

17.3 MEDICATION GUIDE

MEDICATION GUIDE

THALOMID® (tha-lo-mid)

(thalidomide)

Capsules

Read the Medication Guide that comes with THALOMID before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about THALOMID?

- Before you begin taking THALOMID, you must read and agree to all of the instructions in the *S.T.E.P.S.*® program.
- **THALOMID can cause severe and life-threatening human birth defects (deformed babies) or death of an unborn baby. Females who are pregnant or who plan to become pregnant must not take THALOMID.**

Females must not become pregnant:

- for at least 4 weeks before starting THALOMID
- during any breaks (interruptions) in your treatment with THALOMID
- while taking THALOMID
- for at least 4 weeks after stopping THALOMID

Talk to your healthcare provider right away if you have unprotected sex or if you think your birth control has failed. If your healthcare provider is not available, you can call 1-888-668-2528 for emergency contraception information.

If you become pregnant while taking THALOMID, stop taking it right away and call your healthcare provider.

Healthcare providers and patients should report all pregnancies to:

- FDA MedWatch at 1-800-FDA-1088, and
- Celgene Corporation at 1-888-423-5436

Males should know that THALOMID passes into semen or sperm.

- Males, including those who have had a vasectomy, must use a latex or synthetic condom during any sexual contact with a pregnant female or a female that can become pregnant, while taking THALOMID, and for 4 weeks after stopping THALOMID.
- Do not have unprotected sexual contact with a female who is or could become pregnant. Tell your healthcare provider if you do have unprotected sexual contact with a female who is or could become pregnant.
- Do not donate sperm while taking THALOMID, and for 4 weeks after stopping THALOMID. If a female becomes pregnant with your sperm, the baby may be exposed to THALOMID and may be born with birth defects.

Men, if your female partner becomes pregnant, you should call your healthcare provider right away.

- **Venous thromboembolism (blood clots).** If you are taking THALOMID in combination with dexamethasone to treat multiple myeloma you have an increased risk for blood clots in your veins and lungs. Call your healthcare provider or get medical help right away if you get any of these signs or symptoms:
 - shortness of breath
 - chest pain
 - arm or leg swelling

What is THALOMID?

THALOMID is a prescription medicine taken, with the medicine dexamethasone, to treat people who have been newly diagnosed with multiple myeloma. Multiple myeloma is a cancer of plasma cells. Plasma cells are found in the bone marrow. Normal plasma cells produce proteins called antibodies. Some antibodies can attack and kill disease-causing germs. People with multiple myeloma may have low blood cell counts and immune problems, giving them a higher risk for getting infections such as pneumonia. They may also have bone pain and breaks (fractures).

THALOMID is also used to treat people when new lesions of leprosy flare up. THALOMID is not used by itself to treat the skin lesions when there is moderate to severe nerve pain. THALOMID is used as a treatment to keep the lesions in check or to prevent the skin lesions of leprosy from coming back (recurring).

It is not known if THALOMID is safe and effective in children under 12 years of age.

Who should not take THALOMID?

- **Do not take THALOMID if you are pregnant, plan to become pregnant, or become pregnant during THALOMID treatment.** See “What is the most important information I should know about THALOMID?”
- **Do not take THALOMID if you are a female who may become pregnant and are not using 2 forms of birth control or are not continually abstaining from sexual contact with a male.** See “How should I take THALOMID?”
- **Do not take THALOMID if you are allergic to anything in it.** See the end of this Medication Guide for a complete list of ingredients in THALOMID.

What should I tell my healthcare provider before taking THALOMID?

Before you take THALOMID, tell your healthcare provider if you:

- have a history of seizures
- drink alcohol
- plan to have surgery
- **are pregnant or breastfeeding.** THALOMID must not be used by women who are pregnant or breastfeeding. See “What is the most important information I should know about THALOMID?” It is not known if THALOMID passes into your breast milk and harms your baby.

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. THALOMID and other medicines may affect each other causing serious side effects.

Certain medicines can affect the way that birth control pills, injections, patches, or implants work. You could become pregnant.

Especially tell your healthcare provider if you also take:

- a pain medicine
- antihistamines
- a medicine for psychoses
- a medicine for anxiety
- a medicine for your heart
- a medicine for depression
- famotidine (Pepcid, Duexis)
- cimetidine (Tagamet)
- lithium (lithobid)
- bortezomib (Velcade)
- amiodarone (Cordarone, Pacerone)
- cisplatin
- paclitaxel (Abraxane)
- vincristine

- disulfiram (Antabuse)
- metronidazole (Flagyl, Metrocream, Metro lotion, Metrogel, Helidac, Noritate, Plera)
- a penicillin antibiotic
- an anti-HIV medicine
- phenytoin (Fosphenytoin, Cerebyx, Dilantin-125, Extended Phenytoin Sodium, Prompt Phenytoin Sodium, Phenytek, Dilantin, Phenytoin Sodium)
- carbamazepine (Carbatrol, Equetro, Tegretol, Tegretol-XR, Teril, Eptol)
- rifampin (Rifater, Rifamate, Rimactane, Rifadin)
- the herbal supplement St. John's Wort (*Hypericum perforatum*)
- modafinil (Nuvigil, Provigil)
- griseofulvin (Grifulvin V, Gris-Peg)

Ask your healthcare provider if you are not sure if your medicine is one of these.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist.

How should I take THALOMID?

Take THALOMID exactly as prescribed and follow all the instructions of the *S.T.E.P.S.* program.

Before prescribing THALOMID, your healthcare provider will:

- explain the *S.T.E.P.S.* program to you
- have you sign the Patient-Physician Agreement Form
- Keep THALOMID in the blister pack until you take your daily dose.
- Swallow THALOMID capsules whole with water.
- THALOMID is taken one time each day, at least 1 hour after your evening meal. Bedtime is the preferred time to take THALOMID.
- Do not open the THALOMID capsules or handle them any more than needed. If you touch a broken THALOMID capsule or the medicine in the capsule, wash the area of your body with soap and water.
- If you miss a dose of THALOMID and it has been less than 12 hours since your regular time, take it as soon as you remember. If it has been more than 12 hours, just skip your missed dose. Do **not** take 2 doses at the same time.
- If you take too much THALOMID or overdose, call your healthcare provider or poison control center right away.

Females who can become pregnant:

- will have pregnancy tests weekly for 4 weeks, then every 4 weeks if your menstrual cycle is regular, or every 2 weeks if your menstrual cycle is irregular.

If you miss your period or have unusual bleeding, you will need to have a pregnancy test and receive counseling.

- must agree to use 2 different forms of effective birth control at the same time, for at least 4 weeks before, while taking, and for at least 4 weeks after stopping THALOMID®.

Males who take THALOMID, even those who have had a vasectomy, must agree to use a latex or synthetic condom during sexual contact with a pregnant female or a female who can become pregnant.

What should I avoid while taking THALOMID?

- **Females: Do not get pregnant and do not breastfeed while taking THALOMID.**
Males: Do not donate sperm. See “What is the most important information I should know about THALOMID?”, “Who should not take THALOMID?”, and “What should I avoid while taking THALOMID?”
- **Do not share THALOMID® with other people.** It may cause birth defects and other serious problems.

- **Do not donate blood** while you take THALOMID, and for 4 weeks after stopping THALOMID. If someone who is pregnant gets your donated blood, her baby may be exposed to THALOMID and may be born with birth defects.
- THALOMID can cause dizziness and drowsiness. Avoid drinking alcohol, operating machinery, and driving a car when taking THALOMID. Avoid taking other medicines that may cause drowsiness without talking to your healthcare provider first.

What are the possible side effects of THALOMID?

THALOMID may cause serious side effects, including:

- See “What is the most important information I should know about THALOMID?”
- **Drowsiness and sleepiness.** See “What should I avoid while taking THALOMID?”
- **Nerve damage.** Nerve damage is common with THALOMID. If the nerve damage is severe, it may not go away. Stop taking THALOMID and call your healthcare provider right away if you have any of these early symptoms of nerve damage in your hands, legs, or feet:
 - numbness
 - tingling
 - pain
 - burning sensation
- **Dizziness and decreased blood pressure when changing positions.** THALOMID may cause a decrease in your blood pressure, and you may feel dizzy when you go from a lying down or sitting position to standing up. When changing positions, sit upright for a few minutes before standing to help prevent this.
- **Decreased white blood cell count.** THALOMID can cause decreased white blood cell counts, including neutrophils. Neutrophils are a type of white blood cell that is important in fighting bacterial infections. Your healthcare provider should check your white blood count before and regularly while you take THALOMID. If your neutrophils are too low you should not start THALOMID and if they are low during treatment, your dose of THALOMID may need to be changed.
- **Increased HIV virus in the blood.** If you are HIV positive, your healthcare provider should check your viral load after one month and three months of treatment, then every 3 months after that.
- **Slow heartbeat (bradycardia).** Tell your healthcare provider if you have a slow heartbeat, fainting, dizziness or shortness of breath.
- **Serious skin reactions.** Serious skin reactions can happen with THALOMID and may cause death. Call your healthcare provider right away if you have any skin reaction while taking THALOMID.
- **Seizures.** Tell your healthcare provider right away if you have a seizure while taking THALOMID.
- **Tumor Lysis Syndrome (TLS).** TLS is caused by a fast breakdown of cancer cells. TLS can cause a build up of potassium, phosphorus, uric acid, and low calcium levels in your blood. This can cause you to have serious kidney problems, an abnormal heart beat and can cause death. Your healthcare provider will check your blood for these problems.
- **Birth control.** Certain birth control methods may pose a higher risk of serious side effects and should not be used in some women. These risks include severe decreased white blood cell count, low platelet counts, and blood clots. Use of an intrauterine device (IUD) or implantable birth control may also increase your risk of infection or bleeding during insertion, removal or during use of the device.
- **Allergic reaction.** Allergic reactions can happen with THALOMID and may be severe. Call your healthcare provider or get medical help right away if you have any of these symptoms of allergic reaction:
 - a red, itchy rash
 - fever
 - fast heartbeat
 - feel dizzy or faint

The most common side effects of THALOMID for treatment of multiple myeloma include:

- tiredness
- decreased calcium levels
- swelling of the hands and feet
- constipation
- numbness or tingling
- muscle weakness
- skin rash or peeling
- confusion
- decreased appetite
- nausea
- anxiety
- decreased energy or strength

- tremor
- fever
- weight loss
- muscle twitching and cramping
- weight gain
- dizziness
- dry skin

The most common side effects THALOMID for treatment of leprosy include:

- sleepiness
- rash
- headache
- dizziness
- impotence
- decreased energy or strength
- not feeling well
- pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of THALOMID. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store THALOMID?

- Store THALOMID at 77°F (25°C).
- Protect from light.

Keep THALOMID and all medicines out of the reach of children.

General information about THALOMID

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. **Do not** take THALOMID for conditions for which it was not prescribed. **Do not** give THALOMID to other people, even if they have the same symptoms you have. It may harm them and may cause birth defects.

This Medication Guide provides a summary of the most important information about THALOMID. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about THALOMID that is written for healthcare professionals. You can also call 1-888-423-5436 or visit www.THALOMID.com.

What are the ingredients in THALOMID?

Active ingredient: thalidomide

Inactive ingredients: pregelatinized starch and magnesium stearate.

The 50 mg capsule shell contains gelatin, titanium dioxide and black ink. The 100 mg capsule shell contains black iron oxide, yellow iron oxide, titanium dioxide, gelatin, and black ink. The 150 mg capsule shell contains FD&C blue #2, black iron oxide, yellow iron oxide, titanium dioxide, gelatin, and black and white ink. The 200 mg capsule shell contains FD&C blue #2, titanium dioxide, gelatin, and white ink.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for Celgene Corporation

Summit, NJ 07901

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