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 platelets. This may raise your risk of bleeding
- Decrease in the number of white blood cells. This may raise your risk of infection.
- Nausea
- Constipation (unable to move your bowels)
- Fever
- Tiredness and weakness
- Swelling in your legs, ankles, and/or feet
- Electrolyte changes
- Decreased hunger (decreased appetite)
- Muscle weakness (lack of muscle strength)
- Confusion/agitation
- Feeling nervous or worried (anxiety)
- Tremors (shaking)
- Weight loss/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 be weeping (peeling off)
- 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. Not all possible side effects are included above.

Warnings and Precautions

- This drug may increase your risk of a heart attack and stroke. 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.
- 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.
- 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.
- This drug may impair your ability to drive or use machinery. Use caution and tell your nurse or doctor if you feel dizzy, very sleepy, and/or experience low blood pressure.
- Avoid drinking alcohol when taking this drug.
- Do not donate blood during your treatment and for 4 weeks after your treatment.
• Men should not donate sperm during treatment because this drug is present in semen and may cause harm to a baby.

How to Take Your Medication

• Take this drug by mouth without food, 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, in your nose, mouth or in your eyes, you should wash the area of the skin well with soap and water right away. 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.
• Drink plenty of fluids (a minimum of eight glasses per day is recommended).
• If you throw up or have loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
• To help with nausea, 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, 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 are feeling anxious, talk to your nurse or doctor about it and they may be able to offer you some stress-relief techniques and/or support groups that may help relieve your anxiety.
• If you are dizzy, get up slowly after sitting or lying.
• 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 day.
• Avoid sun exposure and apply sunscreen routinely when outdoors.
• Get regular exercise. If you feel too tired to exercise vigorously, try taking a short walk.

Food and Drug Interactions

• There are no known interactions of thalidomide with food, however this medication should be taken on empty stomach.
• 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 causes 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 nervous or worried (anxiety)
• 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 or trouble breathing
• Your leg or arm is swollen, red, warm and/or painful
• Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
• No bowel movement in 3 days or when you feel uncomfortable.
• Weight gain of 5 pounds in one week (fluid retention)
• 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
• A new rash or a rash that is not relieved by prescribed medicines
• 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
• 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 1 dose taken by a pregnant woman can cause these very harmful effects, including death of the unborn baby.
• Two negative pregnancy tests are required to be able to take this drug if you are at an age that you can get pregnant. You will also need to have routine pregnancy tests while you are taking this drug.
• Women of childbearing potential should 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 for at least 4 weeks after treatment. A highly effective method of birth control includes), hormonal (birth control pills, injections, patch and/or implants) and a partner’s vasectomy. Men with female partners of childbearing potential should always use a latex or synthetic condom
during your cancer treatment and for at least 4 weeks after your cancer 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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