

**Male Patients**

- Provide counseling not to share drug, not to donate blood or sperm, and on contraceptive use, including counseling on emergency 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
- Use the patient education materials provided in the S.T.E.P.S.® Patient Resource Pack
- Male patients must be instructed to always use a latex condom every time they have heterosexual sexual contact with a woman who is or can get pregnant, even if they have undergone a successful vasectomy, as THALOMID® (thalidomide) is present in semen. The risk to the fetus from the semen of male patients taking thalidomide is unknown

**Completing Telephone Surveys**

- Instruct the patient to complete a brief telephone survey by calling 1-888-423-5436
  - For all males, the Patient Registration/Patient-Physician Agreement Form is considered the initial telephone survey
- Prescriber will complete a brief telephone survey by calling 1-888-423-5436 for every patient before each prescription is written
  - An authorization number will be issued upon completion of the survey and must be written on the prescription. This prescription and authorization number is valid only for 7 days
  - Write authorization number on the prescription

**Additional Prescribing Information**

- Prescriptions cannot be issued by telephone; faxed prescriptions to pharmacies are permissible if state laws allow
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills
- Inform the patient that all prescriptions must be filled within 7 days

**For Subsequent THALOMID® (thalidomide) Prescriptions**

The prescriber must complete a brief telephone survey to obtain a new authorization number *EVERY TIME* a prescription for THALOMID® (thalidomide) is written.

**For female patients:**

- Repeat counseling for every patient
- Follow pregnancy test requirements as outlined in the Female Patients section
- Female patients must complete a brief telephone survey according to the following schedule:
  - **Monthly**
    - Adult females of childbearing potential
    - All female children
  - **Every 6 months**
    - Adult females not of childbearing potential

**For male patients:**

- Provide patient counseling as outlined in the Male Patients section
- Male patients must complete a brief telephone survey once a month

# Instructions for Prescribers

**Review the S.T.E.P.S.® Starter Kit****S.T.E.P.S.® Prescriber Resources (1 per registered prescriber)**

- CD-ROM to generate Patient Registration/Patient-Physician Agreement Forms (for Windows® and Macintosh®)
- S.T.E.P.S.® At-A-Glance
- Prescriber Guide to English and Non-English Materials
- Instructions for Prescribers
- THALOMID® (thalidomide) Patient Chart Sticker for each chart (located on Patient Resource Pack)
- Full Prescribing Information for THALOMID® (thalidomide)

**S.T.E.P.S.® Patient Resource Pack (1 per patient)**

- S.T.E.P.S.® Guide to Patient Surveys
- Important Information for Men and Women Taking THALOMID® (thalidomide) Brochure
- Emergency Contraception Brochure
- Your Contraceptive Choices Brochure

**S.T.E.P.S.® System Setup for Prescribers**

- Insert appropriate computer software (CD-ROM)
- Install S.T.E.P.S.® Patient Registration/Patient-Physician Agreement Form Program
- Computer software is installed only once

**Patient Registration**

Before a patient can receive THALOMID® (thalidomide), he or she must understand and, along with the prescriber, sign a completed Patient Registration/Patient-Physician Agreement Form (available on CD-ROM).

Prescribers who do not have access to a computer or whose computer systems are not compatible with the Windows®/Macintosh® CD-ROM provided with S.T.E.P.S.® materials should use the Prescriber Guide to English and Non-English Materials. These services provide Patient Registration/Patient-Physician Agreement Forms, Patient Brochures, and Survey Forms in 16 languages, including English.



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**Patient Registration (continued)**

- Generate appropriate Patient Registration/Patient-Physician Agreement Form
  - Enter patient data
  - Enter prescriber data
- Print and complete the Patient Registration/Patient-Physician Agreement Form
  - Patient, parent/legal guardian, and/or authorized representative must read the Patient Registration/Patient-Physician Agreement Form in the language of their choice (available in 16 languages through the Celgene Customer Care Center at 1-888-423-5436)
  - **Each statement must be initialed by the patient to indicate understanding**
  - **The form must be completed and signed by both prescriber and patient**
  - If the patient is under 18 years of age, his or her legal guardian must read this material, initial the statements, sign the form, and agree to ensure compliance
  - For an incompetent adult patient, an authorized representative must sign the Patient Registration/Patient-Physician Agreement Form. An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient's behalf. The authorized representative must read the material, initial the statements, sign the form, and agree to ensure compliance.

Along with the Patient Registration/Patient-Physician Agreement Form, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center.** This letter must contain the following: A statement that the incompetent patient lacks the capacity to complete the Patient Registration/Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with S.T.E.P.S.® and is authorized to consent to THALOMID® (thalidomide) treatment on behalf of the patient

  - **Do not write on Patient-Physician Agreement Form except in designated boxes**
- Fax the completed Patient Registration/Patient-Physician Agreement Form to the Celgene Customer Care Center at 1-888-432-9325
- A confirmation letter stating that surveys can be taken as required will be faxed to your office once the patient is registered. In the event that you do not receive this confirmation letter, call the Celgene Customer Care Center at 1-888-423-5436

**Note:** If THALOMID® (thalidomide) therapy is discontinued for 12 consecutive months, the patient must register again in the S.T.E.P.S.® program. Follow the above procedures to reregister the patient.

**Initial THALOMID® (thalidomide) Prescriptions**

After the appropriateness of THALOMID® (thalidomide) therapy has been established, please refer to the following step-by-step guidelines:

- Provide comprehensive counseling on the benefits and risks of THALOMID® (thalidomide) therapy
  - Patients must be counseled on the risks of birth defects, venous thromboembolic events, other side effects, and important precautions associated with THALOMID® (thalidomide)

**Female Patients**

Two categories:

- 1 – Females not of childbearing potential include females who have had a natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy
- 2 – Females of childbearing potential are all other females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal

- For all female patients:
  - Provide counseling not to share drug, not to donate blood, and on appropriate contraceptive use, including counseling on emergency 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
  - Use the patient education materials provided in the S.T.E.P.S.® Patient Resource Pack
- For female patients of childbearing potential:
  - Female patients must thoroughly understand the need for two of the recommended forms of birth control beginning at least 4 weeks before therapy, during therapy, and for at least 4 weeks following discontinuation of THALOMID® (thalidomide) therapy
  - Contraceptive methods must include at least one highly effective method (e.g., intrauterine device [IUD], hormonal [birth control pills, injections, hormonal patches, or implants], tubal ligation, or partner's vasectomy) **AND** one additional effective barrier method (e.g., latex condom, diaphragm, or cervical cap)
  - If hormonal contraception is chosen as a highly effective method, concomitant use of prescription drugs including modafinil, penicillins, or certain herbal supplements such as St. John's Wort may reduce the effectiveness of the contraception and up to 1 month after discontinuation of these concomitant therapies. For patients using any hormonal therapy, one additional effective barrier method must be used **AT THE SAME TIME**
  - If hormonal or IUD contraception is medically contraindicated, another highly effective method or two barrier methods must be used **AT THE SAME TIME**
  - Perform an in-office pregnancy test, sensitive to at least 50 mIU/mL (urine or serum), even if continuous abstinence is the chosen method of birth control
    - The in-office pregnancy test must be performed, **with negative results**, within the 24 hours prior to beginning THALOMID® (thalidomide) therapy
  - Perform a pregnancy test weekly during the first 4 weeks of therapy
  - Pregnancy testing should be repeated every month if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
  - Negative pregnancy tests are valid only for 7 days
  - Pregnancy testing and counseling should be performed if a patient misses her period or if there is any abnormality in menstrual bleeding
  - If pregnancy does occur during treatment, THALOMID® (thalidomide) must be immediately discontinued. Any suspected fetal exposure to THALOMID® (thalidomide) must be reported immediately to the Celgene Customer Care Center at 1-888-423-5436. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling