

**S.T.E.P.S.**  
*System for Thalidomide Education and Prescribing Safety*  
**INSTRUCTIONS FOR PHYSICIANS**

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**PHYSICIAN REGISTRATION**

- All physicians must register in the S.T.E.P.S. Physician Registry via the Physician Registration Card that is located in every S.T.E.P.S. folder. Only licensed Medical Doctors or Doctors of Osteopathy may register.
- Complete, sign, and return the Physician Registration Card. By doing so, you agree to prescribe THALOMID™ (thalidomide) in accordance with all the terms listed on the card.
- Wait for confirmation of your registration prior to prescribing THALOMID™ (thalidomide).

**S.T.E.P.S. PROGRAM MATERIALS**

- All materials that are necessary to comply with S.T.E.P.S. program requirements are contained in the S.T.E.P.S. folder.
- The contents of **ONE FOLDER** should be used with **ONE PATIENT**, and kept with the patient's medical record.
- Additional S.T.E.P.S. folders can be obtained from your Celgene Immunology Specialist, or by calling 1-888-4-CELGENE.

**S.T.E.P.S. FOLDER CONTENTS**

The S.T.E.P.S. Folder contains the following information and materials to help ensure that fetal exposure to THALOMID™ (thalidomide) does not occur:

- **Physician Registration Card:** All physicians must register.
- **Thalidomide Victims Association of Canada letter:** A cautionary message to the physician and patient from thalidomide victims.
- **Information for Men and Women Taking THALOMID™ (thalidomide):** Use this brochure for patient counseling regarding the teratogenic risks, as well as other side effects and precautions associated with THALOMID™ (thalidomide) therapy. A video presentation of this information will be provided to your office upon registration.
- **Your Contraceptive Choices:** This brochure is provided to assist in counseling patients on the selection of two appropriate contraceptive methods.
- **Emergency Contraception:** Use this brochure to assist patients in the event they have unprotected sexual intercourse while taking THALOMID™ (thalidomide).
- **Patient Referral Form:** A form that must be used if you choose to have another health care professional provide contraceptive counseling for your patient.
- **Patient Quiz:** The quiz is provided to verify patient understanding of risks and requirements of therapy.
- **Consent Form:** This informed consent document **must be understood** and **signed** before your patient can receive THALOMID™ (thalidomide).
- **Thalidomide Survey Forms:** These mandatory and confidential enrollment and follow-up surveys must be completed by the patient and physician. Men must participate, as well as women, because fetal exposure to THALOMID™ (thalidomide) could occur as a result of the presence of the drug in semen or through sharing of the medication. Included are forms for patients ages 18 or older. **Forms for patients under 18 years of age are available by calling 1-888-4-CELGENE.**

*Important Information for Men and Women Taking THALOMID™ (thalidomide), the Consent Form, the Patient Quiz and the Survey Forms are available in 14 languages and can be obtained through your Celgene Immunology Specialist or by calling 1-888-4-CELGENE.*

## PRESCRIBING THALOMID™ (thalidomide) FOR FEMALE PATIENTS

### INITIAL VISIT

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- **Establish appropriateness of THALOMID™ (thalidomide) therapy versus therapeutic alternatives.**
  - THALOMID™ (thalidomide) is indicated for the treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). THALOMID™ (thalidomide) is not indicated as monotherapy for ENL 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. Efficacy has not been established in HIV disease.
- **Provide comprehensive counseling on the risks and benefits of THALOMID™ (thalidomide) therapy.**
  - Patients must be counseled on the risk of birth defects, other side effects, and important precautions associated with THALOMID™ (thalidomide) therapy.
  - Utilize the patient education materials provided.
- **Determine if patient has childbearing potential.**
  - If patient has undergone a hysterectomy, been post-menopausal or had no menses for at least 24 consecutive months, or agrees to abstain from sexual intercourse with men, continue with the instructions provided in the INITIATING THALOMID™ (thalidomide) THERAPY section below.
  - If patient does not meet the above criteria, provide contraceptive counseling, including counseling on emergency contraception.
    - Female patients must thoroughly understand the need for two forms of contraception to be used AT THE SAME TIME, beginning 4 weeks before therapy, throughout therapy, and for 4 weeks after stopping therapy with THALOMID™ (thalidomide).
    - Contraceptive methods must include at least one highly effective method (eg, IUD, hormonal, tubal ligation, or partner's vasectomy) and one additional effective method (eg, condom, diaphragm, or cervical cap).
    - If hormonal or IUD contraception is medically contraindicated, two other effective or highly effective methods must be used.
    - Utilize the patient education materials provided.
  - Physicians may refer patients to another health care professional for contraceptive counseling using the Patient Referral Form.
- **Continue selected birth control options for 4 weeks prior to initiating THALOMID™ (thalidomide).**

### INITIATING THALOMID™ (thalidomide) THERAPY

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- **Repeat patient counseling.**
- **Perform pregnancy test, even if continuous abstinence is the chosen method of birth control.**
  - Test must be performed in the physician's office or lab and satisfy a sensitivity of at least 50 mIU/mL.
  - Test must be performed on female patients with childbearing potential, **with negative results**, within the 24 hours before beginning THALOMID™ (thalidomide) therapy.
  - Women of childbearing potential must also receive a pregnancy test every week for the first 4 weeks, then every 4 weeks thereafter if their menstrual cycles are regular.
  - If the menstrual cycle is irregular, they must receive a pregnancy test every 2 weeks thereafter.
  - Pregnancy testing must also be performed if a patient misses her period or if there is any abnormality in menstrual bleeding.
  - If pregnancy does occur during treatment, the drug must be immediately discontinued and the physician and patient should discuss the implications of the pregnancy. Under these conditions, the patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity.

## PRESCRIBING THALOMID™ (thalidomide) FOR FEMALE PATIENTS

- **Administer the THALOMID™ (thalidomide) Patient Quiz.**
  - Gauge patient understanding of the requirements for taking the drug.
  - If the patient cannot answer all of the questions correctly, review the material that she does not understand.
  - Re-administer patient quiz. Repeat until the patient satisfactorily understands all risks and correctly answers all questions or reconsider the appropriateness of THALOMID™ (thalidomide) therapy.
- **Complete the informed consent form.**
  - The consent form must be read to the patient in the language of their choice. Each statement must be initialed by the patient to indicate understanding, and the form must be completed and signed by both physician and patient.
  - The signature of a parent or guardian will also be required if the patient is under 18 years of age. Patients under 12 years of age must have a parent or guardian sign on their behalf.
  - Retain "Physician" copy with patient record.
  - Mail "Survey Coordinator" copy (via self-mailing format).
  - Instruct patient to retain "Patient" copy and to present "Pharmacist" copy with prescription to pharmacist.
- **Complete the mandatory and confidential survey enrollment form.**
  - Instruct patients to complete the confidential section, seal the survey and return to you.
  - Complete physician section and return in envelope provided to the Slone Epidemiology Unit of Boston University School of Public Health.
- **Provide prescription.**
  - Initial prescriptions cannot be issued by telephone.
  - Prescribe no more than 4 weeks (28 days) of therapy with no automatic refills.
  - It is recommended that female patients initially receive no more than a 1-week supply for each of the first 4 weeks to coincide with weekly pregnancy testing requirements.

### PATIENT MONITORING DURING FIRST 4 WEEKS OF THERAPY

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- Repeat patient counseling.
- Perform pregnancy tests every week for the first 4 weeks of therapy.
  - It is recommended that pregnancy tests be performed within the 24 hours before providing subsequent prescriptions.
  - Pregnancy tests must be performed even if continuous abstinence is the chosen method of birth control.
- If pregnancy test is negative, provide prescription for a 1-week supply of THALOMID™ (thalidomide).

### SUBSEQUENT PATIENT VISITS (after the first 4-week period)

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- Repeat patient counseling.
- Perform pregnancy test every 4 weeks if patient's menstrual cycles are regular, every 2 weeks if cycles are irregular.
  - It is recommended that pregnancy tests be performed within the 24 hours before providing subsequent prescriptions.
  - Pregnancy tests must be performed even if continuous abstinence is the chosen method of birth control.
- If pregnancy test is negative, provide prescription for no more than a 4-week (28-day) supply of THALOMID™ (thalidomide) therapy.
- Complete the follow-up survey form.
  - Forms are included in the S.T.E.P.S. folder.
  - Female patients must complete the form every month.

## PRESCRIBING THALOMID™ (thalidomide) FOR MALE PATIENTS

### INITIAL VISIT

- **Establish appropriateness of THALOMID™ (thalidomide) therapy versus therapeutic alternatives.**
  - THALOMID™ (thalidomide) is indicated for the treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). THALOMID™ (thalidomide) is not indicated as monotherapy for ENL 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. Efficacy has not been established in HIV disease.
- **Provide comprehensive counseling on the risks and benefits of THALOMID™ (thalidomide) therapy.**
  - Patients must be counseled on the risk of birth defects, other side effects, and important precautions associated with THALOMID™ (thalidomide) therapy.
  - Utilize the patient education materials provided.
- **Provide contraceptive counseling, including counseling on emergency contraception.**
  - Men must be instructed to use a latex condom every time they have sexual intercourse with a woman.
  - Utilize patient education materials provided.
- **Administer the THALOMID™ (thalidomide) Patient Quiz.**
  - Gauge patient understanding of the requirements for taking the drug.
  - If the patient cannot answer all of the questions correctly, review the material that he does not understand.
  - Re-administer patient quiz. Repeat until the patient satisfactorily understands all risks and correctly answers all questions or reconsider the appropriateness of THALOMID™ (thalidomide) therapy.
- **Complete the informed consent form.**
  - The consent form should be read to the patient in the language of their choice. Each statement must be initialed by the patient to indicate understanding, and the form must be completed and signed by both physician and patient.
  - The signature of a parent or guardian will also be required if the patient is under 18 years of age. Patients under 12 years of age must have a parent or guardian sign on their behalf.
  - Retain "Physician" copy with patient record.
  - Mail "Survey Coordinator" copy (via self-mailing format).
  - Instruct patient to retain "Patient" copy and to present "Pharmacist" copy with prescription to pharmacist.
- **Complete the mandatory and confidential survey enrollment form.**
  - Instruct patients to complete the confidential section, seal the survey and return to you.
  - Complete physician section and return in envelope provided to the Slone Epidemiology Unit of Boston University School of Public Health.
- **Provide prescription.**
  - Initial prescriptions can not be issued by telephone.
  - Prescribe no more than 4 weeks (28 days) of therapy with no automatic refills.

### SUBSEQUENT PATIENT VISITS

- **Repeat patient counseling.**
- **Complete the follow-up survey form.**
  - Forms are included in the *S.T.E.P.S.* folder.
  - Male patients must complete the form at each visit or at least once every 3 months.