaks (interruptions), and for up to 4 weeks after stopping treatment. Men should always wear a condom even if they have undergone a successful vasectomy. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm banking.

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