



## Thalidomide

(tha li' doe mide)

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### **IMPORTANT WARNING:**

Risk of severe, life-threatening birth defects caused by thalidomide.

For all people taking thalidomide:

Thalidomide must not be taken by women who are pregnant or who could become pregnant while taking this medication. Even a single dose of thalidomide taken during pregnancy can cause severe birth defects (physical problems present in the baby at birth) or death of the unborn baby. A program called System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.®) has been approved by the Food and Drug Administration (FDA) to make sure that pregnant women do not take thalidomide and that women do not become pregnant while taking thalidomide. All people who are prescribed thalidomide, including men and women who cannot become pregnant, must be registered with S.T.E.P.S.®, have a thalidomide prescription from a doctor who is registered with S.T.E.P.S.®, and have the prescription filled at a pharmacy that is registered with S.T.E.P.S.® in order to receive this medication.

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.

Do not donate blood while you are taking thalidomide.

Do not share thalidomide with anyone else, even someone who may have the same symptoms that you have.

For women taking thalidomide:

If you can become pregnant, you will need to meet certain requirements during your treatment with thalidomide. You need to meet these requirements even if you have a history of not being able to become pregnant. You may be excused from meeting these requirements only if you have not menstruated (had a period) for 24 months in a row, or you have had a hysterectomy (surgery to

remove your uterus).

You must use two acceptable forms of birth control for 4 weeks before you begin to take thalidomide, during your treatment, and for 4 weeks after your treatment. Your doctor will tell you which forms of birth control are acceptable. You must use these two forms of birth control at all times unless you can guarantee that you will not have any sexual contact with a male for 4 weeks before your treatment, during your treatment, and for 4 weeks after your treatment.

Some medications can cause hormonal contraceptives to be less effective. If you plan to use hormonal contraceptives (birth control pills, patches, implants, injections, rings, or intrauterine devices) during your treatment with thalidomide, tell your doctor about all the medications, vitamins, and herbal supplements you are taking or plan to take. Be sure to mention: griseofulvin (Grifulvin); certain medications to treat human immunodeficiency virus (HIV) including amprenavir (Agenerase), atazanavir (Reyataz), darunavir (Prezista), fosamprenavir (Lexiva), indinavir (Crixivan), lopinavir (in Kaletra), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), saquinavir (Invirase), and tipranavir (Aptivus); certain medications for seizures including carbamazepine (Carbatrol, Equetro, Tegretol) and phenytoin (Dilantin, Phenytek); modafinil (Provigil); penicillin; rifampin (Rimactane, Rifadin); rifabutin (Mycobutin); and St. John's wort. Many other medications may interfere with the action of hormonal contraceptives, so be sure to tell your doctor all of the medications you are taking or plan to take, even those that do not appear on this list.

You must have a negative pregnancy test within the 24 hours before beginning treatment with thalidomide. You will also need to be tested for pregnancy in a laboratory weekly during the first 4 weeks of your treatment and then once every 4 weeks if you have regular menstrual cycles or once every 2 weeks if you have irregular menstrual cycles.

Stop taking thalidomide and call your doctor right away if you think you are pregnant, you have a late, irregular, or missed menstrual period, you have any change in your menstrual bleeding, or you have sex without using two forms of birth control. In some cases, your doctor can prescribe emergency contraception ('the morning after pill') to prevent pregnancy. If you become pregnant during your treatment, your doctor is required to call the FDA and the manufacturer. Your doctor will also make sure you talk with a doctor who specializes in problems during pregnancy who can help you make choices that are best for you and your baby.

For men taking thalidomide:

Thalidomide is present in semen (fluid containing sperm that is released through the penis during orgasm). You must either use a latex condom or completely avoid any sexual contact with a woman who is pregnant or may become pregnant while you are taking this medication and for 4 weeks after your treatment. This is required even if you have had a vasectomy (surgery to prevent sperm from leaving your body and causing pregnancy). Tell your doctor immediately if you have had unprotected sex with a woman who can become pregnant or if you think for any reason that your partner is pregnant.

Do not donate semen or sperm while you are taking thalidomide.

Risk of blood clots

If you are taking thalidomide to treat multiple myeloma (a type of cancer of the bone marrow), 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. Call your doctor immediately if you experience any of the following symptoms: pain, tenderness, redness, warmth, or swelling in the arms or legs; shortness of breath; or chest pain. Your doctor may prescribe an anticoagulant ('blood thinner') or aspirin to help stop clots from forming during your treatment with thalidomide.

Talk to your doctor about the risks of taking thalidomide.

### ***Why is this medication prescribed?***

Thalidomide is used along with dexamethasone to treat multiple myeloma in people who have been recently found to have this disease. It is also used alone or with other medications to treat and prevent skin symptoms of erythema nodosum leprosum (ENL);

episodes of skin sores, fever, and nerve damage that occur in people with Hansen's disease [leprosy]). Thalidomide is in a class of medications called immunomodulatory agents. It treats multiple myeloma by strengthening the immune system to fight cancer cells. It treats ENL by blocking the action of certain natural substances that cause swelling.

### ***How should this medicine be used?***

Thalidomide comes as a capsule to take by mouth. Thalidomide is usually taken with water once a day at bedtime and at least 1 hour after an evening meal. If you are taking thalidomide to treat ENL, your doctor may tell you to take it more than once a day, at least 1 hour after meals. Take thalidomide at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take thalidomide exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Keep the capsules in their packaging until you are ready to take them. Do not open the capsules or handle them more than necessary. If your skin comes into contact with broken capsules or powder, wash the exposed area with soap and water.

The length of your treatment depends on how your symptoms respond to thalidomide and whether your symptoms return when you stop taking the medication. Your doctor may need to interrupt your treatment or reduce your dose if you experience certain side effects. Do not stop taking thalidomide without talking to your doctor. When your treatment is complete your doctor will probably decrease your dose gradually.

### ***Other uses for this medicine***

Thalidomide is also sometimes used to treat certain skin conditions involving swelling and irritation. It is also used to treat certain complications of human immunodeficiency virus (HIV) such as aphthous stomatitis (condition in which ulcers form in the mouth), HIV-associated diarrhea, HIV-associated wasting syndrome, certain infections, and Kaposi's sarcoma (a type of skin cancer). Thalidomide has also been used to treat some types of cancer and tumors, severe weight loss in patients with weakened immune systems, chronic graft versus host disease (a complication that can occur after a bone marrow transplant in which the newly transplanted material attacks the transplant recipient's body), and Crohn's disease (a condition in which the body attacks the lining of the digestive tract, causing pain, diarrhea, weight loss, and fever). Talk to your doctor about the risks of using this medication for your condition.

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

### ***What special precautions should I follow?***

Before taking thalidomide,

- tell your doctor and pharmacist if you are allergic to thalidomide or any other medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: antidepressants; barbiturates such as pentobarbital (Nembutal), phenobarbital, and secobarbital (Seconal); chlorpromazine; didanosine (Videx); medications for anxiety, mental illness, or seizures; certain chemotherapy medications for cancer such as cisplatin (Platinol), paclitaxel (Abraxane, Taxol), and vincristine; reserpine (Serpalan); sedatives; sleeping pills; and tranquilizers. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), a low level of white blood cells in your blood, or seizures.
- tell your doctor if you are breast-feeding.
- you should know that 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.

- ask your doctor about the safe use of alcoholic beverages while you are taking thalidomide. Alcohol can make the side effects from thalidomide worse.
- you should know that thalidomide may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. To help avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- you should know that thalidomide is 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.

### ***What special dietary instructions should I follow?***

Unless your doctor tells you otherwise, continue your normal diet.

### ***What should I do if I forget a dose?***

Take the missed dose at least one hour after a meal, as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

### ***What side effects can this medication cause?***

Thalidomide may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- drowsiness
- dizziness
- confusion
- anxiety
- depression or mood changes
- difficulty falling asleep or staying asleep
- bone, muscle, joint, or back pain
- weakness
- headache
- change in appetite
- weight changes
- nausea
- constipation
- dry mouth
- dry skin
- pale skin
- itching
- uncontrollable shaking of a part of the body
- swelling of the hands, feet, ankles, or lower legs
- difficulty achieving or maintaining an erection

Some side effects can be serious. If you experience any of the following symptoms, call your doctor immediately:

- rash
- blistering and peeling skin
- swelling of the face, throat, tongue, lips, or eyes
- hoarseness
- difficulty swallowing or breathing

- fever, sore throat, chills, cough, or other signs of infection
- slow or fast heartbeat
- seizures

Thalidomide may cause nerve damage that can be severe and permanent. This damage may occur any time during or after your treatment. Your doctor will examine you regularly to see how thalidomide has affected your nervous system. If you experience any of the following symptoms, call your doctor immediately: numbness, tingling, pain, or burning in the hands and feet.

Thalidomide may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/MedWatch/index.html>] or by phone [1-800-332-1088].

### ***What storage conditions are needed for this medicine?***

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

### ***In case of emergency/overdose***

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

### ***What other information should I know?***

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to thalidomide.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

### ***Brand names***

- Thalomid®

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