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## Pharmacy Guide to

((THALOMID REMS<sup>®</sup> logo))

## Risk Evaluation and Mitigation Strategy (REMS) Program

### Important information about THALOMID<sup>®</sup> (thalidomide) and the THALOMID REMS<sup>®</sup> program

- THALOMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called “THALOMID REMS<sup>®</sup>” (formerly known as the *S.T.E.P.S.*<sup>®</sup> program)
- Only prescribers and pharmacies certified with the THALOMID REMS<sup>®</sup> program can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the THALOMID REMS<sup>®</sup> program
- Dispensing pharmacists must be educated on the THALOMID REMS<sup>®</sup> program and on dispensing procedures for THALOMID
- Information about THALOMID and the THALOMID REMS<sup>®</sup> program can be obtained by visiting [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

((THALOMID logo))

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## Guidelines for ordering, counseling, and dispensing THALOMID<sup>®</sup> (thalidomide)

Dispensing pharmacies must be certified in the THALOMID REMS<sup>®</sup> program with Celgene and must be educated in the following dispensing procedures.

### Step 1. Review incoming THALOMID prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them.
  - Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted
  - Faxed prescriptions are permissible depending on state laws
- B. Make sure the prescription is signed and dated.
- C. Confirm the prescription is written for a 4-week (28-day) supply or less.
- D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription.

### Step 2. Counsel patients

- A. Make sure a **certified THALOMID REMS<sup>®</sup>** counselor counsels the patient.
- B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.
- C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID, make sure to document these experiences using acceptable documentation as noted on the checklist.
  - **Acceptable documentation examples:**
    1. Celgene Adverse Drug Event form and fax confirmation
    2. Pharmacy log
- D. Report adverse drug experiences that are suspected to be associated with the use of THALOMID to Celgene Drug Safety within 24 hours. See the Adverse Drug Experience Reporting Procedure on page 7 for more information.

## Guidelines for ordering, counseling, and dispensing THALOMID<sup>®</sup> (thalidomide) (continued)

### Step 3. Obtain confirmation number from Celgene Customer Care

- A. Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week. Eligible pharmacies may also use the Celgene REMS Pharmacy Portal at [www.CelgeneREMSPharmacyPortal.com](http://www.CelgeneREMSPharmacyPortal.com). Call your Celgene Account Manager to see if your pharmacy is eligible.
- Enter the pharmacy NABP number or DEA number
  - Enter the authorization number written on the prescription
  - Enter the number of capsules and milligram strength being dispensed
- B. Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.
- C. If you do not obtain a confirmation number, do not dispense THALOMID.

### Step 4. Dispensing

- A. No Refills. A new prescription is required for each dispense. **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.**
- B. Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.
- C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.

#### Acceptable documentation examples:

1. Signed Education and Counseling Checklist (if counseling pharmacist and dispensing pharmacist are the same)
  2. Pharmacy log
- D. Document the dispense date and maintain a record on acceptable documentation

#### Acceptable documentation examples:

1. Shipping receipt
  2. Pharmacy dispensing log
- E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.

F. A signature is required for all shipping and dispense if picked up by patient.

**Step 5. Perform drug accountability**

- A. Pharmacy shall keep an inventory log for THALOMID, by strength, reflecting its on-hand inventory at all times.
- B. Do not transfer THALOMID to another pharmacy without prior authorization from Celgene.
- C. Accept unused THALOMID (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal.

## **THALOMID Risk Evaluation Mitigation Strategy (REMS) Education and Counseling Checklist for Pharmacies**

### **Ensure your patients know the risks**

Before you are able to fill a prescription for THALOMID<sup>®</sup> (thalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off ([✓]) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.

Be prepared to provide the following information for each checklist: ((IMAGE OF CHECKLIST))

Authorization Number	Confirmation Number	Confirmation Date
Pharmacy Name	Pharmacy Address (including City, State, ZIP Code)	
Counselor Name	Work Phone Number	Extension
Patient Name	Patient Date of Birth	

### **Rules for dispensing and shipping**

#### **Making sure before you release THALOMID**

#### **DO NOT DISPENSE OR SHIP THALOMID TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:**

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing THALOMID prescription

**For further information about THALOMID, please refer to the full Prescribing Information, enclosed.**

## **Adverse drug experience reporting procedure for healthcare professionals**

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of THALOMID® (thalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID to Celgene using any of the following methods.

### **REPORTING TO CELGENE**

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

### **REPORTING TO THE FDA**

Adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online at: **<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>**
- Telephone: **1-800-FDA-1088**
- Fax: **1-800-FDA-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

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Celgene Corporation

86 Morris Ave

Summit, NJ 07901

**THALOMID is only available under a restricted distribution program, THALOMID REMS<sup>®</sup>.**

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

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