

This is a summary of the most important information about Thalomid. For details, talk to your healthcare professional.

What is Thalomid (thalidomide) used for?

Thalomid (thalidomide) is used to treat:

- erythema nodosum leprosum (ENL), an inflammatory complication of leprosy. When there is inflammation of the nerves in addition to skin sores, Thalomid (thalidomide) should not be used as the only drug treatment.
- newly diagnosed multiple myeloma in combination with a drug called dexamethasone.

SPECIAL WARNINGS CONCERNING THALOMID:

Thalomid (thalidomide) causes severe birth defects. If even one dose of Thalomid (thalidomide) is taken, it can cause severe birth defects or death to an unborn baby. Major birth defects include babies with no arms and legs, short arms and legs, and missing bones. The greatest risk of severe birth defects is in the first 1-2 months of pregnancy, before a woman may know she is pregnant. You should NEVER use Thalomid (thalidomide) if you could become pregnant, are already pregnant, or could make someone pregnant. Both men and women must agree in writing to their understanding of the risks of Thalomid (thalidomide) and the actions they must take while being treated with Thalomid (thalidomide).

For Women:

When no other treatment is appropriate for a woman of child-bearing age, she must agree in writing to many important actions she must take to avoid pregnancy. These actions include:

- Not having heterosexual sexual contact starting 4 weeks before beginning to take Thalomid (thalidomide) and continuing until 4 weeks after the last dose of Thalomid (thalidomide). Or, using TWO methods of birth control. No method of birth control is completely reliable except for not having heterosexual sexual contact at all. One birth control method must be highly effective, such as an Intrauterine Device (IUD), birth control pills, or tying of the fallopian tubes, and one additional effective method of birth control, such as a diaphragm or partner's condom, must be used. Begin using both birth control methods 4 weeks before beginning to take Thalomid (thalidomide) and continue until 4 weeks after the last dose of Thalomid (thalidomide).

These steps must be taken even if you have a history of infertility, unless your uterus has been surgically removed or you have had no periods for at least 24 months.

You must have a pregnancy test within 24 hours before beginning treatment. Your doctor must see a written report of a negative pregnancy test before Thalomid (thalidomide) can

be prescribed. Another pregnancy test must be taken every week during the first month of taking Thalomid (thalidomide) and during every month for the rest of the treatment, if your cycles are regular. For women with irregular cycles, pregnancy tests must be taken every 2 weeks.

If you miss your period or have abnormal menstrual bleeding while taking Thalomid (thalidomide), contact your health professional right away.

Some medications can reduce the effectiveness of birth control pills. These include some HIV medications, griseofulvin (an anti-fungus medication), phenytoin (an anti-seizure medication), rifampin (an anti-tuberculosis medication), and carbamazepine (a medication used for epilepsy). If you are being treated with any of these drugs, you should use two methods of birth control other than birth control pills or not have heterosexual sexual contact.

For Men:

Because Thalomid (thalidomide) is present in semen, you must agree in writing to use a latex condom when engaging in any sexual contact with a woman of child-bearing age even if you have had a successful vasectomy.

For All Patients:

You will be told about these risks and receive the information in writing and be given the opportunity to view a video. Then you will be asked to sign a form saying that you understand the risks and the actions you must take to avoid them.

You will be required to submit your name and address to a national registry of patients taking Thalomid (thalidomide) so that health professionals can track any side effects. You will be asked to complete a telephone survey for this registry.

If you are under 18 years old, a parent or guardian must read the information and agree to comply with the instructions.

The use of Thalomid (thalidomide) in multiple myeloma results in an increased risk of blood-clotting events, such as deep venous thrombosis and pulmonary embolus. This risk increases significantly when Thalomid (thalidomide) is used in combination with standard chemotherapeutic drugs including dexamethasone. Patients and doctors are advised to watch for signs and symptoms of clotting events. Patients should contact a doctor if they have symptoms like shortness of breath, chest pain, or arm/leg swelling.

General Precautions with Thalomid:

- Thalomid (thalidomide) causes severe birth defects (see "Special Warnings" section).

- You must never share Thalomid (thalidomide) with anyone. You must take it only as prescribed.
- Thalomid (thalidomide) can cause significant nerve damage (called peripheral neuropathy) that can be permanent. Your doctor will examine you regularly for signs of this condition. If you have numbness, tingling, or pain or a burning sensation in your hands or feet, tell your doctor right away.
- Thalomid (thalidomide) causes sleepiness. Avoid situations where sleepiness may be a problem. For example, it may be difficult for you to drive a car or use other complex machinery. Do not take other medications that can cause additional sleepiness unless you have consulted with your healthcare professional.
- Thalomid (thalidomide) can cause rapid changes in blood pressure when you stand up resulting in dizziness, weakness or feeling faint. If you have been lying down or sitting, take a few moments to sit on the edge of the bed or chair before standing up.
- Some people have had an allergic reaction to Thalomid (thalidomide). If you have a rash, fever, rapid heartbeat, or very low blood pressure (e.g., feeling faint, weak or dizzy), contact your doctor right away.
- Thalomid (thalidomide) can cause a decrease in your white blood cell count. Your doctor should check your blood regularly while you are taking Thalomid (thalidomide) if there are any concerns about this.

What should I tell my doctor or healthcare provider?

Certain drugs cause sleepiness. Thalomid (thalidomide) frequently increases this effect for some other drugs, including barbiturates, chlorpromazine (a tranquilizer), and reserpine (a high blood pressure medicine), as well as alcohol. Some medications cause peripheral neuropathy (numbness, tingling, or pain and inflammation of the nerves), which can be a side effect of Thalomid (thalidomide). Any of these drugs should be used with caution while taking Thalomid (thalidomide). Review all the medications that you are taking with your healthcare professional, including those you take without a prescription.

Women must not become pregnant while taking Thalomid (thalidomide). Men must ensure they take adequate precautions to help prevent pregnancies. Even one dose of Thalomid (thalidomide) can cause severe birth defects or death to an unborn baby as early as the first month of pregnancy. (See Special Warnings section.) Because of potential side effects on the infant, do not breast-feed a child if you're taking Thalomid (thalidomide).

What are some possible side effects of Thalomid (thalidomide)? *(This is NOT a complete list of side effects reported with Thalomid (thalidomide). Your healthcare provider can discuss with you a more complete list of side effects.)*

The most serious side effect of Thalomid (thalidomide) is its ability to cause birth defects. (See "Special Warnings" section.)

There is also a concern that Thalomid (thalidomide) may cause an increase in viral load for HIV-positive patients.

Reports of patients' experience after Thalomid (thalidomide) became available:

Seizures, including grand mal convulsions, have been reported since Thalomid (thalidomide) has been approved for use. Most patients had disorders that may have made them more likely to develop seizure activity, and it is not currently known whether Thalomid(thalidomide) has any seizure-causing influence. During therapy with Thalomid (thalidomide), patients with a history of seizures or with other risk factors for the development of seizures should be monitored closely for clinical changes that could cause seizures to occur.

For more detailed information about Thalomid (thalidomide), ask your healthcare provider.

[Link to Thalomid's Approved Labeling](#) 