

S.T.E.P.S.® At-A-Glance

Initial Prescription

1. Counsel and perform pregnancy testing (if applicable)
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraception. Patients should be instructed to not extensively handle or open THALOMID® (thalidomide) Capsules and to maintain storage of capsules in blister packs until ingestion
3. Complete, print, and sign Patient Registration/ Patient-Physician Agreement Form
 - **Males (adults and children)**
 - **Females of childbearing potential include females who have not undergone a natural menopause** for at least 24 months
 - **Adult females not of childbearing potential include females who have had a natural menopause** for more than 24 consecutive months, a hysterectomy, or bilateral oophorectomy
4. Fax Patient Registration/Patient-Physician Agreement Form to 1-888-432-9325
5. Instruct patient to complete phone survey by calling 1-888-423-5436 prior to prescriber obtaining an authorization number
 - **All males:** Patient Registration/Patient-Physician Agreement Form is considered the initial phone survey
 - **All females:** Complete the appropriate phone survey
6. Complete a prescriber phone survey by calling 1-888-423-5436, and obtain a new authorization number for each prescription
 - You will need to enter the following information:
 - Prescriber's DEA number or Social Security number
 - Patient's Social Security number
 - Date and result of patient's last pregnancy test (if applicable); valid only for 7 days
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
7. Write the authorization number on the prescription; prescription and authorization number are valid only for 7 days
8. If drug is not dispensed within 7 days, surveys must be repeated. To cancel authorization number(s), call 1-888-423-5436

Subsequent Prescriptions

1. Perform scheduled pregnancy testing (if applicable)
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraception. Patients should be instructed to not extensively handle or open THALOMID® (thalidomide) Capsules and to maintain storage of capsules in blister packs until ingestion
3. Instruct patient to complete surveys **as scheduled**, prior to prescriber obtaining an authorization number and filling prescription
 - Monthly:
 - **Males (adults and children)**
 - **Females of childbearing potential (adults and children), female children not of childbearing potential**
 - Every 6 months:
 - **Adult females not of childbearing potential** (if had **natural menopause** for more than 24 consecutive months, a hysterectomy, or bilateral oophorectomy)
4. Complete a prescriber phone survey, which should be done on the day the prescription is written
 - You will need to enter the following information:
 - Prescriber's DEA number or Social Security number
 - Patient's Social Security number
 - Date and result of patient's last pregnancy test (if applicable); valid only for 7 days
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
5. Obtain authorization number for each new prescription; faxed prescriptions are permissible if state law allows
6. Write the authorization number on the new prescription; prescription and authorization number are valid only for 7 days
7. If drug is not dispensed within 7 days, surveys must be repeated. To cancel authorization number(s), call 1-888-423-5436

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE EVENTS, enclosed in pocket.

Multiple Myeloma

THALOMID® (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma. The effectiveness of THALOMID® (thalidomide) is based on response rates (see **CLINICAL STUDIES** section). There are no controlled trials demonstrating a clinical benefit, such as an improvement in survival.

Erythema Nodosum Leprosum

THALOMID® (thalidomide) is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). THALOMID® (thalidomide) is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. THALOMID® (thalidomide) is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

WARNINGS:

1. SEVERE, LIFE-THREATENING HUMAN BIRTH DEFECTS.

IF THALIDOMIDE IS TAKEN DURING PREGNANCY, IT CAN CAUSE SEVERE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. THALIDOMIDE SHOULD NEVER BE USED BY WOMEN WHO ARE PREGNANT OR WHO COULD BECOME PREGNANT WHILE TAKING THE DRUG. EVEN A SINGLE DOSE [1 CAPSULE (REGARDLESS OF STRENGTH)] TAKEN BY A PREGNANT WOMAN DURING HER PREGNANCY CAN CAUSE SEVERE BIRTH DEFECTS.

BECAUSE OF THIS TOXICITY AND IN AN EFFORT TO MAKE THE CHANCE OF FETAL EXPOSURE TO THALOMID® (thalidomide) AS NEGLIGIBLE AS POSSIBLE, THALOMID® (thalidomide) IS APPROVED FOR MARKETING ONLY UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM APPROVED BY THE FOOD AND DRUG ADMINISTRATION. THIS PROGRAM IS CALLED THE "SYSTEM FOR THALIDOMIDE EDUCATION AND PRESCRIBING SAFETY (S.T.E.P.S.®)." UNDER THIS RESTRICTED DISTRIBUTION PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM ARE ALLOWED TO PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, PATIENTS MUST BE ADVISED OF, AGREE TO, AND COMPLY WITH THE REQUIREMENTS OF THE S.T.E.P.S.® PROGRAM IN ORDER TO RECEIVE PRODUCT.

2. VENOUS THROMBOEMBOLIC EVENTS.

THE USE OF THALOMID® (thalidomide) IN MULTIPLE MYELOMA RESULTS IN AN INCREASED RISK OF VENOUS THROMBOEMBOLIC EVENTS, SUCH AS DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLUS. THIS RISK INCREASES SIGNIFICANTLY WHEN THALIDOMIDE IS USED IN COMBINATION WITH STANDARD CHEMOTHERAPEUTIC AGENTS INCLUDING DEXAMETHASONE. IN ONE CONTROLLED TRIAL, THE RATE OF VENOUS THROMBOEMBOLIC EVENTS WAS 22.5% IN PATIENTS RECEIVING THALIDOMIDE IN COMBINATION WITH DEXAMETHASONE COMPARED TO 4.9% IN PATIENTS RECEIVING DEXAMETHASONE ALONE ($P=0.002$). PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. PRELIMINARY DATA SUGGEST THAT PATIENTS WHO ARE APPROPRIATE CANDIDATES MAY BENEFIT FROM CONCURRENT PROPHYLACTIC ANTICOAGULATION OR ASPIRIN TREATMENT.

IMPORTANT SAFETY INFORMATION

Hypersensitivity: THALOMID® (thalidomide) is contraindicated in any patients who have demonstrated hypersensitivity to the drug or its components.

Nursing mothers: It is not known whether THALOMID® (thalidomide) is excreted in human milk. Because of the potential for adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

Peripheral neuropathy: THALOMID® (thalidomide) is known to cause nerve damage that may be permanent. Peripheral neuropathy is a common, potentially severe, side effect of treatment with thalidomide that may be irreversible.

Other most common adverse events: Multiple Myeloma (THALOMID®/dexamethasone): The most frequently reported adverse events were constipation (55%), sensory neuropathy (54%), confusion (28%), hypocalcemia (72%), edema (57%), dyspnea (42%), thrombosis/embolism (23%), and rash/desquamation (30%) (occurring in $\geq 20\%$ of patients and with a frequency $\geq 10\%$ in patients treated with THALOMID®/dexamethasone compared with dexamethasone alone).

ENL (THALOMID®): The most frequently reported adverse events were somnolence (38%), rash (21%), headache (13%), asthenia (8%), impotence (8%), malaise (8%), pain (8%), pruritus (8%), and vertigo (8%) (occurring in $\geq 5\%$ of patients). In placebo-controlled clinical trials of HIV-seropositive patient populations, there have been reports of increased plasma HIV RNA levels.

THALOMID must be administered in compliance with all of the terms outlined in the S.T.E.P.S.® program by prescribers, pharmacists, and patients registered with S.T.E.P.S.®. Patients should be instructed to not extensively handle or open thalidomide capsules and to maintain storage of capsules in blister packs until ingestion.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS, enclosed in pocket.

For further information about THALOMID®, please call the Celgene Customer Care Center at 1-888-423-5436 or visit www.THALOMID.com