

Initial REMS Approval August/2010

Most Recent Modification 06/2017

**THALOMID<sup>®</sup> (thalidomide)**

**NDA # 020785**

Celgene Corporation

86 Morris Avenue

Summit, NJ 07901

Contact Information:

**1-908-673-9000**

**www.celgene.com**

**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**1. GOALS**

The goals of the THALOMID risk evaluation and mitigation strategy are as follows:

- To prevent the risk of embryo-fetal exposure to THALOMID.
- To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for THALOMID.

**2. REMS ELEMENTS**

**2.1. Elements to Assure Safe Use**

**2.1.1. Healthcare providers who prescribe THALOMID are specially certified.**

Celgene will ensure that healthcare providers who prescribe THALOMID are specially certified in the THALOMID REMS<sup>®</sup> program. THALOMID<sup>®</sup> (thalidomide) is available only through a restricted distribution program, THALOMID REMS<sup>®</sup>.

To become certified, each prescriber must complete the Prescriber Enrollment Form and agree to do the following:

- a. Provide patient counseling on the benefits and risks of THALOMID therapy, including risks described in the BOXED WARNINGS.
- b. Enroll each patient by completing and submitting to the Celgene Customer Care Center via mail (86 Morris Avenue, Summit, NJ 07901), email ([customer care@celgene.com](mailto:customer care@celgene.com)), fax (1-888-432-9325), or online ([www.celgeneriskmanagement.com](http://www.celgeneriskmanagement.com)), a signed Patient-Physician Agreement Form (PPAF) identifying the patient's risk category (see PPAFs) for all six risk categories) for each new patient. In signing the PPAF, each prescriber acknowledges that they understand that THALOMID is available only through the THALOMID REMS<sup>®</sup> program, and that they must comply with program requirements.

- c. Provide contraception and emergency contraception counseling with each new prescription prior to and during THALOMID treatment.
- d. Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions.
- e. Report any pregnancies in female patients or female partners of male patients prescribed THALOMID immediately to Celgene Drug Safety (or Celgene Customer Care Center (1-888-423-5436)).
- f. Complete a prescriber survey (phone or online) for every patient (new and follow-up), obtain a unique prescription authorization number for each prescription written, and include this authorization number on the prescription. The authorization number can be obtained by contacting the Celgene Customer Care Center, using the automated IVR system, or via the [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) website.
  - o For females of reproductive potential, authorization numbers are valid only for 7 days from date of last pregnancy test.
  - o Authorization numbers are valid for 30 days from the date it is issued for all other patients.
- g. Facilitate compliance with the mandatory THALOMID REMS<sup>®</sup> patient survey by instructing patients to complete the mandatory surveys (phone or online) at program specified frequencies.
- h. Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions.
- i. Contact a pharmacy certified by the THALOMID REMS<sup>®</sup> program to fill the THALOMID prescription.
- j. Return all unused THALOMID brought in by patients to Celgene Customer Care.
- k. Re-enroll patients in the THALOMID REMS<sup>®</sup> program if THALOMID is required and previous therapy with THALOMID has been discontinued for 12 consecutive months.

Celgene will:

1. Ensure that the THALOMID REMS<sup>®</sup> program materials including prescriber enrollment are available on the [CelgeneRiskManagement.com](http://CelgeneRiskManagement.com) website or can be obtained by contacting Celgene Customer Care Center at 1-888-423-5436
2. Maintain a secure database of all THALOMID REMS<sup>®</sup> certified prescribers.
3. Monitor to ensure that only THALOMID REMS<sup>®</sup> certified prescribers are prescribing THALOMID.
4. Monitor and ensure that patients have been assigned correctly to one of the following patient risk categories. Confirm risk category when completing the PPAFs during the patient enrollment process:
  - a. **Adult female of reproductive potential:** all females who are menstruating, amenorrheic from previous medical treatments, under 50 years, and/or perimenopausal.
  - b. **Female child of reproductive potential:** all females under 18 years who are menstruating.
  - c. **Adult female NOT of reproductive potential:** females who have had a natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy.

- d. **Female child NOT of reproductive potential:** all females under 18 years who are not menstruating.
  - e. **Adult males 18 years or older**
  - f. **Male child under 18 years**
5. Monitor certified prescriber compliance with the THALOMID REMS<sup>®</sup> program, including patient risk categorization and the appropriate corresponding counseling requirements, contraception requirements, pregnancy testing, and survey completion for all patients treated with THALOMID.
  6. Institute corrective action and prevent the certified prescriber from prescribing THALOMID if the prescriber is found to be non-compliant with the THALOMID REMS<sup>®</sup> program.
  7. Train THALOMID REMS<sup>®</sup> program certified prescribers in adverse experience reporting procedures, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to THALOMID if a pregnancy occurs.
  8. Ensure that once the prescriber submits the completed PPAF, the prescriber will receive a confirmation letter via fax or online to confirm the patient's enrollment and signify that the prescriber and patient surveys can be taken to receive an authorization number for the THALOMID prescription (for all males, the PPAF is considered the initial survey). The authorization number is written on the THALOMID prescription.
  9. Ensure that, for subsequent prescriptions, the prescriber completes a telephone or online survey designed to look for signals of at-risk behavior (e.g., pending or outdated pregnancy test), report the patient's pregnancy test results, correct assignment of risk category, and confirm or re-enforce patient understanding of contraceptive requirements. The completion of the survey will allow the prescriber to obtain a new authorization number every time a prescription for THALOMID is written.

The following materials are part of the REMS, and are appended:

- [Prescriber Enrollment Form](#)
- [Patient Prescription Form](#)
- [Patient Prescription Form \(Veterans Health Administration\)](#)
- [Prescriber Guide to THALOMID REMS<sup>®</sup> Program](#)
- [THALOMID REMS<sup>®</sup> At-A-Glance](#)
- [Welcome Letter](#)
- [Celgene Risk Management.com website](#)

**2.1.2. THALOMID will only be dispensed by pharmacies that are specially certified.**

Celgene will ensure that THALOMID is only dispensed from THALOMID REMS<sup>®</sup> program certified pharmacies. To become a THALOMID REMS<sup>®</sup> program certified pharmacy, the pharmacy must agree to do the following before filling a THALOMID prescription:

- a. Only accept prescriptions with a prescription authorization number. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients.
- b. Dispense no more than a 4-week (28-day) supply, and require a new prescription from the patient prior to dispensing additional THALOMID.

- c. Dispense subsequent prescriptions only if there are 7 days or less remaining on an existing THALOMID prescription.
- d. Obtain a THALOMID REMS<sup>®</sup> confirmation number from the Celgene Customer Care Center (phone or online) and write this confirmation number on the prescription. The THALOMID REMS<sup>®</sup> confirmation number may be obtained using the following procedure:
  - 1. Enter the pharmacy identification number (NABP or DEA);
  - 2. Enter the prescription authorization number written on the prescription;
  - 3. Enter the number of capsules and milligram (mg) strength being dispensed;
  - 4. Dispense or ship the prescribed THALOMID within 24 hours of obtaining and recording the THALOMID REMS<sup>®</sup> confirmation number and confirmation date.
- e. Dispense THALOMID only after a THALOMID REMS<sup>®</sup> confirmation number is obtained. If no confirmation is obtained, then no THALOMID is dispensed. Contact the patient's physician and Celgene for further instruction.
- f. Accept unused THALOMID (previously dispensed) from a patient or patient caregiver and return to Celgene Corporation for proper disposal.
- g. For each patient receiving treatment, retain a record of each THALOMID prescription dispensed and the corresponding completed Education and Counseling Checklist.
- h. Complete the checklist that applies to the patient risk category written on the front of the Education and Counseling Checklist for Pharmacies.
- i. Provide counseling to patients and/or guardians of patients under 18 years of age receiving THALOMID treatment.
  - a. Counsel all patients and guardians of patients under 18 years of age on the following:
    - 1. The benefits and risks of THALOMID therapy.
    - 2. Not sharing THALOMID medication.
    - 3. Not donating blood while taking THALOMID, during dose interruptions, and for 4 weeks after stopping THALOMID.
    - 4. Not to break, chew, or open THALOMID capsules.
    - 5. Instructions on THALOMID dose and administration.
    - 6. To read the THALOMID REMS<sup>®</sup> program education materials and encourage compliance with the requirements.
  - b. In addition to above, counsel **Females of Reproductive Potential** on the following:
    - 1. The potential for embryo-fetal toxicity with exposure to THALOMID.
    - 2. Using 2 methods of effective birth control (at least one highly effective method and one effective method) at the same time or abstaining from heterosexual sexual intercourse.
    - 3. Continuing to use 2 methods of effective of birth control (at least one highly effective method and one effective method) at the same time if THALOMID therapy is interrupted and for at least 4 weeks after therapy is discontinued.
    - 4. Obtaining a pregnancy test weekly during the first 4 weeks of THALOMID use, then a repeat pregnancy test every 4 weeks in females with regular menstrual cycles, and every 2 weeks in females with irregular menstrual cycles.
    - 5. The need to stop taking THALOMID and notify their THALOMID prescriber immediately if they become pregnant or suspect they may be pregnant.

- c. In addition to items listed for all patients above, counsel **Males** receiving THALOMID treatment about the potential for embryo-fetal toxicity with exposure to THALOMID and the importance of using barrier contraception by wearing a latex or synthetic condom when engaging in sexual intercourse with a female of reproductive potential even if the male receiving THALOMID has had a successful vasectomy.
  1. The need to not donate sperm while taking THALOMID, during dose interruptions, and for 4 weeks after stopping THALOMID.
- d. Counsel the **Parent or legal guardian of Female Child NOT of reproductive potential** who is receiving THALOMID treatment about the need to inform their THALOMID prescriber when the child begins menses.

Before a certified pharmacy dispenses THALOMID, Celgene will train the appropriate pharmacy staff:

- a. About the THALOMID REMS<sup>®</sup> program
  - b. About the procedures for reporting adverse experiences to Celgene, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to THALOMID if a pregnancy occurs.
1. The following materials are part of the REMS and are appended:
    - [Pharmacy Guide to the THALOMID REMS<sup>®</sup> Program](#)
    - [Education and Counseling Checklist for Pharmacies](#)
    - [Celgene REMS Programs Pharmacy Training: the THALOMID REMS<sup>®</sup> Program](#)
    - [Pharmacy Certification Quiz \(the THALOMID REMS<sup>®</sup> Program\)](#)

**2.1.3. Celgene will ensure that THALOMID will only be dispensed to patients enrolled in the THALOMID REMS<sup>®</sup> program with evidence or other documentation of safe-use conditions.**

Celgene will ensure that all patients treated with THALOMID are enrolled by a certified prescriber. The prescriber will enroll the patient by completing Patient-Physician Agreement Form and submitting the form via mail (86 Morris Avenue, Summit, NJ 07901), fax (1-888-432-9325), email ([customer care@celgene.com](mailto:customer care@celgene.com)) or online ([www.celgeneriskmanagement.com](http://www.celgeneriskmanagement.com)) for each patient who receives THALOMID. Each patient and/or guardian of patients under 18 years of age consents to participate in the program by:

- a. acknowledging that he or she understands that:
  - i. severe birth defects or death to an unborn baby may occur if a female becomes pregnant while she is receiving THALOMID;
  - ii. THALOMID must not be shared with anyone, even someone with similar symptoms;
  - iii. THALOMID must be kept out of the reach of children and should NEVER be shared with females who are able to have children;
  - iv. they cannot donate blood while receiving THALOMID, including dose interruptions, and for 4 weeks after stopping THALOMID;

- v. they might be asked to participate in the THALOMID Pregnancy Exposure Registry; and
  - vi. they may be contacted by Celgene about following the rules of the REMS.
- b. In addition, each patient and/or guardian of patients under 18 years of age consents to participate in the program by:
- i. agreeing to return unused THALOMID to Celgene or their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them;
  - ii. agreeing to participate in a monthly (telephone or online) survey while on THALOMID (with the exception of Adult Females Not of Reproductive Potential who are required to take a survey once every six months); and
  - iii. reviewing the THALOMID REMS® program educational materials and asking their prescriber any questions that have not been answered.

In addition, **Females and guardians of female children** must attest to their understanding of their/their child's reproductive potential, as categorized by the prescribing physician.

**Females of Reproductive Potential and guardians of Female Children of Reproductive Potential** will attest that they/their child:

- a. is not currently pregnant, and will try to refrain from becoming pregnant while receiving THALOMID therapy, during dose interruptions, and for at least 4 weeks after completely stopping THALOMID therapy;
- b. must not take THALOMID if pregnant, breastfeeding a baby, or not using birth control as defined in the REMS;
- c. will, unless abstinent, use contraception as defined within the REMS: for at least 4 weeks before starting THALOMID, while receiving THALOMID, during dose interruptions, and for at least 4 weeks after stopping THALOMID;
- d. will have pregnancy testing done as ordered by the certified prescriber within 10 to 14 days and 24 hours prior to starting THALOMID, every week for at least the first 4 weeks of THALOMID therapy, and then every 4 weeks if the Female of Reproductive Potential has regular menstrual cycles, or every 2 weeks if the Female of Reproductive Potential has irregular menstrual cycles, while receiving THALOMID;
- e. will immediately stop taking THALOMID and inform the certified prescriber if the patient becomes pregnant, misses a menstrual period, experiences unusual menstrual bleeding, stops using contraception, or thinks for any reason that she might be pregnant; if the prescriber is not available, the Female of Reproductive Potential or guardian of a Female Child of Reproductive Potential can call the Celgene Customer Care Center at 1-888-423-5436.

**Males or guardians of Males** will attest that they/their child will:

- a. never have unprotected sexual contact with a female who can become pregnant;
- b. wear a latex or synthetic condom every time the male patient has sexual contact with a female who is or who can become pregnant; continue condom use with sexual contact while the male patient is receiving THALOMID treatment, during dose interruptions, and for 4 weeks after the male patient stops taking THALOMID, even if the patient has had a successful vasectomy; and
- c. inform their certified prescriber if the male patient has unprotected sexual contact with a female who can become pregnant, or if they think for any reason that the male patient's sexual partner might be pregnant; if the prescriber is not available, the male patient or

- guardian of an underage male patient can call the Celgene Customer Care Center at 1-888-423-5436;
- d. not donate sperm while taking (including dose interruptions) and for 4 weeks after stopping THALOMID.

The following appended materials are part of the REMS:

- [Patient-Physician Agreement Form for Adult Male](#)
- [Patient-Physician Agreement Form for Male Child](#)
- [Patient-Physician Agreement Form Adult Female Who Can Not Get Pregnant](#)
- [Patient-Physician Agreement Form Adult Female Who Can Get Pregnant](#)
- [Patient-Physician Agreement Form Female Child Who Can Not Get Pregnant](#)
- [Patient-Physician Agreement Form Female Child Who Can Get Pregnant](#)
- [Patient Guide to THALOMID REMS® Program](#)
- [Emergency Contraception Brochure](#)
- [Patient Survey Reminder Card](#)
- [THALOMID Risk Evaluation and Mitigation Strategy \(REMS\) Program Education and Prescribing Safety Kit](#)
- [THALOMID REMS® Patient Resource Pack Envelope](#)

**2.1.4. Female patients or female partners of male patients receiving THALOMID who report a pregnancy that occurred during THALOMID therapy will be enrolled in the THALOMID Pregnancy Exposure Registry. The registry will collect the following information:**

Upon receiving a report of pregnancy from the THALOMID REMS® program, Celgene Pregnancy Prevention Plan programs in the rest of the world, clinical trials, or directly from a prescriber, a pharmacy, or a patient, Celgene will enroll the female patient or female partner of the male patient taking THALOMID into the THALOMID Pregnancy Exposure Registry. The objectives of the registry are to monitor pregnancy outcomes (should one occur) in female patients of reproductive potential and female partners of male patients who are exposed to THALOMID and to understand the root cause of the pregnancy.

## **2.2. Implementation System**

The implementation system will include the following:

- 1) Celgene will maintain a secure database of all certified entities, including enrolled patients and certified prescribers and pharmacies to monitor and evaluate implementation of the elements provided for in Sections [2.1.1](#), [2.1.2](#), and [2.1.3](#).
- 2) Celgene will monitor THALOMID REMS® program pharmacy certification compliance and address deviations by monitoring real time dispensing activity and conducting pharmacy audits.

- a. The Celgene Customer Care Center will monitor the certified pharmacies in the manner described in the REMS supporting document to ensure only enrolled and authorized patients are receiving THALOMID. If a certified pharmacy is found to be non-compliant with the THALOMID REMS<sup>®</sup> program, Celgene will institute corrective action and may de-activate pharmacies for which re-training has proven ineffective, removing them from the THALOMID REMS<sup>®</sup> program.
  - b. Celgene will perform regular audits of contract pharmacies participating in the THALOMID REMS<sup>®</sup> program. For pharmacies that have been in the program for more than two years, Celgene will perform a risk-based assessment to select which pharmacies will be audited. The THALOMID REMS<sup>®</sup> program compliance audits will be performed by internal auditors of Celgene and/or outside auditors contracted and trained by Celgene.
- 3) Celgene will monitor and ensure that the prescriptions are filled within the allowed timeframes.
  - 4) Celgene Customer Care Center will address customer complaints received that are related to the THALOMID REMS<sup>®</sup> program and distribution and dispensing of THALOMID.
  - 5) Celgene will maintain a reporting and collection system for safety information that includes a process to monitor pregnancy testing results and pregnancy outcomes (should one occur) through the THALOMID Pregnancy Exposure Registry and to understand the root cause of the pregnancy.
  - 6) Based on monitoring and evaluation of these elements to assure safe use, Celgene will take reasonable steps to work to improve implementation of these elements as applicable.
  - 7) Celgene will develop and follow written procedures related to the implementation of the REMS.

### **2.3. Timetable for Submission of Assessment Reports**

Celgene will submit REMS assessments every two years beginning with submission of the next assessment by August 3, 2016. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Celgene will submit each assessment so it will be received by the FDA on or before the due date.

# THALOMID<sup>®</sup> (thalidomide) Patient Prescription Form

Today's Date \_\_\_\_\_ Date Rx Needed \_\_\_\_\_  
 Patient Last Name \_\_\_\_\_ Patient First Name \_\_\_\_\_  
 Phone Number (\_\_\_\_) \_\_\_\_\_  
 Shipping Address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
 Date of Birth \_\_\_\_\_ Patient ID# \_\_\_\_\_  
 Language Preference:  English  Spanish  
 Other \_\_\_\_\_  
 Best Time to Call Patient:  AM \_\_\_\_\_  PM \_\_\_\_\_  
 Patient Diagnosis \_\_\_\_\_  
 Patient Allergies \_\_\_\_\_  
 \_\_\_\_\_  
 Other Current Medications \_\_\_\_\_  
 \_\_\_\_\_

Prescriber Name \_\_\_\_\_  
 State License Number \_\_\_\_\_  
 Prescriber Phone Number (\_\_\_\_) \_\_\_\_\_  
 Fax Number (\_\_\_\_) \_\_\_\_\_  
 Prescriber Address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
**Patient Type From PPAF (Check one)**  
 Adult Female – NOT of Reproductive Potential  
 Adult Female – Reproductive Potential  
 Adult Male  
 Female Child – Not of Reproductive Potential  
 Female Child – Reproductive Potential  
 Male Child

## PRESCRIPTION INSURANCE INFORMATION

(Fill out entirely and fax a copy of patient's insurance card, both sides)

**Primary Insurance** \_\_\_\_\_  
 Insured \_\_\_\_\_  
 Policy # \_\_\_\_\_  
 Group # \_\_\_\_\_  
 Phone # \_\_\_\_\_  
 Rx Drug Card # \_\_\_\_\_  
**Secondary Insurance** \_\_\_\_\_  
 Insured \_\_\_\_\_  
 Policy # \_\_\_\_\_  
 Group # \_\_\_\_\_  
 Phone # \_\_\_\_\_  
 Rx Drug Card # \_\_\_\_\_

For further information on THALOMID, please refer to the full Prescribing Information

## TAPE PRESCRIPTION HERE PRIOR TO FAXING REFERRAL, OR COMPLETE THE FOLLOWING:

**Recommended Starting Dose:** See below for dosage

**Multiple Myeloma:** The recommended starting dose of THALOMID is 200 mg/day orally with water for a 28-day treatment cycle. Dosing is continued or modified based upon clinical and laboratory findings.

**Erythema Nodosum Leprosum:** The recommended starting dose of THALOMID is 100 to 300 mg/day with water for an episode of cutaneous ENL. Up to 400 mg/day for severe cutaneous ENL. Dosing is continued or modified based upon clinical and laboratory findings.

### THALOMID

Dose	Quantity	Directions
<input type="checkbox"/> 50 mg	_____	_____
<input type="checkbox"/> 100 mg	_____	_____
<input type="checkbox"/> 150 mg	_____	_____
<input type="checkbox"/> 200 mg	_____	_____

Dispense as Written  Substitution Permitted

**NO REFILLS ALLOWED (Maximum Quantity = 28 days)**

Prescriber Signature \_\_\_\_\_ Date \_\_\_\_\_

Authorization # \_\_\_\_\_ Date \_\_\_\_\_

(To be filled in by healthcare provider)

Pharmacy Confirmation # \_\_\_\_\_ Date \_\_\_\_\_

(To be filled in by pharmacy)

## ***How to Fill a THALOMID® (thalidomide) Prescription***

1. Healthcare provider (HCP) instructs female patients to complete initial patient survey
2. HCP completes survey
3. HCP completes patient prescription form
4. HCP obtains THALOMID REMS® authorization number
5. HCP provides authorization number on patient prescription form
6. HCP faxes form, including prescription, to one of the Celgene Certified Pharmacy Network participants (see below)
7. HCP advises patient that a representative from the certified pharmacy will contact them
8. Certified pharmacy conducts patient education
9. Certified pharmacy obtains confirmation number
10. Certified pharmacy ships THALOMID to patient with MEDICATION GUIDE

***Please see [www.Celgene.com/PharmacyNetwork](http://www.Celgene.com/PharmacyNetwork) for the list of pharmacy participants***

Information about THALOMID and the THALOMID REMS® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com).



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REMS-THA16909

# THALOMID® (thalidomide) Patient Prescription Form – Veterans Health Administration (VHA) ONLY

Today's Date _____ Date Rx Needed _____ Patient Last Name _____ Patient First Name _____ Phone Number (____) _____ Shipping Address _____ City _____ State _____ Zip _____ Date of Birth _____ Patient ID# _____ Language Preference: <input type="checkbox"/> English <input type="checkbox"/> Spanish <input type="checkbox"/> Other _____ Best Time to Call Patient: <input type="checkbox"/> AM _____ <input type="checkbox"/> PM _____ Patient Diagnosis _____ Patient Allergies _____ Other Current Medications _____	Prescriber Name _____ State License Number _____ Prescriber Phone Number (____) _____ Ext. _____ Fax Number (____) _____ Prescriber Address _____ City _____ State _____ Zip _____ <b>Patient Type From PPAF (Check one)</b> <input type="checkbox"/> Adult Female – NOT of Reproductive Potential <input type="checkbox"/> Adult Female – Reproductive Potential <input type="checkbox"/> Adult Male <input type="checkbox"/> Female Child – Not of Reproductive Potential <input type="checkbox"/> Female Child – Reproductive Potential <input type="checkbox"/> Male Child
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**VHA Pharmacy Information (Fill out entirely)**  
**VHA Name** \_\_\_\_\_  
 Address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
**VHA Pharmacist Name** \_\_\_\_\_  
 Phone # \_\_\_\_\_ Fax # \_\_\_\_\_  
 McKesson Specialty Distribution Account # \_\_\_\_\_

**For further information on THALOMID, please refer to the full Prescribing Information**

**TAPE PRESCRIPTION HERE PRIOR TO FAXING REFERRAL, OR COMPLETE THE FOLLOWING:**

**Recommended Starting Dose:** See below for dosage

**Multiple Myeloma:** The recommended starting dose of THALOMID is 200 mg/day orally with water for a 28-day treatment cycle. Dosing is continued or modified based upon clinical and laboratory findings.

**Erythema Nodosum Leprosum:** The recommended starting dose of THALOMID is 100 to 300 mg/day with water for an episode of cutaneous ENL. Up to 400 mg/day for severe cutaneous ENL. Dosing is continued or modified based upon clinical and laboratory findings.

THALOMID	Dose	Quantity	Directions
<input type="checkbox"/>	50 mg	_____	_____
<input type="checkbox"/>	100 mg	_____	_____
<input type="checkbox"/>	150 mg	_____	_____
<input type="checkbox"/>	200 mg	_____	_____

Dispense as Written      Substitution Permitted

**NO REFILLS ALLOWED (Maximum Quantity = 28 days)**

Prescriber Signature \_\_\_\_\_ Date \_\_\_\_\_

Authorization # \_\_\_\_\_ Date \_\_\_\_\_  
 (To be filled in by healthcare provider)

Pharmacy Confirmation # \_\_\_\_\_ Date \_\_\_\_\_  
 (To be filled in by pharmacy)

# How to Fill a THALOMID® (thalidomide) Prescription in the Veterans Health Administration (VHA)

1. Healthcare Provider (HCP) instructs female patients to complete initial patient survey
2. HCP completes survey
3. HCP completes patient prescription form (include cell number for patient if possible)
4. HCP obtains THALOMID REMS® authorization number
5. HCP provides authorization number on patient prescription form
6. HCP sends prescription to the VHA Pharmacy  
The following information must be filled in:
  - Rx must include **McKesson Specialty Distribution account number**
  - Rx must include **VHA address** (Name, Street, City, State, ZIP)
  - Rx must include **VHA Pharmacist contact information** (Name, Phone and Fax #)
7. VHA Pharmacist faxes the form, including prescription, to:  
The **THALOMID REMS® certified OncologyRx Care Advantage Specialty at 1-855-637-9446**
8. HCP advises patient that a representative from THALOMID REMS® certified pharmacy will be in contact
9. The THALOMID REMS® certified OncologyRx Care Advantage Pharmacist conducts patient education
10. The THALOMID REMS® certified OncologyRx Care Advantage Pharmacist obtains confirmation number
11. The THALOMID REMS® certified OncologyRx Care Advantage Pharmacist ships THALOMID to the VHA Pharmacy or directly to the patient with MEDICATION GUIDE
12. VHA Pharmacist gives THALOMID to VHA patient with MEDICATION GUIDE

## THALOMID REMS® Veterans Health Administration (VHA) Pharmacy OncologyRx Care Advantage

Phone: 1-855-637-9433 Fax: 1-855-637-9446

Information about THALOMID and the THALOMID REMS® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com).

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**Prescriber Guide to  
((THALOMID REMS® logo))  
Risk Evaluation and Mitigation Strategy (REMS) Program**

**A known teratogen, THALOMID® (thalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the THALOMID Risk Evaluation and Mitigation Strategy (REMS) program.**

This guide contains important information for prescribers about:

- The risks of THALOMID, including a boxed warning for
  - Embryo-fetal toxicity
  - Venous thromboembolism (deep venous thrombosis [DVT] and pulmonary embolism [PE])
- The THALOMID REMS® program
  - Prescriber Certification
  - Patient Enrollment
  - Contraceptive Requirements and Counseling for Patients
  - Initial and Subsequent Prescription Requirements

**THALOMID REMS® Resources for Prescribers Include:**

- Prescriber Guide to THALOMID REMS® Program
- Full Prescribing Information for THALOMID

((THALOMID logo))

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## **About THALOMID® (thalidomide)**

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

## **Risks of THALOMID**

**THALOMID has a Boxed Warning for embryo-fetal toxicity and venous thromboembolism (deep venous thrombosis [DVT] and pulmonary embolism [PE]).**

**A known teratogen,** THALOMID is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID if they take adequate precautions to avoid pregnancy.

**The use of THALOMID in MM results in an increased risk of venous thromboembolism, such as deep venous thrombosis and pulmonary embolism.** This risk increases significantly when THALOMID is used in combination with standard chemotherapeutic agents including dexamethasone. Patients and physicians should be observant for the signs and symptoms of thromboembolism. Instruct patients to seek medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Consider thromboprophylaxis based on an assessment of individual patients' underlying risk factors.

**This is not a comprehensive description of risks associated with the use of THALOMID. Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed, for further information regarding the use of THALOMID.**

## **The THALOMID REMS<sup>®</sup> program**

To avoid embryo-fetal exposure, THALOMID<sup>®</sup> (thalidomide) is only available under a restricted distribution program called “THALOMID Risk Evaluation and Mitigation Strategy (REMS).” Only certified prescribers can prescribe THALOMID and only certified pharmacies can dispense THALOMID in the THALOMID REMS<sup>®</sup> program.

In order to receive THALOMID, all patients must be enrolled in THALOMID REMS<sup>®</sup> and agree to comply with the requirements of the THALOMID REMS<sup>®</sup> program. Information about THALOMID and the THALOMID REMS<sup>®</sup> program can be obtained by visiting [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), accessing the Celgene REMS mobile app, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**.

## **Key points of the THALOMID REMS<sup>®</sup> program**

### **Prescriber**

- The prescriber enrolls and becomes certified with Celgene for the THALOMID REMS<sup>®</sup> program
- The prescriber counsels patient on benefits and risks of THALOMID
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends THALOMID prescription to certified pharmacy

### **Pharmacy**

- The pharmacy certifies with Celgene for THALOMID REMS<sup>®</sup>
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy dispenses THALOMID to patient along with a Medication Guide

**Prescribing THALOMID® (thalidomide) under the THALOMID REMS® program**

FEMALES	MALES
<p><b><u>Patient Counseling</u></b>            Instruct your patients on why and how they and their partners should prevent pregnancy. Also inform them not to share the drug, not to donate blood, and about using 2 effective methods of contraception (at least one highly effective method and one effective method) at the same time. Patient should be instructed not to extensively handle or open THALOMID capsules</p> <p><b><u>Pregnancy Tests Only in Females of Reproductive Potential</u></b>            Conduct initial pregnancy test within 10-14 days. Confirm the patient is not pregnant with a second pregnancy test within 24 hours prior to writing an initial prescription. During treatment, pregnancy testing should be repeated every 4 weeks if the patient has regular menses or is amenorrheic, or every 2 weeks if the patient has irregular menses</p> <p><b><u>Enrollment</u></b>            Both you and your patients must understand and agree to comply with the THALOMID REMS® program, including the pregnancy prevention steps. The THALOMID® (thalidomide) Patient-Physician Agreement Form must be signed by both patient and physician and submitted to the Celgene Customer Care Center via mail (86 Morris Avenue, Summit, NJ 07901), email (customer@celgene.com), or fax (1-888-432-9325), or electronically at <a href="http://www.CelgeneRiskManagement.com">www.CelgeneRiskManagement.com</a> or the Celgene REMS mobile app. If enrolling a patient online, the system generates an online prescription that you should complete and print, sign (include the authorization number and risk category), and fax to the certified pharmacy</p> <p><b><u>Complete Mandatory Confidential Survey</u></b>            Your female patients need to complete a brief survey by phone or online. You will also need to complete a mandatory survey by phone or online, after which you will receive an authorization number. You must complete this survey to obtain a new authorization number every time a THALOMID prescription is written. Female patients of reproductive potential and all female children must complete surveys monthly in order to obtain subsequent prescriptions. Adult female patients not of reproductive potential must complete surveys every 6 months</p>	<p><b><u>Patient Counseling</u></b>            Instruct your patients on why and how they and their partners should prevent pregnancy. Also inform them not to share the drug, not to donate blood or sperm, and about appropriate contraceptive use. Patients should be instructed not to extensively handle or open THALOMID capsules.</p> <p><b><u>Enrollment</u></b>            Both you and your patients must understand and agree to comply with the THALOMID REMS® program, including the pregnancy prevention steps. The THALOMID® (thalidomide) Patient-Physician Agreement Form must be signed by both patient and physician and submitted to the Celgene Customer Care Center via mail (86 Morris Avenue, Summit, NJ 07901), email (customer@celgene.com), or fax (1-888-432-9325), or electronically at <a href="http://www.CelgeneRiskManagement.com">www.CelgeneRiskManagement.com</a> or the Celgene REMS mobile app. If enrolling a patient online, the system generates an online prescription that you should complete and print, sign (include the authorization number and risk category), and fax to the certified pharmacy</p> <p><b><u>Complete Mandatory Confidential Survey</u></b>            Your male patients will need to complete a brief survey by phone or online. You will also need to complete a mandatory survey by phone or online, after which you will receive an authorization number. You must complete this survey to obtain a new authorization number every time a THALOMID prescription is written. The <i>initial survey</i> is <i>not required</i> for male patients, but they must complete surveys monthly for subsequent prescriptions</p>

**ALL PATIENTS**

**Fax Prescription** Obtain an authorization number from Celgene and write it on the prescription, along with the patient risk category, and then fax it to a certified pharmacy. The certified pharmacy will contact patients for mandatory counseling and coordinate delivery of THALOMID to them.

## **THALOMID REMS<sup>®</sup> patient enrollment**

- Obtain, review, and complete the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form online by visiting [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), accessing the Celgene REMS mobile app, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**
- Prescribers who do not have access to a computer will be provided with THALOMID REMS<sup>®</sup> program materials. For additional assistance, please contact the Celgene Customer Care Center or your Celgene Hematology Oncology Consultant
- Patient, parent/legal guardian, and/or authorized representative must read the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form in the language of their choice

## **Help ensure timely processing of each prescription**

### **Fill Out Form as Directed**

- Write only in the designated areas on the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form
- The box next to each statement must be marked (with an “X”) to indicate understanding
- The form must be completed and signed by both prescriber and patient

### **Instructions for Female Patients**

- For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

### **Instructions for Minors**

- If the patient is under 18 years of age, his or her legal guardian must read this material, mark the statement in each block of the form (with an “X”) and agree to ensure compliance by signing and dating the form

### **Instructions for Incompetent Adult Patients**

- For an incompetent adult patient, an authorized representative must sign the THALOMID<sup>®</sup> (thalidomide) 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

## **THALOMID REMS<sup>®</sup> patient enrollment (continued)**

- The authorized representative must read the material, mark the statements, and agree to ensure compliance by signing and dating the form
- If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the THALOMID<sup>®</sup> (thalidomide) 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 the THALOMID REMS<sup>®</sup> program and is authorized to consent to treatment with THALOMID on behalf of the patient

### **Send in completed forms**

- Send the completed THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, the Celgene REMS mobile app, or to the Celgene Customer Care Center via mail (86 Morris Avenue, Summit, NJ 07901), email (customer care@celgene.com), or fax (1-888-432-9325)
- You will receive confirmation electronically or via fax to your office once the patient is enrolled
- Once the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys
- In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

**Note:** If therapy with THALOMID is discontinued for 12 consecutive months, the patient must enroll again in the THALOMID REMS<sup>®</sup> program. Follow the above procedures to re-enroll the patient.

## Prescription requirements

### All patients

- Provide comprehensive counseling on the benefits and risks of therapy with THALOMID<sup>®</sup> (thalidomide)
- Patients must be counseled on the risks of birth defects, venous thromboembolism, other side effects, and important precautions associated with THALOMID
- Provide counseling not to share THALOMID capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of THALOMID, as well as counseling on appropriate contraceptive use, including emergency contraception
- Provide patients with educational materials provided in the THALOMID REMS<sup>®</sup> Patient Resource Pack
- Patients should be instructed to not extensively handle or open THALOMID capsules and to maintain storage of capsules in blister packs until ingestion
- Instruct patients to return unused THALOMID capsules for disposal to Celgene or to their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them

### Female patients

#### Determine if female patient is of reproductive potential

<b>Two categories:</b>
<b>1. Females of Reproductive Potential</b> <ul style="list-style-type: none"><li>• All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category</li></ul>
<b>2. Females Not of Reproductive Potential</b> <ul style="list-style-type: none"><li>• Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating</li></ul>

#### 1. Females of Reproductive Potential

##### Pregnancy test requirements

- Obtain a **negative** pregnancy test 10 to 14 days prior to writing an initial prescription for THALOMID<sup>®</sup> (thalidomide) and again within 24 hours prior to writing an initial prescription for THALOMID even if continuous abstinence is the chosen method of birth control
  - The pregnancy test must be sensitive to at least 50 mIU/mL
  - Pregnancy testing should occur weekly during the first 4 weeks of use

### Prescription requirements (continued)

- Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
- If a patient misses her period or if there is any abnormality in menstrual bleeding, THALOMID should be discontinued immediately. Obtain a pregnancy test and counsel the patient
- **If pregnancy does occur during treatment, THALOMID must be immediately discontinued.** Any suspected embryo-fetal exposure to THALOMID must be reported immediately to the FDA via the MedWatch number at **1-800-FDA-1088** and also 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
  - The patient must not breastfeed a baby while being treated with THALOMID

### Patient Counseling on Contraception Requirements

#### Contraception requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 effective methods of contraception (at least one highly effective method and one effective method) at the same time
- The 2 effective contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male
- The 2 effective contraceptive methods must be started at least 4 weeks before THALOMID® (thalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

### Effective Methods of Birth Control Used at the Same Time

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom
Tubal ligation (having your tubes tied)	Diaphragm
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Cervical cap

## Prescription requirements (continued)

Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.

- **Unacceptable forms of contraception:**
  - Progesterone-only “mini-pills”
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield\*
- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after stopping therapy

\*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

## 2. Females Not of Reproductive Potential

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy
- The parent or guardian must confirm that a prepubertal female child is not now pregnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before THALOMID<sup>®</sup> (thalidomide) therapy, during therapy, during dose interruptions, and for at least 4 weeks after stopping therapy

### Male patients

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking THALOMID is unknown
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of THALOMID

## **Initial mandatory confidential survey**

### **Females**

- Instruct the female patient to complete a brief initial mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, accessing the Celgene REMS mobile app, or by calling **1-888-423-5436**. See page 12 for subsequent prescription requirements

### **Males**

- Males do not need to take the initial survey

### **Prescribers**

- Prescriber will complete a brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, accessing the Celgene REMs mobile app, or by calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:
  - Prescriber's identification number
  - Patient's identification number
  - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
  - Average daily dose
  - Total number of days supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted

### **Additional information for the prescriber**

- Healthcare provider must send the prescription to a THALOMID REMS<sup>®</sup> certified pharmacy. To locate a certified pharmacy, please visit **www.Celgene.com/PharmacyNetwork**
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

## **Subsequent prescription requirements**

The prescriber must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for THALOMID® (thalidomide) is written.

No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

### **Female patients**

- Provide counseling as outlined in the “Female patients” section on pages 8-10
- Follow pregnancy test requirements as outlined in “Pregnancy test requirements” section on page 8
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
  - Before prescription is obtained
  - Monthly
    - Adult females of reproductive potential
    - All female children
  - Every 6 months
    - Adult females not of reproductive potential

### **Male patients**

- Provide patient counseling as outlined in the “Male patients” section on page 10
- Male patients must complete a brief mandatory confidential survey once a month
  - Males do not complete an initial survey

## **After the last dose of THALOMID® (thalidomide)**

After patients have stopped taking THALOMID, they must do the following:

### **All patients**

- Must not share THALOMID capsules—especially with females of reproductive potential
- Must return any unused THALOMID capsules for disposal to Celgene or their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them
- Must not donate blood for 4 weeks after stopping THALOMID

### **Female patients of reproductive potential**

- Must not get pregnant for at least 4 weeks after stopping THALOMID by using at the same time, 2 effective methods of contraception (at least one highly effective method and one effective method) each time engaging in sexual activity with a male

### **Male patients**

- Must use a latex or synthetic condom each time when engaging in sexual activity for 4 weeks after stopping THALOMID, even if they have undergone a successful vasectomy
- Must not donate sperm for 4 weeks after stopping THALOMID

## Ordering English and non-English materials

Call the Celgene Customer Care Center AT 1-888-423-5436

- Materials are available in 16 languages and include:
  - THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Forms
  - Patient Guide to THALOMID REMS<sup>®</sup> Program
  - Mandatory confidential survey forms

### Available languages:

Arabic	French	Japanese	Portuguese
Cambodian	German	Korean	Russian
Chinese	Greek	Laotian	Spanish
English	Italian	Polish	Vietnamese

- THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Forms, Patient Guide to THALOMID REMS<sup>®</sup> Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

#### Prescriber's:

Name  
Identification Number  
Full Address  
Fax Number

#### Patient's:

Name  
Full Address  
Phone Number  
Date of Birth  
Identification Number  
Diagnosis (most recent version of ICD code)

## **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**

- Online: [www.celgene.com/contact-us/](http://www.celgene.com/contact-us/)
- 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, 86 Morris Avenue, Summit, New Jersey 07901
- Other: Per individual agreement between the reporting organization and Celgene Global Drug Safety & Risk Management

### **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: **<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

[Back Cover]

For more information about THALOMID<sup>®</sup> (thalidomide) and the THALOMID REMS<sup>®</sup> program, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at 1-888-423-5436.

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.**

((Celgene logo))  
((THALOMID logo))

((THALOMID REMS<sup>®</sup> logo))

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## **THALOMID REMS®** *At-A-Glance*

### **Important information about THALOMID® (thalidomide) and the THALOMID Risk Evaluation and Mitigation Strategy (REMS) 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®”
- Only prescribers and pharmacies certified by the THALOMID REMS® program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS® program
- Information about THALOMID and the THALOMID REMS® 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**

**There are other risks associated with THALOMID treatment. Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**

((Celgene logo)) ((THALOMID REMS® logo)) ((THALOMID logo))

## Prescribing THALOMID under the THALOMID REMS® program

### Initial prescription (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for THALOMID® (thalidomide).
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive methods. For appropriate contraceptive use, refer to the Prescriber Guide to THALOMID REMS®. Patients should be instructed to not extensively handle or open THALOMID capsules and to maintain storage of capsules in blister packs until ingestion.
3. Obtain, review, and complete the THALOMID® (thalidomide) Patient-Physician Agreement Form online by visiting **www.CelgeneRiskManagement.com**, accessing the Celgene REMS mobile app, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**.
  - **Males (adults and children)**
  - **Females of reproductive potential include all females who are menstruating**, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
  - **Females not of reproductive potential include females who have been in natural menopause for at least 24 consecutive months**, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating
4. Send the completed and signed THALOMID® (thalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, the Celgene REMS mobile app, or to the Celgene Customer Care Center via fax (1-888-432-9325), email ([customercare@celgene.com](mailto:customercare@celgene.com)), or mail (86 Morris Avenue, Summit, NJ, 07901).
5. Instruct female patients to complete a brief initial mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, accessing the Celgene REMS mobile app, or by calling **1-888-423-5436**, prior to prescriber obtaining an authorization number.
  - Males do not need to complete the initial survey
6. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, accessing the Celgene REMS mobile app, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written.
  - You will need to enter the following information:
    - Prescriber's identification number
    - Patient's identification number
    - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
    - Average daily dose
    - Total number of days supplied (cannot exceed 28 days)
7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
8. Send the prescription to a certified pharmacy.



[PAGE 3]  
[Left Column]

**Prescribing THALOMID under the THALOMID REMS® program**

(Note: Prescriber has already enrolled in THALOMID REMS® program)

**1. New Patient: Complete the Patient-Physician Agreement Form (PPAF)**

Send the completed PPAF via

- **www.CelgeneRiskManagement.com**
- The Celgene REMS mobile app, or
- Fax (1-888-432-9325), email ([customercare@celgene.com](mailto:customercare@celgene.com)), or mail (86 Morris Avenue, Summit, NJ) the Celgene Customer Care Center

(arrow)



**2. Complete Prescriber Survey**

Complete the Prescriber Survey via

- **www.CelgeneRiskManagement.com**
- The Celgene REMS mobile app, or
- Call the Celgene Customer Care Center at **1-888-423-5436**

(arrow)



(arrow)

**3. Obtain Authorization Number**

An authorization number will be issued upon completion of the survey

(arrow)

**4. Write Prescription**

Include the authorization number, patient risk category, daily dose, and total number of days supplied

(arrow)

**5. Send the Prescription to a Certified Pharmacy**

Prescribe no more than a 28-day supply, with no automatic refills or telephone prescriptions

[Right Column]

**Initial Prescription**

**Provide mandatory counseling:**

- No drug sharing
- No blood or sperm donation

- Appropriate contraceptive methods. Please refer to the table on the back page for appropriate contraception
- Patients should be instructed to not extensively handle or open THALOMID<sup>®</sup> (thalidomide) capsules

**For Females of Reproductive Potential:**

- Obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control (blood or urine test by laboratory or prescriber’s office depending on test sensitivity)
  - 10 to 14 days prior
  - 24 hours prior to writing prescription

**Initial Patient Survey**

- Instruct female patients to complete the survey via
  - **www.CelgeneRiskManagement.com**
  - The Celgene REMS mobile app, or
  - Call the Celgene Customer Care Center at **1-888-423-5436**
- Males do not need to complete the initial survey

**Subsequent Prescriptions**

- **For Females of Reproductive Potential**, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- A prescriber survey is needed for every prescription. An authorization number from Celgene is needed for every prescription
- **Patient surveys**
  - Monthly:
    - Males (adults and children)
    - Females of reproductive potential (adults and children)
    - Female children not of reproductive potential
  - Every 6 months:
    - Adult females not of reproductive potential

**Questions**

- Call the Celgene Customer Care Center at **1-888-423-5436**
- Contact your local Hematology Oncology Consultant

**Please see important information about THALOMID and the THALOMID REMS<sup>®</sup> program on back.**

[PAGE 4]

**Effective Methods of Birth Control Used at the Same Time**

[Text inside chart below]

[left column]

**Highly effective birth control methods**

Intrauterine device (IUD)

Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)

Tubal ligation (having your tubes tied)  
Partner’s vasectomy (tying of the tubes to prevent the passing of sperm)

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**[right column]**

**Additional effective birth control methods**

Male latex or synthetic condom

Diaphragm

Cervical cap

**[table footer]**

Unacceptable forms of contraception:

progesterone-only “mini-pills,” IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception).

**THALOMID Risk Evaluation and Mitigation Strategy (REMS) 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®”
- Only prescribers and pharmacies certified by the THALOMID REMS® program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS® program
- Information about THALOMID and the THALOMID REMS® 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

[Celgene Logo] [THALOMID REMS Logo] [THALOMID Logo]

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REMS-THA16906-S

[Front]

## **THALOMID REMS® Prescriber Enrollment Form**

All prescribers **must** be certified to prescribe THALOMID® (thalidomide). To become certified the prescriber must:

1. Complete the Prescriber Enrollment Form, which is required for THALOMID REMS® certification.
2. Agree to steps on the following page that **must** be followed with every patient.

To submit this form electronically, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) or access the Celgene REMS mobile app.

To submit this form via fax, please complete the following page and fax it to 1-888-432-9325.

**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.**

Please review the steps on the following page that **must** be followed with every patient.

**THALOMID is only available under a restricted distribution program, THALOMID REMS®.**

(THALOMID logo)

[Back]

## **THALOMID REMS® Prescriber Enrollment Form**

**When prescribing THALOMID® (thalidomide), I agree to:**

- Provide patient counseling on the benefits and risks of THALOMID therapy, including Boxed Warnings
- Submit a completed THALOMID® (thalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during THALOMID treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed THALOMID immediately to Celgene Drug Safety (or the Celgene Customer Care Center)
- Complete a mandatory and confidential prescriber survey online or by telephone for all patients and obtain a new authorization number for each prescription written. The authorization number and patient risk category must be written on each prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions

- Contact a THALOMID REMS<sup>®</sup> certified pharmacy to fill the prescription
- Remind patients to return all THALOMID capsules to Celgene Corporation or their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them
- Return to Celgene all THALOMID capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Re-enroll patients in the THALOMID REMS<sup>®</sup> program if THALOMID is required and previous therapy with THALOMID has been discontinued for 12 consecutive months

**Please fill out the spaces below completely.**

Prescriber Name \_\_\_\_\_

Degree: MD/DO/PA/NP/Fellow/Medical Resident Specialty \_\_\_\_\_

Prescriber Identification Number (eg, DEA Number, Social Security Number, NPI Number, etc.)  
\_\_\_\_\_

**Please indicate which office(s) will receive THALOMID REMS<sup>®</sup> materials and updates:**

Primary Office Name \_\_\_\_\_

Attention \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_

Phone \_\_\_\_\_ Ext. \_\_\_\_\_ Fax \_\_\_\_\_

Email Address \_\_\_\_\_

Secondary Office Name \_\_\_\_\_

Attention \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_

Phone \_\_\_\_\_ Ext. \_\_\_\_\_ Fax \_\_\_\_\_

Email Address \_\_\_\_\_

**I understand that if I fail to comply with all requirements of the THALOMID REMS<sup>®</sup> program, my prescriptions for THALOMID<sup>®</sup> (thalidomide) will not be honored at certified pharmacies.**

Prescriber Signature \_\_\_\_\_ Date \_\_\_\_\_

**Return this form to the Celgene Customer Care Center via fax or mail.**

Mail to: Celgene Customer Care Center, 86 Morris Avenue, Summit, NJ 07901

Phone: **1-888-423-5436**

Fax: **1-888-432-9325**

**www.CelgeneRiskManagement.com**

((Celgene logo))

((THALOMID REMS<sup>®</sup> logo))

((THALOMID logo))

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REMS-THA16900

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Get Pregnant

Please read the following statements carefully.

**Your healthcare provider has prescribed THALOMID for you. THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS). Before taking THALOMID, you must read and agree to all of the instructions in the THALOMID REMS<sup>®</sup> program.**

**If you are pregnant or become pregnant while taking THALOMID, it is important for you to know that your unborn baby can have severe birth defects or even die.**

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

### INSTRUCTIONS

*Before starting your treatment with THALOMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the THALOMID REMS<sup>®</sup> materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

### Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the THALOMID<sup>®</sup> (thalidomide) 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 the THALOMID REMS<sup>®</sup> program and is authorized to consent to treatment with THALOMID on behalf of the patient.

For more information, visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at **1-888-423-5436**.

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**Page 1 of 6**

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an “X”) if you agree with the statement. Please do not mark or write outside of designated areas.

### Section 1. Patient Agreement

#### I understand and confirm that:

- THALOMID can cause severe birth defects or death to my unborn baby if I am pregnant or become pregnant during treatment
- I am not pregnant now and will not get pregnant while being treated with THALOMID
- It is possible for me to get pregnant if:
  - I am having my period (am menstruating), or
  - My period has stopped because of my treatment
  - And I have sex with a male
- Not having sex is the only birth control method that is 100% effective
- I am not breastfeeding now and will not breastfeed while being treated with THALOMID
- My THALOMID prescription is **only** for me and is not to be shared with others
- I have read and understood the THALOMID Patient Guide to THALOMID REMS<sup>®</sup> Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- My healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by Celgene to assist with the THALOMID REMS<sup>®</sup> program
- I will NOT donate blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

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**Page 2 of 6**

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Get Pregnant

- I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male unless otherwise recommended by my healthcare provider. My healthcare provider may recommend that I use **at the same time** 2 different birth control methods **every time** I have sex with a male if I cannot use a hormonal or intrauterine device (IUD) method

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	+ Male latex or synthetic condom Diaphragm Cervical cap

Not having any sex is the only birth control that is 100% effective. Unacceptable methods of birth control are progesterone-only “mini-pills”, IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, and cervical shield (A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception).

- I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male:
- Starting at least 4 weeks before taking THALOMID
  - While taking THALOMID
  - During breaks (dose interruptions)
  - For at least 4 weeks after stopping THALOMID

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Page 3 of 6

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Get Pregnant

- I will have pregnancy tests—performed by my healthcare provider—according to the schedule listed below:
- 10 to 14 days before receiving my first prescription for THALOMID, and again 24 hours before receiving my first prescription for THALOMID
  - Every week during the first 4 weeks of my treatment with THALOMID
  - Every 4 weeks during the rest of my treatment if I have a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if I have an irregular menstrual cycle
- I will have these pregnancy tests even if I do not get my period because of my treatment
- I will need to take another pregnancy test performed by my healthcare provider if my medication is not dispensed within 7 days of taking my pregnancy test
- I will stop taking THALOMID and call my healthcare provider right away if:
- I become pregnant while taking THALOMID, or
  - I miss my period or have unusual menstrual bleeding, or
  - I stop using birth control, or
  - I think—**for any reason**—that I am pregnant or may be pregnant
- If my healthcare provider is not available I will call the Celgene Customer Care Center at **1-888-423-5436**
- I will stop taking THALOMID immediately and call my healthcare provider right away if I have sex with a male without using birth control or if I think my birth control has failed. My healthcare provider will discuss my options, which may include emergency birth control. If I become pregnant or think I may be pregnant, and my healthcare provider is not available, I will call the Celgene Customer Care Center at **1-888-423-5436**
- I will complete the mandatory confidential monthly survey while taking THALOMID
- I will keep my THALOMID prescription out of the reach of children
- I will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused THALOMID capsules can also be returned to my THALOMID prescriber or to the pharmacy that dispensed the THALOMID to me

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Get Pregnant

### Section 2. Authorization

#### I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support<sup>®</sup>, and other companies
  - Analyze data for internal business purposes on the use of THALOMID
  - Evaluate the effectiveness of the THALOMID REMS<sup>®</sup> program
  - Use in any other manner as required or permitted by law
- This authorization will remain in effect for 12 months after I stop THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the THALOMID REMS<sup>®</sup> program
- Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want to participate in the THALOMID REMS<sup>®</sup> program. I understand that by refusing to participate in the THALOMID REMS<sup>®</sup> program, I will not be able to receive THALOMID. However, I understand that I can speak with my healthcare provider about other treatment options for my condition
- Upon signing this form, **I authorize my healthcare provider to begin my treatment with THALOMID**



**THALOMID REMS<sup>®</sup>**

**THALOMID<sup>®</sup>**  
(thalidomide) Capsules

THALOMID<sup>®</sup> and THALOMID REMS<sup>®</sup> are registered trademarks of Celgene Corporation.

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

**THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form**

**Adult Female Who Can Get Pregnant**

**Section 3. Authorization to Start Treatment**

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the THALOMID REMS<sup>®</sup> program, I will not be able to receive THALOMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with THALOMID, including the use of two methods of effective birth control (at least one highly effective method and one effective method) at the same time, and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS<sup>®</sup> program.**

Patient		Prescriber	
<i>Name</i>		<i>Name</i>	
<i>Identification Number</i>		<i>Identification Number</i>	
<i>Address</i>		<i>Address</i>	
<i>Telephone Number</i>		<i>Telephone Number</i>	
<i>Date of Birth</i>	<i>Sex</i>	<i>Fax Number</i>	
<i>Risk Category</i>			
Menstruating: Surgical Menopause: Natural Menopause (24 months):			
<i>Diagnosis</i>			
<i>Patient or Authorized Representative's Signature:</i> <i>Signature Date:</i>		<i>Prescriber's Signature:</i> <i>Signature Date:</i>	

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the patient.

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**Page 6 of 6**

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

**Adult Female Who Can Not Get Pregnant**

Please read the following statements carefully.

**Your healthcare provider has prescribed THALOMID for you. THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS). Before taking THALOMID, you must read and agree to all of the instructions in the THALOMID REMS<sup>®</sup> program.**

**Any unborn baby of a female taking THALOMID can have severe birth defects or even die.**

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

INSTRUCTIONS *Before starting your treatment with THALOMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 5.
2. Read the THALOMID REMS<sup>®</sup> materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

**Authorized Representatives:**

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the THALOMID<sup>®</sup> (thalidomide) 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 the THALOMID REMS<sup>®</sup> program and is authorized to consent to treatment with THALOMID on behalf of the patient.

For more information, visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at 1-888-423-5436.

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**Page 1 of 5**

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an “X”) if you agree with the statement. Please do not mark or write outside of designated areas.

### Section 1. Patient Agreement

#### I understand and confirm that:

- THALOMID can cause severe birth defects or death to unborn babies of females taking THALOMID
- I am not pregnant
- I am not able to get pregnant because:
  - I have had both of my ovaries and/or my uterus removed, or
  - I have been in menopause for at least 2 years
- My THALOMID prescription is **only** for me and is not to be shared with others
- I have read and understood the THALOMID Patient Guide to THALOMID REMS<sup>®</sup> Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- My healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by Celgene to assist with the THALOMID REMS<sup>®</sup> program

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**Page 2 of 5**

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

**Adult Female Who Can Not Get Pregnant**

**I will:**

- I will complete the mandatory confidential survey every 6 months while taking THALOMID
- I will keep my THALOMID prescription out of the reach of children
- I will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused THALOMID capsules can also be returned to my THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to me

**I will not:**

- I will **not** share my THALOMID capsules with anyone even if they have symptoms like mine
- I will **not** donate blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

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**Page 3 of 5**

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Not Get Pregnant

### Section 2. Authorization

#### I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support<sup>®</sup>, and other companies
  - Analyze data for internal business purposes on the use of THALOMID
  - Evaluate the effectiveness of the THALOMID REMS<sup>®</sup> program
  - Use in any other manner as required or permitted by law
  - Provide me with information about THALOMID or my condition
- This authorization will remain in effect for 12 months after I stop THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the THALOMID REMS<sup>®</sup> program
- Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want to participate in the THALOMID REMS<sup>®</sup> program. I understand that by refusing to participate in the THALOMID REMS<sup>®</sup> program, I will not be able to receive THALOMID. However, I understand that I can speak with my healthcare provider about other treatment options for my condition
- Upon signing this form, **I authorize my healthcare provider to begin my treatment with THALOMID**



**THALOMID REMS<sup>®</sup>**

**THALOMID<sup>®</sup>**  
(thalidomide) Capsules

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Not Get Pregnant

### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the THALOMID REMS<sup>®</sup> program, I will not be able to receive THALOMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with THALOMID and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS<sup>®</sup> program.**

Patient		Prescriber
<i>Name</i>		<i>Name</i>
<i>Identification Number</i>		<i>Identification Number</i>
<i>Address</i>		<i>Address</i>
<i>Telephone Number</i>		<i>Telephone Number</i>
<i>Date of Birth</i>	<i>Sex</i>	<i>Fax Number</i>
<i>Risk Category</i>		
Menstruating: Surgical Menopause: Natural Menopause (24 months):		
<i>Diagnosis</i>		
<i>Patient or Authorized Representative's Signature:</i>		<i>Prescriber's Signature:</i>
<i>Signature Date:</i>		<i>Signature Date:</i>

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.  
Give a copy of the form to the patient.

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Please read the following statements carefully.

**Your healthcare provider has prescribed THALOMID for your child.\* THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS). Before taking THALOMID, patients must read and agree to all of the instructions in the THALOMID REMS<sup>®</sup> Program.**

**If your child is pregnant or becomes pregnant while taking THALOMID, it is important to know that the unborn baby can have severe birth defects or even die.**

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

INSTRUCTIONS

*Before your child starts treatment with THALOMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the THALOMID REMS<sup>®</sup> materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at **1-888-423-5436**.

\*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an “X”) if you agree with the statement. Please do not mark or write outside of designated areas.

### Section 1. Patient Agreement

#### I understand and confirm that:

- THALOMID can cause severe birth defects or death to the unborn baby if my child is pregnant or becomes pregnant during treatment
- My child is not pregnant now and will not get pregnant while being treated with THALOMID
- It is possible for my child to get pregnant if:
  - She has her period (is menstruating) or has shown any sign of puberty, or
  - Her period has stopped because of treatment
  - And she has sex with a male
- Not having sex is the only birth control method that is 100% effective
- My child is not breastfeeding now and will not breastfeed while being treated with THALOMID
- My child’s THALOMID prescription is **only** for her and is not to be shared with others
- We have read and understood the THALOMID Patient Guide to THALOMID REMS<sup>®</sup> Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- My child’s healthcare provider has reviewed this information with us and answered any questions we have asked
- We may be contacted by Celgene to assist with the THALOMID REMS<sup>®</sup> program
- My child will NOT donate blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

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**Page 2 of 6**

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

**I will tell my child that:**

- She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male unless otherwise recommended by her healthcare provider. Her healthcare provider may recommend that she use **at the same time** 2 different birth control methods **every time** she has sex with a male if she cannot use a hormonal or intrauterine device (IUD) method

Unless she chooses not to have sexual intercourse with a male at any time (abstinence), she must always use acceptable birth control methods.

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings or implants) Tubal ligation (having your tubes tied) Partner’s vasectomy (tying of the tubes to prevent the passing of sperm)	+ Male latex or synthetic condom Diaphragm Cervical cap

Not having any sex is the only birth control that is 100% effective. Unacceptable methods of birth control are progesterone-only “mini-pills”, IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, and cervical shield (A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.).

- She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male:
  - Starting at least 4 weeks before taking THALOMID
  - While taking THALOMID
  - During breaks (dose interruptions)
  - For at least 4 weeks after stopping THALOMID

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

## THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

### Female Child Who Can Get Pregnant

- She must have pregnancy tests—performed by her healthcare provider—according to the schedule listed below:
  - 10 to 14 days before receiving her first prescription for THALOMID, and again 24 hours before receiving her first prescription for THALOMID
  - Every week during the first 4 weeks of her treatment with THALOMID
  - Every 4 weeks during the rest of her treatment if she has a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if she has an irregular menstrual cycle
- She must have these pregnancy tests even if she does not get her period because of her treatment
- She must take another pregnancy test performed by her healthcare provider if her medication is not dispensed within 7 days of taking her pregnancy test
- She must stop taking THALOMID and I will call her healthcare provider right away if:
  - She becomes pregnant while taking THALOMID, or
  - She misses her period or has unusual menstrual bleeding, or
  - She stops using birth control, or
  - She thinks—**for any reason**—that she is pregnant or may be pregnant

If my child's healthcare provider is not available I will call the Celgene Customer Care Center **1-888-423-5436**

- She must stop taking THALOMID immediately and you should call her healthcare provider right away if she had sex with a male without using birth control or if she thinks her birth control has failed. Her healthcare provider will discuss her options, which may include emergency birth control. If she becomes pregnant or thinks she may be pregnant, and my child's healthcare provider is not available, I will call the Celgene Customer Care Center at **1-888-423-5436**
- We will complete the mandatory confidential monthly survey while she is taking THALOMID
- We will keep her THALOMID prescription out of the reach of other children
- We will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused THALOMID capsules can also be returned to my child's THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to my child

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

### Section 2. Authorization

**I understand and confirm that:**

- By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support<sup>®</sup>, and other companies
  - Analyze data for internal business purposes on the use of THALOMID
  - Evaluate the effectiveness of the THALOMID REMS<sup>®</sup> program
  - Use in any other manner as required or permitted by law
  - Provide me and my child with information about THALOMID or my child's condition
- This authorization will remain in effect for 12 months after my child stops THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the THALOMID REMS<sup>®</sup> program
- Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want my child to participate in the THALOMID REMS<sup>®</sup> program. I understand that by refusing to have my child participate in the THALOMID REMS<sup>®</sup> program, she will not be able to receive THALOMID. However, I understand that I can speak with my child's healthcare provider about other treatment options for my child's condition
- Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with THALOMID**



**THALOMID REMS<sup>®</sup>**

**THALOMID<sup>®</sup>**  
(thalidomide) Capsules

THALOMID<sup>®</sup> and THALOMID REMS<sup>®</sup> are registered trademarks of Celgene Corporation.

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the THALOMID REMS<sup>®</sup> program, she will not be able to receive THALOMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with THALOMID, including the use of two methods of effective birth control (at least one highly effective method and one effective method) at the same time, and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS<sup>®</sup> program.**

Patient		Prescriber
<i>Name</i>		<i>Name</i>
<i>Identification Number</i>		<i>Identification Number</i>
<i>Address</i>		<i>Address</i>
<i>Telephone Number</i>		<i>Telephone Number</i>
<i>Date of Birth</i>	<i>Sex</i>	<i>Fax Number</i>
<i>Risk Category</i>		
Menstruating: Surgical Menopause: Natural Menopause (24 months):		
<i>Diagnosis</i>		
<i>Patient or Authorized Representative's Signature:</i>		<i>Prescriber's Signature:</i>
<i>Signature Date:</i>		<i>Signature Date:</i>

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.  
Give a copy of the form to the parent/guardian.

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Male

Please read the following statements carefully.

**Your healthcare provider has prescribed THALOMID for you. THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS). Before taking THALOMID, you must read and agree to all of the instructions in the THALOMID REMS<sup>®</sup> program.**

**If a female you have sex with is pregnant or becomes pregnant by you while you are taking THALOMID, it is important for you to know that your unborn baby can have severe birth defects or even die.**

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

### INSTRUCTIONS

*Before starting your treatment with THALOMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the THALOMID REMS<sup>®</sup> materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

### **Authorized Representatives:**

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the THALOMID<sup>®</sup> (thalidomide) 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 the THALOMID REMS<sup>®</sup> program and is authorized to consent to treatment with THALOMID on behalf of the patient.

For more information, visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at **1-888-423-5436**.

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**Page 1 of 6**

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Male

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

### Section 1. Patient Agreement

#### I understand and confirm that:

- THALOMID can cause severe birth defects or death to my unborn baby if I have sex with a female who is pregnant or who is able to get pregnant during my treatment
- My semen may contain THALOMID even after I stop treatment. I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID
- Not having sex is the only birth control method that is 100% effective
- My THALOMID prescription is **only** for me and is not to be shared with others
- I have read and understood the THALOMID Patient Guide to THALOMID REMS<sup>®</sup> Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- My healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by Celgene to assist with the THALOMID REMS<sup>®</sup> program

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

## THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

### Adult Male

- I will use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant, even if I have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- I will use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant:
  - While taking THALOMID
  - During breaks (dose interruptions)
  - For 4 weeks after stopping THALOMID
- I will call my healthcare provider right away if:
  - I have unprotected sex with a female who is pregnant or who is able to get pregnant
  - I think—**for any reason**—that my sexual partner is pregnant or may be pregnant
  - My partner becomes pregnant or she thinks she may be pregnant

If my healthcare provider is not available I will call the Celgene Customer Care Center at **1-888-423-5436**
- I will complete the mandatory confidential monthly survey while taking THALOMID
- I will keep my THALOMID prescription out of the reach of children
- I will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused THALOMID capsules can also be returned to my THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to me

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Male

- I will **not** share my THALOMID capsules with anyone even if they have symptoms like mine
- I will **not** donate blood or sperm while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID

### Section 2. Authorization

#### I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support<sup>®</sup>, and other companies
  - Analyze data for internal business purposes on the use of THALOMID
  - Evaluate the effectiveness of the THALOMID REMS<sup>®</sup> program
  - Use in any other manner as required or permitted by law
  - Provide me with information about THALOMID or my condition

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

## THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

### Adult Male

- This authorization will remain in effect for 12 months after I stop THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the THALOMID REMS<sup>®</sup> program
- Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want to participate in the THALOMID REMS<sup>®</sup> program. I understand that by refusing to participate in the THALOMID REMS<sup>®</sup> program, I will not be able to receive THALOMID. However, I understand that I can speak with my healthcare provider about other treatment options for my condition
- Upon signing this form, **I authorize my healthcare provider to begin my treatment with THALOMID**



**THALOMID REMS<sup>®</sup>**

**THALOMID<sup>®</sup>**  
(thalidomide) Capsules

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Adult Male

### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the THALOMID REMS<sup>®</sup> program, I will not be able to receive THALOMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if he has any questions regarding his treatment with THALOMID (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS<sup>®</sup> program.**

Patient	Prescriber
<i>Name</i>	<i>Name</i>
<i>Identification Number</i>	<i>Identification Number</i>
<i>Address</i>	<i>Address</i>
<i>Telephone Number</i>	<i>Telephone Number</i>
<i>Date of Birth</i>	<i>Fax Number</i>
<i>Sex</i>	
<i>Diagnosis</i>	
<i>Patient or Authorized Representative's Signature:</i>	<i>Prescriber's Signature:</i>
<i>Signature Date:</i>	<i>Signature Date:</i>

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.  
Give a copy of the form to the patient.

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

**Female Child Who Can Not Get Pregnant**

Please read the following statements carefully.

**Your healthcare provider has prescribed THALOMID for your child.\* THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS). Before taking THALOMID, patients must read and agree to all of the instructions in the THALOMID REMS<sup>®</sup> program.**

**Any unborn baby of a girl taking THALOMID can have severe birth defects or even die.** THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

INSTRUCTIONS

*Before your child starts treatment with THALOMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 5.
2. Read the THALOMID REMS<sup>®</sup> materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at **1-888-423-5436**.

\*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

**Female Child Who Can Not Get Pregnant**

Please read the following statements carefully. Mark the box (with an “X”) if you agree with the statement. Please do not mark or write outside of designated areas.

**Section 1. Patient Agreement**

**I understand and confirm that:**

- THALOMID can cause severe birth defects or death to unborn babies of females taking THALOMID
- My child is not pregnant
- My child is not able to get pregnant because she has not yet started her period (is not menstruating)
- My child’s THALOMID prescription is **only** for her and is not to be shared with others
- We have read and understood the THALOMID Patient Guide to THALOMID REMS<sup>®</sup> Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- My child’s healthcare provider has reviewed this information with us and answered any questions we have asked
- We may be contacted by Celgene to assist with the THALOMID REMS<sup>®</sup> program

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

**Female Child Who Can Not Get Pregnant**

**I will tell my child that:**

- We will complete the mandatory confidential monthly survey while my child is taking THALOMID
- We will keep my child's THALOMID prescription out of the reach of other children
- We will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused THALOMID capsules can also be returned to my child's THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to my child
- She must **not** share THALOMID capsules with anyone even if they have symptoms like hers
- She must **not** donate blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Female Child Who Can Not Get Pregnant

### Section 2. Authorization

**I understand and confirm that:**

- By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support<sup>®</sup>, and other companies
  - Analyze data for internal business purposes on the use of THALOMID
  - Evaluate the effectiveness of the THALOMID REMS<sup>®</sup> program
  - Use in any other manner as required or permitted by law
  - Provide me and my child with information about THALOMID or my child's condition
- This authorization will remain in effect for 12 months after my child stops THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the THALOMID REMS<sup>®</sup> program
- Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want my child to participate in the THALOMID REMS<sup>®</sup> program. I understand that by refusing to have my child participate in the THALOMID REMS<sup>®</sup> program, she will not be able to receive THALOMID. However, I understand that I can speak with my child's healthcare provider about other treatment options for my child's condition
- Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with THALOMID**



**THALOMID REMS<sup>®</sup>**

**THALOMID<sup>®</sup>**  
(thalidomide) Capsules

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Female Child Who Can Not Get Pregnant

### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the THALOMID REMS<sup>®</sup> program, she will not be able to receive THALOMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with THALOMID and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS<sup>®</sup> program.**

Patient		Prescriber
<i>Name</i>		<i>Name</i>
<i>Identification Number</i>		<i>Identification Number</i>
<i>Address</i>		<i>Address</i>
<i>Telephone Number</i>		<i>Telephone Number</i>
<i>Date of Birth</i>	<i>Fax Number</i>	<i>Date of Birth</i>
<i>Sex</i>		
<i>Diagnosis</i>		
<i>Patient or Authorized Representative's Signature:</i>		<i>Prescriber's Signature:</i>
<i>Signature Date:</i>		<i>Signature Date:</i>

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.  
Give a copy of the form to the parent/guardian.

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For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Male Child

Please read the following statements carefully.

**Your healthcare provider has prescribed THALOMID for your child.\* THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS). Before taking THALOMID, patients must read and agree to all of the instructions in the THALOMID REMS<sup>®</sup> program.**

**If a female your child has sex with is pregnant or becomes pregnant by your child while he is taking THALOMID, it is important to know that the unborn baby can have severe birth defects or even die.**

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

### INSTRUCTIONS

*Before your child starts treatment with THALOMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the THALOMID REMS<sup>®</sup> materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at **1-888-423-5436**.

\*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Male Child

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

### Section 1. Patient Agreement

#### I understand and confirm that:

- THALOMID can cause severe birth defects or death to the unborn baby if my child has sex with a female who is pregnant or who is able to get pregnant during his treatment
- My child's semen may contain THALOMID even after he stops treatment. He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID
- Not having sex is the only birth control method that is 100% effective
- My child's THALOMID prescription is **only** for him and is not to be shared with others
- We have read and understood the THALOMID Patient Guide to THALOMID REMS<sup>®</sup> Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- We may be contacted by Celgene to assist with the THALOMID REMS<sup>®</sup> program

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Male Child

### I will tell my child that:

- He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant, even if he has had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant:
  - While taking THALOMID
  - During breaks (dose interruptions)
  - For 4 weeks after stopping THALOMID
- I will call his healthcare provider right away if:
  - He has unprotected sex with a female who is pregnant or who is able to get pregnant
  - He thinks—**for any reason**—that his sexual partner is pregnant or may be pregnant
  - His partner becomes pregnant or she thinks she may be pregnantIf my child's healthcare provider is not available I will call the Celgene Customer Care Center at **1-888-423-5436**
- We will complete the mandatory confidential monthly survey while my child is taking THALOMID
- We will keep his THALOMID prescription out of the reach of other children
- We will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give us a refund for the capsules my child did not take. Unused THALOMID capsules can also be returned to my child's THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to my child

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**Page 3 of 6**

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

**Male Child**

- He must **not** share his THALOMID capsules with anyone even if they have symptoms like his
- He must **not** donate blood or sperm while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID

**Section 2. Authorization**

**I understand and confirm that:**

- By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support<sup>®</sup>, and other companies
  - Analyze data for internal business purposes on the use of THALOMID
  - Evaluate the effectiveness of the THALOMID REMS<sup>®</sup> program
  - Use in any other manner as required or permitted by law
  - Provide me and my child with information about THALOMID or my child's condition

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**Page 4 of 6**

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Male Child

- This authorization will remain in effect for 12 months after my child stops THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the THALOMID REMS<sup>®</sup> program
- Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want my child to participate in the THALOMID REMS<sup>®</sup> program. I understand that by refusing to have my child participate in the THALOMID REMS<sup>®</sup> program, he will not be able to receive THALOMID. However, I understand that I can speak with my child's healthcare provider about other treatment options for my child's condition.
- Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with THALOMID**



**THALOMID REMS<sup>®</sup>**

**THALOMID<sup>®</sup>**  
(thalidomide) Capsules

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**Page 5 of 6**

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**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

# THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form

## Male Child

### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the THALOMID REMS<sup>®</sup> program, he will not be able to receive THALOMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient and his parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and his parent/guardian if they have any questions regarding the child's treatment with THALOMID (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS<sup>®</sup> program.**

Patient	Prescriber
<i>Name</i>	<i>Name</i>
<i>Identification Number</i>	<i>Identification Number</i>
<i>Address</i>	<i>Address</i>
<i>Telephone Number</i>	<i>Telephone Number</i>
<i>Date of Birth</i>	<i>Fax Number</i>
<i>Sex</i>	
<i>Diagnosis</i>	
<i>Patient or Authorized Representative's Signature:</i> <i>Signature Date:</i>	<i>Prescriber's Signature:</i> <i>Signature Date:</i>

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

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Page 6 of 6

**For Example Purposes Only: Call 1-888-423-5436 for patient enrollment information.**

[Housing Unit Front Cover Flap]  
((THALOMID REMS® logo))

## **THALOMID Risk Evaluation and Mitigation Strategy (REMS) program education and prescribing safety kit**

[Housing Unit Front Cover]

### About THALOMID® (thalidomide)

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

### **Risks of THALOMID**

**THALOMID has a Boxed Warning for embryo-fetal toxicity and venous thromboembolism (deep venous thrombosis [DVT] and pulmonary embolism [PE]).**

**A known teratogen,** THALOMID is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID if they take adequate precautions to avoid pregnancy.

**The use of THALOMID in MM results in an increased risk of venous thromboembolism, such as deep venous thrombosis and pulmonary embolism.** This risk increases significantly when THALOMID is used in combination with standard chemotherapeutic agents including dexamethasone. Patients and physicians should be observant for the signs and symptoms of thromboembolism. Instruct patients to seek medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Consider thromboprophylaxis based on an assessment of individual patients' underlying risk factors.

**This is not a comprehensive description of risks associated with the use of THALOMID.**

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

((THALOMID logo))

[Housing Unit Spine]

## **THALOMID Risk Evaluation and Mitigation Strategy (REMS) program education and prescribing safety kit**

[Housing Unit Back Cover]  
((THALOMID REMS® logo))

### **Prescriber quick reference guide**

1. The prescriber provides comprehensive counseling.
2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
3. The prescriber completes THALOMID® (thalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
4. Female patients complete initial mandatory confidential survey by:
  - Visiting **www.CelgeneRiskManagement.com**
  - Accessing the Celgene REMS mobile app
  - Calling the Celgene Customer Care Center at **1-888-423-5436**Male patients do not need to complete the initial survey.  
All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to THALOMID REMS® Program.
5. The prescriber completes mandatory confidential survey and receives authorization number by:
  - Visiting **www.CelgeneRiskManagement.com**
  - Accessing the Celgene REMS mobile app
  - Calling the Celgene Customer Care Center at **1-888-423-5436**
6. The prescriber writes THALOMID prescription and includes authorization number and patient risk category
7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the THALOMID REMS® procedures.

**THALOMID is only available under a restricted distribution program, THALOMID REMS®.**

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((THALOMID REMS® logo))

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((THALOMID REMS® logo))

## Program for THALOMID® (thalidomide)

### Education and Prescribing Safety

Dear Prescriber:

**Enclosed are your THALOMID REMS® program education materials.**

Celgene Corporation is pleased to provide you with the enclosed materials for use in the THALOMID REMS® program.

Important information about the THALOMID REMS® program

- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called “THALOMID REMS®”
- THALOMID is contraindicated in pregnant females and females of reproductive potential who are not using acceptable contraception or continually abstaining from heterosexual sexual contact. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- Male Patients: Thalidomide is present in semen. Male patients taking THALOMID should not donate sperm. Males receiving THALOMID must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with the THALOMID REMS® program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS® program

As a prescriber certified with the THALOMID REMS® program, please review and familiarize yourself with the contents of the enclosed THALOMID REMS® Kit:

#### **Prescriber Materials**

- Prescriber Guide to THALOMID REMS® Program
- THALOMID Full Prescribing Information

#### **Patient Materials (Patient Resource Pack)**

- Patient Guide to THALOMID REMS® Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, , please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,

Jay T. Backstrom, MD, MPH  
Chief Medical Officer  
Enclosures

## About THALOMID® (thalidomide)

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma.

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

## Risks of THALOMID

**THALOMID has a Boxed Warning for embryo-fetal toxicity and venous thromboembolism (deep venous thrombosis [DVT] and pulmonary embolism [PE]).**

**A known teratogen,** THALOMID is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID if they take adequate precautions to avoid pregnancy.

**The use of THALOMID in MM results in an increased risk of venous thromboembolism, such as deep venous thrombosis and pulmonary embolism.** This risk increases significantly when THALOMID is used in combination with standard chemotherapeutic agents including dexamethasone. Patients and physicians should be observant for the signs and symptoms of thromboembolism. Instruct patients to seek medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Consider thromboprophylaxis based on an assessment of individual patients' underlying risk factors.

**This is not a comprehensive description of risks associated with the use of THALOMID. Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**

((Celgene logo))

((THALOMID REMS® logo))

((THALOMID logo))

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[Front Cover]

**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>”
- 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® (thalidomide)**

Dispensing pharmacies must be certified in the THALOMID REMS® 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®** 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® (thalidomide) (continued)**

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

- A. Prior to each prescription, contact the 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 the 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® (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**

- Online: [www.celgene.com/contact-us/](http://www.celgene.com/contact-us/)
- 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, 86 Morris Avenue, Summit, New Jersey 07901
- Other: Per individual agreement between the reporting organization and Celgene Global Drug Safety & Risk Management

### **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

[Back Cover]

For more information about THALOMID<sup>®</sup> (thalidomide) and the THALOMID REMS<sup>®</sup> program, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at **1-888-423-5436**.

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.**

((Celgene logo))

((THALOMID REMS<sup>®</sup> logo))

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## Education and Counseling Checklist for Pharmacies

### THALOMID Risk Evaluation and Mitigation Strategy (REMS) program education and prescribing safety

Authorization No.:                      Confirmation No.:      Confirmation Date:

Pharmacy Name:

Pharmacy Address:

Counselor Name:

Work Phone:

Ext.:

Patient Name:

Date of Birth:

Risk Category:

#### Checklist for female patients of reproductive potential

- I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

#### I COUNSELED ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity
- Not taking THALOMID® (thalidomide) if pregnant or breastfeeding
- Using **at the same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner’s vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male
- Unacceptable methods of birth control are progesterone-only “mini-pills”, IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, and cervical shield (A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception).
- Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking THALOMID, while taking THALOMID, during dose interruptions, and for at least 4 weeks after stopping THALOMID **every time they have sex with a male**, or abstaining from sex with a male
- Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- The need to stop taking THALOMID right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately
- Possible side effects include deep vein thrombosis and pulmonary embolism
- Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- Not breaking, chewing, or opening THALOMID capsules
- Instructions on THALOMID dose and administration

Milligram (mg) Strength \_\_\_\_\_ Number of Capsules Dispensed \_\_\_\_\_

**FEMALE CHILDREN (<18 YEARS OF AGE):**

- Parent or legal guardian must have read the THALOMID REMS® education material and agreed to ensure compliance

**Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)**

- I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

**I COUNSELED ADULTS AND CHILDREN ON:**

- Possible side effects include deep vein thrombosis and pulmonary embolism
- Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- Not breaking, chewing, or opening THALOMID capsules

- Instructions on THALOMID dose and administration

Milligram (mg) Strength \_\_\_\_\_ Number of Capsules Dispensed \_\_\_\_\_

**FEMALE CHILDREN (<18 YEARS OF AGE):**

- Parent or legal guardian must have read the THALOMID REMS® education material and agreed to ensure compliance
- Parent or legal guardian must inform the child’s healthcare provider when the child begins menses

**Checklist for male patients**

- I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

**I COUNSELED ADULTS AND CHILDREN ON:**

- Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant, even if the patient has had a successful vasectomy)
- Female partners of males taking THALOMID® (thalidomide) must call their healthcare provider right away if they get pregnant
- Possible side effects include deep vein thrombosis and pulmonary embolism
- Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- Not donating blood or sperm while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- Not breaking, chewing, or opening THALOMID capsules
- Instructions on THALOMID dose and administration

Milligram (mg) Strength \_\_\_\_\_ Number of Capsules Dispensed \_\_\_\_\_

**MALE CHILDREN (<18 YEARS OF AGE):**

- Parent or legal guardian must have read the THALOMID REMS<sup>®</sup> education material and agreed to ensure compliance

**All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.**

**Counselor Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

For more information about THALOMID and the THALOMID REMS<sup>®</sup> program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

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.**

((Celgene logo))

((THALOMID REMS<sup>®</sup> logo))

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REMS-THA16907

## THALOMID REMS® Pharmacy Certification Quiz

1. Authorization numbers for females of reproductive potential are valid for up to \_\_\_\_\_ days: *(Mandatory Question)*
  - a. **7 days**
  - b. 10 days
  - c. 14 days
  - d. 28 days
2. It is not necessary to obtain a confirmation number to dispense. *(Mandatory Question)*
  - a. True
  - b. **False**
3. Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for each treatment. *(Mandatory Question)*
  - a. **True**
  - b. False
4. It is not required to retain the prescription with the authorization and confirmation numbers for each filled prescription. It is not necessary to complete the Education and Counseling Checklist.
  - a. True
  - b. **False**
5. According to the package insert's boxed warnings and warnings and precautions, deep venous thrombosis and pulmonary embolism have been reported in patients receiving THALOMID. *(Mandatory Question)*
  - a. **True**
  - b. False
6. THALOMID can cause serious birth defects. *(Mandatory Question)*
  - a. **True**
  - b. False
7. What pregnancy precautions are required for a female of reproductive potential with respect to heterosexual sexual contact?
  - a. **Must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time she has sex with a male, beginning at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks after stopping therapy**
  - b. Abstain from having any heterosexual sexual contact only while taking therapy
  - c. After stopping therapy it is okay to get pregnant at any time
  - d. Use 2 forms of birth control 2 weeks before taking therapy

8. What precautions are required for a male with respect to sexual contact with his female partner of reproductive potential?
- Use of a latex or synthetic condom every time he has sexual intercourse with a female of reproductive potential during therapy (including dose interruptions) and for 4 weeks after stopping therapy, even if he has undergone a successful vasectomy**
  - Abstain from having any sexual contact with a female of reproductive potential only while taking therapy
  - Use latex or synthetic condoms while taking therapy. No precautions are necessary once treatment has stopped
  - Males taking therapy who have had a vasectomy do not need to use latex or synthetic condoms
9. For all Celgene REMS programs, female patients of reproductive potential must have a negative pregnancy test: *(Mandatory Question)*
- Prior to initial prescription
  - Prior to subsequent prescription
  - Prior to initial prescription and prior to subsequent prescription**
  - None of these
10. Adverse drug experiences that are suspected to be associated with the use of therapy, and any suspected pregnancy occurring during treatment, must be reported to Celgene. *(Mandatory Question)*
- True**
  - False
11. The Medication Guide must be provided every time THALOMID is dispensed. *(Mandatory Question)*
- True**
  - False
12. A certified Celgene REMS pharmacy cannot dispense more than a \_\_\_\_\_ supply of THALOMID.
- 28 day**
  - 3 month
  - 2 week
  - 1 year

13. Authorization numbers for patient risk categories other than females of reproductive potential are valid for up to \_\_\_\_\_ days. (*Mandatory Question*)
- a. **30 days**
  - b. 10 days
  - c. 7 days
  - d. 28 days
14. A male patient can donate sperm at any time during therapy.
- a. True
  - b. **False**

REMS-THA16780

**((THALOMID REMS<sup>®</sup> logo))**  
**Patient Resource Pack**  
**THALOMID Risk Evaluation and Mitigation Strategy (REMS) program**

**The Patient Resource Pack contains:**

- Patient Guide to THALOMID REMS<sup>®</sup> Program
- Emergency Contraception Brochure
- Medication Guide

**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, ADVERSE REACTIONS, and Medication Guide, enclosed.**

((Celgene logo))

((THALOMID logo))

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7/17

REMS-THA16904

[Front Cover]

**Patient Guide to  
((THALOMID REMS® logo))  
Risk Evaluation and Mitigation Strategy (REMS) Program**

This guide provides you important information about:

- The risks of THALOMID® (thalidomide)
  - Birth defects (deformed babies) or death of an unborn baby
  - Blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)
  
- The THALOMID REMS® program
  - What females who can get pregnant need to know
    - Birth control options
  - What females who can not get pregnant need to know
  - What males need to know

((THALOMID logo))

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## **Risks of THALOMID® (thalidomide)**

THALOMID can cause harm to an unborn baby when given to a pregnant female. THALOMID causes a high frequency of severe and life-threatening birth defects (deformed babies) or death of an unborn baby, even after a single dose (1 capsule [regardless of strength]). THALOMID must not be used by pregnant females or by females who are able to get pregnant who are not using acceptable birth control or avoiding sex with a male. Females who are able to get pregnant must avoid pregnancy while taking THALOMID.

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

**This is not a comprehensive description of risks associated with the use of THALOMID. Please read the Medication Guide for THALOMID for additional information regarding risks associated with its use and see the full Prescribing Information, including Boxed Warnings, enclosed.**

((Image of a baby with severe birth defects caused by THALOMID))

*THALOMID can cause severe birth defects, including missing or severely deformed legs and arms. These babies often have hands attached directly to their shoulders and feet attached directly to their hips. Photo reprinted by permission.*

### **What is the THALOMID REMS® program?**

To avoid serious risks to unborn babies, THALOMID is only available under a restricted distribution program called the “THALOMID Risk Evaluation and Mitigation Strategy (REMS)”. Only certified prescribers can prescribe THALOMID and only certified pharmacies can dispense THALOMID. In order to receive THALOMID, patients must be enrolled in the THALOMID REMS® program and agree to follow the requirements.

For more information about THALOMID and the THALOMID REMS® program, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center toll-free at **1-888-423-5436**.

**How to receive your first prescription for THALOMID® (thalidomide)  
For Females:**

<p><b>Counseling</b> Your healthcare provider will counsel you on why and how you and your partner should prevent pregnancy. Your healthcare provider will also inform you not to share the drug, not to donate blood, and about using two effective birth control methods (at least one highly effective method and one effective method) at the same time. You should be instructed not to extensively handle or open THALOMID capsules</p>
<p><b>Pregnancy Test #1</b> If you can get pregnant, you must take an initial pregnancy test within 10-14 days before getting a THALOMID prescription</p>
<p><b>Pregnancy Test #2</b> If you can get pregnant, you must take a second pregnancy test within 24 hours before getting a THALOMID prescription</p>
<p><b>Enrollment</b> You and your healthcare provider will then complete and submit the THALOMID® (thalidomide) Patient-Physician Agreement Form</p>
<p><b>Complete Mandatory Confidential Survey</b> You and your healthcare provider will each complete a survey. Visit <a href="http://www.CelgeneRiskManagement.com">www.CelgeneRiskManagement.com</a>, access the Celgene REMS mobile app, or call 1-888-423-5436 and press 1 to take your survey</p>
<p><b>Prescription</b> Your healthcare provider will send your prescription to a certified pharmacy</p>
<p><b>Pharmacy Call</b> The certified pharmacy will contact you to provide counseling on the serious risks and safe-use conditions of THALOMID before you receive your prescription. They will also coordinate delivery of THALOMID to you</p>
<p><b>Receive THALOMID</b> THALOMID will be shipped with a Medication Guide to the address you provide. A signature will be required to receive this shipment</p>

**For each of your following prescriptions, pregnancy tests will be required depending on your ability to get pregnant. For specific pregnancy test requirements, please refer to page 9 of this guide. For full detailed information about the THALOMID REMS® program requirements, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) or review the Patient Guide to THALOMID REMS® Program.**

## For Males:

**For each of your following prescriptions, you will need to follow a similar process.**

<p><b>Counseling</b> Your healthcare provider will counsel you on why and how you and your partner should prevent pregnancy. Your healthcare provider will also inform you not to share the drug, not to donate blood or sperm, and about appropriate contraceptive use. You should be instructed not to extensively handle or open THALOMID<sup>®</sup> (thalidomide) capsules</p>
<p><b>Enrollment</b> You and your healthcare provider will then complete and submit the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form</p>
<p><b>Complete Mandatory Confidential Survey</b> You will not have to take a survey for your first prescription, but will have to for the following ones. Visit <a href="http://www.CelgeneRiskManagement.com">www.CelgeneRiskManagement.com</a>, access the Celgene REMS mobile app, or call <b>1-888-423-5436</b> and press 1 to take your survey</p>
<p><b>Prescription</b> Your healthcare provider will send your prescription to a certified pharmacy</p>
<p><b>Pharmacy Call</b> The certified pharmacy will contact you to provide counseling on the serious risks and safe-use conditions of THALOMID before you receive your prescription. They will also coordinate delivery of THALOMID to you</p>
<p><b>Receive THALOMID</b> THALOMID will be shipped with a Medication Guide to the address you provide. A signature will be required to receive this shipment</p>

**For full detailed information about the THALOMID REMS<sup>®</sup> program requirements, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) or review the Patient Guide to THALOMID REMS<sup>®</sup> Program.**

((DO NOT GET PREGNANT logo))

## What do all patients need to know about the THALOMID REMS<sup>®</sup> program?

### General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. Just **one capsule** taken by a pregnant female can cause severe birth defects
- THALOMID<sup>®</sup> (thalidomide) does not induce abortion of the fetus and should never be used for contraception
- THALOMID must be kept out of the reach of children
- Do not open or unnecessarily handle THALOMID capsules. If a broken capsule (or the powder in the capsule) comes in contact with your skin, wash the area with soap and water
- Keep THALOMID in a cool, dry place
- Do **not** donate blood while you are taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID
- Unused THALOMID capsules should be returned for disposal to Celgene by calling **1-888-423-5436** or to your THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to you

### Warning

- **Blood clots** have been reported in patients taking THALOMID<sup>®</sup> (thalidomide), especially when used with other cancer drugs. Your healthcare provider may recommend treatment that could help prevent blood clots. Talk to your healthcare provider if you have shortness of breath, chest pains, or arm or leg swelling
- THALOMID can cause other health problems called “side effects.” For a complete listing of possible side effects, please refer to the Medication Guide
- **Be sure to report all side effects to your healthcare provider immediately.** Ask your healthcare provider about other side effects associated with THALOMID

((DO NOT GET PREGNANT logo))

## What do females who can get pregnant need to know about the THALOMID REMS® program?

### A. Before taking THALOMID® (thalidomide)

- You must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form that says you understand that THALOMID should not be used during pregnancy, and that you agree not to become pregnant while taking THALOMID
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking THALOMID
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for THALOMID, and again within 24 hours before you receive your first prescription for THALOMID. If you are pregnant, you cannot take THALOMID
- You will have pregnancy tests before starting THALOMID and while taking THALOMID, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for THALOMID, you must take part in a mandatory confidential survey. The survey will make sure that you understand and can follow information designed to prevent serious risks to unborn babies
- Before dispensing THALOMID® (thalidomide), your THALOMID REMS® certified pharmacy will contact you to discuss treatment
- Your healthcare provider will talk with you about your birth control options

**1. Choose at least 1 highly effective method and at least 1 additional effective method of birth control.** Talk to your healthcare provider about the following acceptable birth control methods. See below.

### Effective Methods of Birth Control Used at the Same Time

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Male latex or synthetic condom Diaphragm Cervical cap

**2. Use the 2 methods of birth control at the same time**

- **Remember:** You must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons

- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- **Remember, not having sex is the only method of birth control that is 100% effective**

### 3. Unacceptable methods of birth control

- Progesterone-only “mini-pills”
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield\*

### 4. Take pregnancy tests

- You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for THALOMID® (thalidomide) and again within 24 hours before receiving your first prescription for THALOMID. Both pregnancy tests must have a negative result

### B. While taking THALOMID

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use

\*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

- You will have a pregnancy test performed by your healthcare provider:
  - Every week during the first 4 weeks of treatment, then
  - Every 4 weeks if your menstrual cycles are regular, or
  - Every 2 weeks if your cycles are irregular
  - If you miss your period or have unusual menstrual bleeding, or
  - If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control or if you think your birth control has failed, stop taking THALOMID (thalidomide) immediately and call your healthcare

provider right away. Your healthcare provider will discuss your options, which may include emergency birth control. Do not wait until your next appointment to tell your healthcare provider if you miss your menstrual period or if you think you may be pregnant

- If you get pregnant, or think you may be pregnant, you must immediately stop taking THALOMID. Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If your healthcare provider is not available, call the Celgene Customer Care Center at **1-888-423-5436**
  - You must not breastfeed a baby while you are taking THALOMID
  - **In order** to continue receiving THALOMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your THALOMID REMS<sup>®</sup> healthcare provider. To take the survey, please visit **www.CelgeneRiskManagement.com**, access the Celgene REMS mobile app, or call the Celgene Customer Care Center at **1-888-423-5436**
- C. After you have stopped taking THALOMID<sup>®</sup> (thalidomide)**
- You must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
    - For at least 4 weeks after stopping THALOMID, or
    - Do not have any sex with a male for 4 weeks after stopping THALOMID

See also “General guidelines” on page 6 for requirements for all patients.

[PAGE 12]  
[Header]

Attention Females Who Can Get Pregnant:

[Subhead]

Tear out this letter to take with you to your next medical appointment that discusses your birth control options.

This letter will help you and your healthcare provider understand what types of birth control options are the best for you.

[FRONT PAGE OF Tear-out Letter]

[THALOMID REMS Logo]

[Body copy]

Dear Healthcare Provider,

Your patient is being treated with THALOMID<sup>®</sup> (thalidomide). Thalidomide is a known teratogen and is only available under a restricted distribution program approved by the Food and Drug Administration. This program is called the THALOMID REMS<sup>®</sup> (Risk Evaluation and Mitigation Strategy) program.

[Subhead]

The goals of the THALOMID REMS<sup>®</sup> program are:

[Body copy]

1. To prevent the risk of embryo-fetal exposure to THALOMID.
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for THALOMID.

To enroll in the THALOMID REMS<sup>®</sup> program, your patient, with the knowledge of the healthcare provider who prescribed THALOMID, agreed to follow the program's contraception requirements while on THALOMID therapy. Unless she completely abstains from sexual intercourse with a male partner, she is required to use **at the same time at least one highly effective birth control method and at least one additional effective method.**

The two effective contraceptive methods must be started at least 4 weeks before THALOMID<sup>®</sup> (thalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks

following discontinuation of therapy. Please refer to the table below of the acceptable forms of contraception to help facilitate the discussion on contraception.

[Subhead]

Effective Methods of Birth Control Used at the Same Time

[Chart]

<b>Highly effective birth control methods</b>	<b>Additional effective birth control methods</b>
Intrauterine device (IUD)	Male latex or synthetic condom
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Diaphragm Cervical cap
Tubal ligation (having your tubes tied)	+
Partner’s vasectomy (tying of the tubes to prevent the passing of sperm)	
<p><b>Unacceptable forms of contraception:</b>            progesterone-only “mini-pills,” IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception).</p>	

[Footer]

(continued on next page)

[BACK PAGE OF Tear-out Letter]

[Eyebrow copy]

(continued from previous page)

[Subhead]

Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.

[Body Copy]

Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD

contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after. Instruct patient to immediately stop taking THALOMID and contact her doctor if she becomes pregnant while taking this drug, if she misses her menstrual period or experiences unusual menstrual bleeding, if she stops taking birth control or if she thinks FOR ANY REASON that she may be pregnant. Advise patient that if her doctor is not available she can call Celgene Customer Care at 1-888-423-5436.

There are other risks associated with THALOMID treatment as described in the Prescribing Information.

For full Prescribing Information, including Boxed Warnings, or details about the THALOMID REMS<sup>®</sup> program, please visit [www. thalomidrems.com](http://www.thalomidrems.com).

You may contact the Celgene REMS Department at 1-888-423-5436 if you have any questions about the information contained in this letter or the safe and effective use of THALOMID.

Sincerely,

[Signature]

Jay T. Backstrom, MD, MPH  
Chief Medical Officer & Global Head  
Regulatory Affairs

[Celgene Logo]

[End Matter]

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## **What do females who can not get pregnant need to know about the THALOMID REMS<sup>®</sup> program?**

### **A. Before taking THALOMID<sup>®</sup> (thalidomide)**

- You must sign the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
  - You have been in natural menopause for at least 2 years, or
  - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the THALOMID<sup>®</sup> (thalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting THALOMID
- Before your healthcare provider can write your prescription for THALOMID, you must take part in a mandatory confidential survey. The survey will make sure that you understand and can follow information designed to prevent serious risks to unborn babies
- Before dispensing THALOMID, your THALOMID REMS<sup>®</sup> certified pharmacy will contact you to discuss treatment

### **B. While taking THALOMID<sup>®</sup> (thalidomide)**

- In order to continue receiving THALOMID, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your THALOMID REMS<sup>®</sup> healthcare provider. To take the survey, please visit **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, access the Celgene REMS mobile app, or call the Celgene Customer Care Center at **1-888-423-5436**

See also “General guidelines” on page 6 for requirements for all patients.

## What do males need to know about the THALOMID REMS® program?

You must use a latex or synthetic condom, **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

### A. Before taking THALOMID® (thalidomide)

- You must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form. You must agree that while taking THALOMID you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- Before dispensing THALOMID, your THALOMID REMS® certified pharmacy will contact you to discuss treatment

### B. While taking THALOMID

- You must use a latex or synthetic condom **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must tell your healthcare provider right away if you had sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner may be pregnant or if your partner is pregnant. If your healthcare provider is not available, Call the Celgene Customer Care Center at **1-888-423-5436**
- You must **not** donate sperm while taking THALOMID® (thalidomide) (including during breaks [dose interruptions])

In order to continue receiving THALOMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your THALOMID REMS® healthcare provider. To take the survey, please visit **www.CelgeneRiskManagement.com**, access the Celgene REMS mobile app, or call the Celgene Customer Care Center at **1-888-423-5436**

**C. After you have stopped taking THALOMID**

- For 4 weeks after receiving your last dose of THALOMID, you must use a latex or synthetic condom, **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping THALOMID

See also “General guidelines” on page 4 for requirements for all patients.

## **Mandatory confidential patient surveys**

As a patient who is enrolled in the THALOMID REMS<sup>®</sup> program for THALOMID<sup>®</sup> (thalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

### **Adult females who can get pregnant**

- Initial survey before first prescription
- Monthly

### **Adult females who can not get pregnant**

- Initial survey before first prescription
- Every six months

### **Female children**

- Initial survey before first prescription
- Monthly

### **Males**

- No initial survey
- Monthly

### **Mandatory confidential survey process**

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), the Celgene REMS mobile app, or call the Celgene Customer Care Center at **1-888-423-5436**
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a THALOMID REMS<sup>®</sup> certified pharmacy. The THALOMID REMS<sup>®</sup> certified pharmacy will contact you to discuss your THALOMID therapy. You will not receive your medication until you speak with the THALOMID REMS<sup>®</sup> certified pharmacy

For more information, contact the Celgene Customer Care Center at **1-888-423-5436**

((TVAC icon))

## **A letter from the Thalidomide Victims Association of Canada (TVAC)**

*The following letter from the Thalidomide Victims Association of Canada (TVAC) was written in 1998 upon U.S. approval of THALOMID® (thalidomide), and is included in this brochure to be transparent about public concerns for thalidomide victims regarding the marketing of THALOMID.*

Dear Doctor/Patient:

**Have you ever met someone who was born disabled after exposure to thalidomide?**

We have. In fact, we are thalidomiders—the name we have adopted to describe the surviving children of mothers who were prescribed thalidomide during their pregnancy as a sedative or for nausea and other symptoms of “morning sickness.”

You’ve undoubtedly seen the **dramatic photographs of babies with severe birth defects** caused when thalidomide is taken EVEN ONCE by a pregnant woman. You know the risks!

The **Thalidomide Victims Association of Canada (TVAC)** was formed to meet the needs of the approximately 125 thalidomiders alive in Canada today, and to aid the surviving 10 thalidomiders living in the United States. Of the 10,000 to 12,000 children born with thalidomide deformities around the world in the early sixties, 5,000 survive today. No one will ever know how many children were miscarried or were stillborn because of thalidomide.

TVAC exists as a survivors group to determine and find solutions to the ongoing problems we face. TVAC has also undertaken a mandate of monitoring the responsible use of thalidomide and ensuring the tragedy of the past *never happens again*.

Because of our own personal traumas, and those of our families, we have always stated that we can never accept a world with thalidomide in it.

However, as we know first-hand how people may suffer, we also concede that no one should suffer needlessly. If thalidomide can extend a life, or offer a better quality of life to people with debilitating or chronic illnesses, then we are forced to accept the fact that thalidomide use may be their choice.

As well, we are forced to prefer the regulated use of thalidomide over the alternative:  
*One thalidomide baby born out of ignorance is far worse than one born out of a legitimate attempt to regulate and control the distribution process of this drug.*

Since you may soon be involved in prescribing or taking thalidomide, we need for you to be **fully aware of the power you have ...**

- the responsibility to see that you **fully understand the risks thalidomide poses ...**
- the **commitment** to do whatever it takes to make sure that NOT EVEN ONE woman loses a child due to thalidomide

We were as surprised as anyone when the people at Celgene Corporation, makers of THALOMID® (thalidomide), sought the opinions and input of those of us at TVAC concerning the use of thalidomide in the United States. We felt it was a respectful step in the right direction that our feelings, opinions, and knowledge were being considered.

We are also consoled to know that Celgene Corporation has instituted a comprehensive program to help physicians and pharmacists inform patients about side effects and risks and ensure that they are aware of precautions they must take before, during, and after therapy.

The **THALOMID Risk Evaluation and Mitigation Strategy (REMS)** is a multifaceted program developed to help ensure that fetal exposure to THALOMID does not occur. All of the materials you need to comply with this system are enclosed.

Meanwhile, we make you one promise:

*The Thalidomide Victims Association of Canada will continue to watch the progression of events where thalidomide use is concerned.*

We have to!

For further information regarding the history of thalidomide or the status of survivors today, please feel free to contact us.

Sincerely,

((signatures))

Randolph Warren  
Chief Executive Officer  
Thalidomide Victims  
Association of Canada

Giselle Cole  
Past President  
Thalidomide Victims  
Association of Canada

Head Office

**Thalidomide Victims Association of Canada**

Centre Commercial Joseph Renaud  
6830 Boul. Joseph Renaud, Suite 211  
Montreal, Quebec, Canada  
H1K 3V4  
Phone: **1-514-355-0811**  
Fax: **1-514-355-0860**

((DO NOT GET PREGNANT logo))

## **Warning to patients taking THALOMID<sup>®</sup> (thalidomide)**

### **Attention females:**

Do **not** take THALOMID if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

### **Attention males:**

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID.

### **Attention all patients:**

You must **not** donate blood while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. Just **one capsule** taken by a pregnant female can cause severe birth defects.

THALOMID must be kept out of the reach of children. Return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**, or to your THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to you.

[Back Cover]

For more information about THALOMID<sup>®</sup> (thalidomide) and the THALOMID REMS<sup>®</sup> program, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation  
86 Morris Ave  
Summit, NJ 07901

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

**Please read the Medication Guide for THALOMID for additional information regarding risks associated with its use and see the full Prescribing Information, including Boxed Warnings, enclosed.**

((Celgene logo))

((THALOMID REMS<sup>®</sup> logo))

((THALOMID logo))

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# REMS Patient Survey Reminder

Patient Name \_\_\_\_\_ Date Survey Available \_\_\_\_\_

Doctor's Office Contact and Phone # \_\_\_\_\_

Product \_\_\_\_\_ Pharmacy Name \_\_\_\_\_

## Telephone Survey

## OR Website and Mobile App Survey



From a touchtone phone dial  
**1-888-423-5436**

Para español, oprime el numero dos  
to identify that you are a patient  
to take a survey

Enter your 9-digit patient  
identification number  
(the number you provided during  
the enrollment process – for  
example your Social Security  
Number).

From the menu provided, select the drug  
that you have been prescribed.



Your survey will then begin. Please  
answer all of the questions. Confirmation  
that the survey has been completed will  
be provided at the end of your survey.

Access the internet and type in the website address  
**www.CelgeneRiskManagement.com**  
or download the Celgene REMS mobile app for  
your iPad. You can find the Celgene REMS mobile  
app by using the search term Celgene in iTunes for  
iPad only.

You are not required to have a User Name or  
Password to complete a survey. To take your  
survey, left click your mouse on the button



You will be asked for the following  
information. Please enter the information  
exactly as it was provided during your  
enrollment process



After entering the information above, click



Survey questions will be displayed 1 per  
page. Please be sure to complete the  
survey in its entirety. A summary page  
displaying your survey answers will be  
displayed at the end of your survey.  
Upon completion, send the survey to  
Celgene by clicking



# CelgeneRiskManagement.com

## Login Page



**Welcome to the Celgene REMS Program**

To avoid embryo-fetal exposure, Risk Evaluation and Mitigation Strategy (REMS) programs are mandatory for the Celgene products THALOMID® (thalidomide), REVLIMID® (lenalidomide) and POMALYST® (pomalidomide). The THALOMID REMS® program, REVLIMID REMS® program, and POMALYST REMS® program require prescribers and pharmacists to be certified and patients to enroll and comply with all of the requirements for each program.

If you would like to obtain more information about any of the Celgene REMS programs, please click on the program name below:



Visit [www.REVLIMIDREMS.com](http://www.REVLIMIDREMS.com),  
to learn more about the  
REVLIMID REMS® program.



Visit [www.POMALYSTREMS.com](http://www.POMALYSTREMS.com),  
to learn more about the  
POMALYST REMS® program.



Visit [www.THALOMIDREMS.com](http://www.THALOMIDREMS.com),  
to learn more about the  
THALOMID REMS® program.

For prescribers, please enter your User Name and Password to manage your patients through a Celgene REMS program. If you do not have an online account, select Create User Account to establish an account. Patients currently enrolled in a Celgene REMS program are not required to create an online account to complete a survey. Please select Patient Surveys and enter the information requested to begin a survey.

To login to your account:

User Name

Password

[Forgot Password? >](#)

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## Home Page (after prescriber logon)

Home

Click on a button below to access the corresponding REMS menu of operations for that product: enroll a patient, access an existing or save a new Patient-Physician Agreement Form, complete a prescriber survey or write a prescription.

<p data-bbox="354 520 570 548">For <b>REVLIMID REMS</b>®</p>  <p data-bbox="334 695 586 810">Please see full <a href="#">Prescribing Information</a>, including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.</p> <p data-bbox="326 831 594 894">Visit <a href="http://www.REVLIMIDREMS.com">www.REVLIMIDREMS.com</a>, to learn more about the REVLIMID REMS® program.</p>	<p data-bbox="716 520 932 548">For <b>POMALYST REMS</b>®</p>  <p data-bbox="699 695 967 810">Please see full <a href="#">Prescribing Information</a>, including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.</p> <p data-bbox="691 831 959 894">Visit <a href="http://www.POMALYSTREMS.com">www.POMALYSTREMS.com</a>, to learn more about the POMALYST REMS® program.</p>	<p data-bbox="1078 520 1294 548">For <b>THALOMID REMS</b>®</p>  <p data-bbox="1062 695 1330 810">Please see full <a href="#">Prescribing Information</a>, including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.</p> <p data-bbox="1053 831 1321 894">Visit <a href="http://www.THALOMIDREMS.com">www.THALOMIDREMS.com</a>, to learn more about the THALOMID REMS® program.</p>
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The Prescriber Dashboard is an optional resource that displays the status of patients under your care for a specific Celgene REMS program. A patient search function is also included to access detailed patient history information.

Select the "Manage My Account" button to view your Celgene REMS online account information.

[Prescriber Dashboard](#) [Manage My Account](#)

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# THALOMID REMS module

John Doe [Home](#) [Help](#) [Logout](#)

**THALOMID REMS®** **THALOMID REMS® Main Menu**

 <b>New PPAF/Patient Enrollment</b>	 <b>Nuevo formulario de acuerdo de paciente-médico/inscripción de paciente</b>
 <b>Work with Saved/ Submitted PPAF Forms</b> <small>(Click here for more options)</small>	 <b>Trabajar con formulario de acuerdo de paciente-médico guardado/entregado</b> <small>(Presione aquí para más opciones)</small>
 <b>Prescriber Survey</b> <small>(Click here for new/next Rx)</small>	 <b>Encuesta de prescriptor</b> <small>(Presione aquí para la próxima/nueva prescripción)</small>
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## THALOMID REMS®



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For additional information about the THALOMID REMS® program, please contact the Celgene Customer Care Center at 1-888-423-5436

Download the Celgene REMS mobile app to your iPad by clicking here:



### Welcome to the THALOMID REMS® program

THALOMID® (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

#### Important information about THALOMID and the THALOMID Risk Evaluation and Mitigation Strategy (REMS) 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®"
- Only prescribers and pharmacies certified by the THALOMID REMS® program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS® program

The goals of the THALOMID risk evaluation and mitigation strategy are as follows:

1. To prevent the risk of embryo-fetal exposure to THALOMID
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for THALOMID

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For additional information about the THALOMID REMS® program, please contact the Celgene Customer Care Center at 1-888-425-5436

Download the Celgene REMS mobile app to your iPad by clicking here:



## About the THALOMID REMS® program

THALOMID® (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called "THALOMID Risk Evaluation and Mitigation Strategy (REMS)." Only certified prescribers can prescribe THALOMID and only certified pharmacies can dispense THALOMID in the THALOMID REMS® program.

In order to receive THALOMID, all patients must be enrolled in the THALOMID REMS® program and agree to comply with the requirements of the THALOMID REMS® program.

### Key points of the THALOMID REMS® program

#### Prescriber

- The prescriber enrolls and becomes certified with Celgene for the THALOMID REMS® program
- The prescriber counsels patient on benefits and risks of THALOMID
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a THALOMID® (thalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends THALOMID prescription to certified pharmacy

#### Pharmacy

- The pharmacy certifies with Celgene for the THALOMID REMS® program
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy counsels the patient and completes the Education and Counseling Checklist
- The certified pharmacy dispenses THALOMID to patient along with a Medication Guide

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- Prescriber Resources**
- Patient Resources
- Pharmacy Resources

For additional information about the THALOMID REMS<sup>®</sup> program, please contact the Celgene Customer Care Center at 1-800-424-5226.

Download the Celgene REMS mobile app to your iPad by clicking here:

**Prescriber Resources**

THALOMID<sup>®</sup> (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).  
 THALOMID is indicated for the acute treatment of the cutaneous manifestations of relapsed or refractory Hodgkin lymphoma (RH).  
 THALOMID is not indicated as monotherapy for such FDA treatment in the presence of systemic disease. Health.  
 THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of CLL, see below.

**Enrolling in THALOMID REMS<sup>®</sup>**

In order to prescribe THALOMID, you must enroll in the THALOMID REMS<sup>®</sup> program and agree to follow the requirements of the program. You can enroll by visiting [CelgeneRiskManagement.com](http://CelgeneRiskManagement.com). This site also provides the forms for the REMS process for all of the Celgene REMS programs. You can also download the Prescriber Enrollment Form and send it to the Celgene Customer Care Center at 1-800-424-5226.

[Prescriber Enrollment Form](#)

**Prescribing THALOMID for your patients**

In order to prescribe THALOMID, your patients must also enroll in the THALOMID REMS<sup>®</sup> program. You can send your patients and their prescribers forms using [CelgeneRiskManagement.com](http://CelgeneRiskManagement.com). This site also provides the forms for the REMS process for all of the Celgene REMS programs. You can also download the Patient Medication Guide and send it to the Celgene Customer Care Center at 1-800-424-5226.

Additionally, you can also send your patients by visiting the Celgene REMS mobile app for your iPad.

[Send Your Patients at CelgeneRiskManagement.com](#)

[Download the Celgene REMS mobile app](#)

[Patient Medication Guide](#)

**Learning more about THALOMID REMS<sup>®</sup>**

For additional information about the THALOMID REMS<sup>®</sup> program, please visit the following website below:

[Prescriber Guide to THALOMID REMS<sup>®</sup> Program](#)

[THALOMID REMS<sup>®</sup> at a Glance](#)

[Full Prescribing Information](#)

Please report adverse drug experiences. You are encouraged to be vigilant with the use of THALOMID and any related to any safety concerns during the treatment with THALOMID to Celgene using any of the following methods:

**REPORTING TO CELGENE**

**Online:** [www.celgene.com/medwatch](http://www.celgene.com/medwatch)

**Email:** [medwatch@celgene.com](mailto:medwatch@celgene.com)

**Telephone:** 1-800-424-5226

**Toll-free:** 1-800-462-7264 (Global Drug Safety & Risk Management) or 1-800-424-5438 (Celgene Customer Care Center)

**Fax:** 1-800-573-0119

**Mail to:** Global Drug Safety & Risk Management  
 Celgene Corporation  
 30 Morris Avenue  
 Summit, New Jersey 07901

**Online:** For additional information, please see the reporting organization and Celgene Global Drug Safety & Risk Management.

**REPORTING TO THE FDA**

Adverse drug reports should also be reported to the FDA with the use of THALOMID and any related to any safety concerns during the treatment with THALOMID may also be reported to the FDA. You may report safety concerns using any of the following methods:

**Online:** <http://www.accessdata.fda.gov/medwatch/medwatch-online.htm>

**Telephone:** 1-800-FDA-1088

**Fax:** 1-800-FDA-0178

**Mail to:** Medwatch  
 2820 Rockledge Lane  
 Rockville, MD 20850-4107





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For additional information about the THALOMID REMS® program, please contact the Celgene Customer Care Center at 1-888-623-5436

Download the Celgene REMS mobile app to your iPad by clicking here:

**Patient Resources**

THALOMID® (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of myeloma to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of myeloma to severe results.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

**What you need to know about the THALOMID REMS® program**

Your doctor will enroll you in the THALOMID REMS® program so that you can receive your medication. Use the materials below to learn more about the THALOMID REMS® program, and what you need to do.

- [Patient Guide to THALOMID REMS® Program](#)
- [Data you'll receive in THALOMID REMS®](#)
- [Patient Medication Guide](#)
- [Visit Planned Parenthood Site for Emergency Contraception Services](#)
- [Patient Survey Reminder Card](#)

You can take your mandatory confidential patient survey at [CelgeneRiskManagement.com](http://CelgeneRiskManagement.com) in English or Spanish by clicking one of the buttons below.

- [Patient Survey](#)
- [Encuesta del paciente](#)

You can also complete your survey by using the Celgene REMS mobile app for your iPad. Please download the app to your iPad by clicking here:



**Attention Females Who Can Get Pregnant**

Unless you abstain from sexual intercourse with a male partner, you are required to use at the same time at least 1 highly effective birth control method and at least 1 additional effective method every time you have sex with a male. Below, you will find a printable letter that you can bring with you to your next medical appointment that discusses your reproductive health. This will help you and your healthcare provider understand what types of birth control options are best for you.

[Birth Control Options to Discuss With Your Healthcare Provider](#)

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For additional information about the THALOMID REMS<sup>®</sup> program, please contact the Celgene Customer Care Center at 1-888-425-5438.

Download the Celgene REMS mobile app to your iPad by clicking here:



### Pharmacist Resources

THALOMID<sup>®</sup> (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the substantial morbidity of relapsed disease in patients with relapsed and/or refractory MM.

THALOMID is not indicated as monotherapy for such CNS treatment in the presence of underlying spinal cord disease.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the substantial morbidity of CNS recurrences.

#### THALOMID REMS<sup>®</sup> information for certified pharmacies

THALOMID is only dispensed from THALOMID REMS<sup>®</sup> program certified pharmacies. To learn more about how to become a certified pharmacy, please contact the Celgene Customer Care Center at 1-888-425-5438.

As a THALOMID REMS<sup>®</sup> certified pharmacy, you must follow the requirements of the THALOMID REMS<sup>®</sup> program. The only document in place for the program is a contract to dispense patients, and the full program is outlined below.

- Pharmacy Guide to THALOMID REMS<sup>®</sup> Program
- Full Prescribing Information
- Education and Counseling Checklist for Pharmacists
- List of Certified Pharmacies and Subscribers

#### The Celgene REMS Pharmacy Portal

In addition to calling the Celgene Customer Care Center to obtain a confirmation number for a prescription, eligible pharmacies can obtain confirmation numbers using the Celgene REMS Pharmacy Portal at [CelgeneRMSPharmacyPortal.com](http://CelgeneRMSPharmacyPortal.com). Contact your Celgene Area of Manager to see if your pharmacy is eligible.

Celgene REMS Pharmacy Portal

Please report adverse drug experiences that are expected 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**

**Online:** [www.celgene.com/contact-us/](http://www.celgene.com/contact-us/)

**Email:** [druginfo@celgene.com](mailto:druginfo@celgene.com)

**Telephone:** 1-888-425-5438

**Toll-Free:** 1-888-640-7624 (Global Drug Safety & Risk Management) or 1-888-425-5438 (Celgene Customer Care Center)

**Fax:** 1-888-475-9112

**Mail to:** Global Drug Safety & Risk Management  
Celgene Corporation  
39 Morris Avenue  
Summit, New Jersey 07901

**Other:** The individual agreement between the reporting organization and Celgene Global Drug Safety & Risk Management

**REPORTING TO THE FDA**

Adverse drug experiences that are expected 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:** <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/adverse/index.cfm>

**Telephone:** 1-888-DA-1088

**Fax:** 1-888-FDA-0172

**Mail to:** MedWatch  
8887 Rockledge Lane  
Rockville, MD 20850-0172



# THALOMID REMS<sup>®</sup>



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## Welcome to the THALOMID REMS<sup>®</sup> program

THALOMID<sup>®</sup> (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the active treatment of the myeloma in patients with moderate to severe

presence of moderate to severe neuro

suppression of the coarctous

### THALOMID Risk Evaluation

of becoming pregnant. For more

ward precautions are taken to

restricted distribution program

### You Are Now Leaving THALOMIDREMS.com

Click "OK" to proceed or "CANCEL" to return to THALOMIDREMS.com

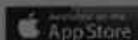
OK

CANCEL



For additional information about the THALOMID REMS<sup>®</sup> program, please contact the Celgene Customer Care Center at 1-888-423-5436

Download the Celgene REMS mobile app to your iPad by clicking here:



• Only prescribers and pharmacists certified by the THALOMID REMS<sup>®</sup> program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS<sup>®</sup> program.

The goals of the THALOMID risk evaluation and mitigation strategy are as follows:

1. To prevent the risk of embryo-fetal exposure to THALOMID
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for THALOMID

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For additional information about the THALOMID REMS® program, please contact the Celgene Customer Care Center at 1-888-423-5436

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Planned Parenthood is the nation's leading provider and advocate of high-quality, affordable health care for women, men, and young people, as well as the nation's largest provider of sex education. With approximately 700 health centers across the country, Planned Parenthood organizations serve all patients with care and compassion, with respect and without judgment. Through health centers, programs in schools and communities, and online resources, Planned Parenthood is a trusted source of reliable health information that allows people to make informed health decisions. We do all this because we care passionately about helping people lead healthier lives.

[www.plannedparenthood.org](http://www.plannedparenthood.org)  
[www.ppfastore.org](http://www.ppfastore.org)

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**What You Should Know About Emergency Contraception**  
2675 3/15-70 2.13.5  
ISBN 1-934100-43-2  
Printed in the U.S.A.



Birth  
Control  
Series

## What You Should Know About Emergency Contraception



# TOP 3 THINGS



## What you should know about emergency contraception (EC)

- 1 EC can prevent pregnancy after you have had unprotected vaginal sex.
- 2 EC must be used within 120 hours (5 days) after vaginal sex.
- 3 There are two different kinds of EC:
  - Copper IUD (ParaGard®)
  - Emergency contraception pills

### You can use EC if:

- You weren't using any birth control when you had sex.
- You made a mistake with your regular birth control.
- The condom broke or slipped off.
- Your partner didn't pull out in time.
- You were forced to have unprotected vaginal sex.

## Copper (ParaGard) IUD as Emergency Contraception

The ParaGard IUD can be used for emergency contraception if put in within 5 days after sex. It is the most effective kind of EC. The IUD is a birth control method that is put into your uterus (womb) by a doctor or nurse and it can stay there as birth control for up to 12 years if you want. It works really well (99% effective) and you don't have to do anything once it's in.



### How the IUD Works

Pregnancy doesn't happen right after sex. It can take up to 6 days for the sperm and egg to meet after having sex. The IUD works mostly by changing the way sperm move so they can't join with an egg. If sperm cannot join with an egg, pregnancy cannot happen.

## Emergency Contraception Pills

Emergency contraception pills are also called the “morning-after pill.” There are two different kinds of emergency contraception pills:

- ella<sup>®</sup> is very effective at preventing pregnancy if taken within 5 days after sex. It is the most effective EC pill, and it stays just as effective for all 5 days. If you are breastfeeding, you will have to pump and throw away the breast milk for 36 hours after taking it.



- Levonorgestrel EC pills, sold as Plan B One-Step<sup>®</sup>, Next Choice One Dose<sup>®</sup> and others, are also pretty effective. You can take these up to 5 days after having sex but they work better the sooner you take them. They may also be less effective for overweight women.



## How EC Pills Work



Emergency contraception pills work by keeping a woman's ovary from releasing an egg for longer than usual. Pregnancy cannot happen if there is no egg to join with sperm. EC will not hurt an existing pregnancy or cause an abortion.

## If You Are Overweight or Obese

Levonorgestrel EC pills may not work as well for overweight or obese women. If you are overweight or obese, the best kind of EC for you is the IUD. If you can't get an IUD, use ella.

## How to Get EC Pills

Anyone, regardless of age or gender, can get EC pills (except ella) over-the-counter, without a prescription, at their local drugstore. You will usually find it in the family planning aisle or near the pharmacy. If you don't see it there, ask the pharmacist. You need a prescription for ella. You can ask your doctor or nurse, or go to [www.ella-kwikmed.com](http://www.ella-kwikmed.com) to get a prescription and buy ella online.

The cost of emergency contraception pills depends on your insurance, where you live, and whether you get it from the drugstore or a health center. You may be able to get it cheaper at a Planned Parenthood health center. It may cost anywhere from \$10 to \$70.

### Get EC Before You Need It

You may want to buy EC or ask your doctor or nurse for a prescription for ella before you need it. This way, you will have it when you need it and can take it quickly.

## Possible Side Effects

- Your next period may come earlier or later than usual.
- You may have more or less bleeding than usual during your next period.
- Your breasts may feel sore, and you might be dizzy or have headaches.
- You may feel nauseous after taking EC. If you vomit within three hours of taking EC, you need to take it again.
- Using EC a lot may make your periods happen at different times each month.

There have been no serious complications among the millions of women who have used EC pills. Side effects usually stop after a day or two.

## After You Take EC

- EC does not always work. If you do not get your period within three weeks of taking EC, or if you have symptoms of pregnancy such as having to pee a lot, being very tired, or feeling nauseous, you should take a pregnancy test.
- It is safe to use EC as often as you need it. But, if you find yourself using it a lot, you may want to consider using a better birth control method like the IUD, shot, or pill.

## EC and Sexually Transmitted Infections

Emergency contraception does not protect you from getting a sexually transmitted infection. You should talk to a doctor or nurse about getting tested.

## Choosing What Type of EC to Use

Here are some things to think about if you need EC:



- The Copper IUD is the most effective type of EC. It can be used as your regular birth control for up to 12 years. The most effective EC pill is ella.
- Levonorgestrel EC pills are the easiest to get quickly because you can buy them over-the-counter, without a prescription, in a drugstore.
- Levonorgestrel EC pills may not work as well for women who are overweight. The IUD or ella is a better option.

## Want More Info?



Our website:  
[PlannedParenthood.org](https://www.plannedparenthood.org)



Facebook:  
[Planned Parenthood](https://www.facebook.com/PlannedParenthood)



Twitter:  
[@PPFA](https://twitter.com/PPFA)



Tumblr:  
[plannedparenthood.tumblr.com](https://plannedparenthood.tumblr.com)



Instagram:  
[@PlannedParenthood](https://www.instagram.com/PlannedParenthood)

# Celgene REMS Programs Pharmacy Training: THALOMID REMS®

## Section 1: What Is a REMS?

# In this section



- What is a REMS?
- Celgene REMS programs
- Pharmacy staff knowledge check

# What is a REMS?



- REMS stands for **Risk Evaluation and Mitigation Strategies**
- REMS programs are mandated by the **US Food and Drug Administration (FDA)**
- According to the FDA, a REMS program is:
  - A strategy to manage a known or potential serious risk associated with a drug or biological product
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

# Celgene REMS programs



- Celgene has REMS programs for THALOMID<sup>®</sup> (thalidomide), REVLIMID<sup>®</sup> (lenalidomide), and POMALYST<sup>®</sup> (pomalidomide):
  - THALOMID REMS<sup>®</sup> program for THALOMID
  - REVLIMID REMS<sup>®</sup> program for REVLIMID
  - POMALYST REMS<sup>®</sup> for POMALYST
- If these treatments are used during pregnancy, they can cause serious birth defects or embryo-fetal death
- The goals of these REMS programs are:
  - To prevent the risk of embryo-fetal exposure to these treatments
  - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

# Celgene REMS programs (continued)



For more information on Celgene REMS programs:

- Call the Celgene Customer Care Center at 1-888-423-5436
- Visit the specific product website

## Did you know?

The Celgene Customer Care Center has Compliance Specialists to educate and train pharmacy staff on Celgene REMS program guidelines and compliance.

# Pharmacy staff knowledge check



- REMS stands for Risk Evaluation and Mitigation Strategies.
  - A. True
  - B. False

**Correct Answer: A. True**

- REMS stands for **Risk Evaluation and Mitigation Strategies**
- A REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product

# Pharmacy staff knowledge check (continued)



- Who mandates REMS programs?
  - A. Celgene
  - B. The FDA
  - C. The EPA

**Correct Answer: B. The FDA**

- REMS programs are mandated by the FDA
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

# Pharmacy staff knowledge check (continued)



- Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment.
  - A. True
  - B. False

**Correct Answer: A. True**

- The goals of the Celgene REMS programs are:
  - To prevent the risk of embryo-fetal exposure to these treatments
  - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

# Celgene REMS Programs Pharmacy Training: THALOMID REMS®

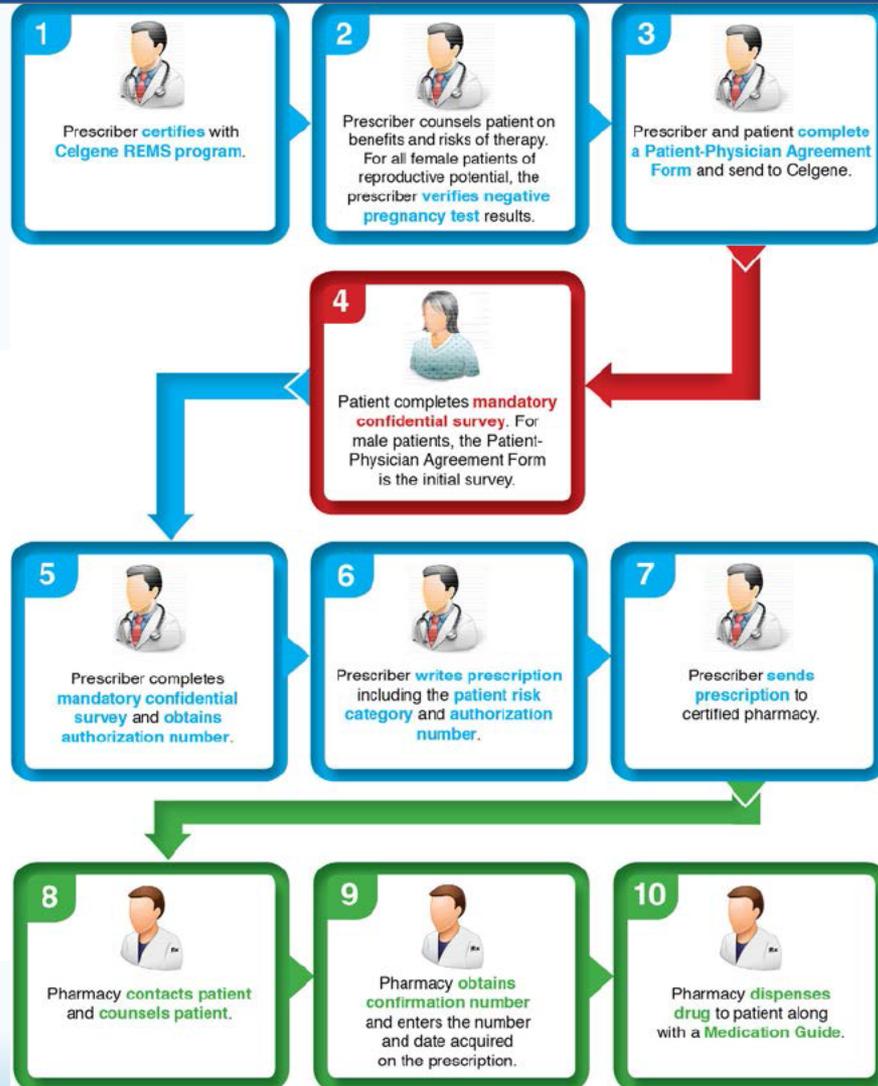
## Section 2: Program Requirements for Patients and Prescribers

# In this section



- Program overview
- Certification and enrollment requirements for prescribers and patients
- Patient risk categories
- Contraception requirements
- Pregnancy test requirements
- Mandatory confidential surveys
- Pharmacy staff knowledge check

# Celgene REMS program overview



# Certification and enrollment requirements for prescribers and patients



- Prescribers must be certified with the Celgene REMS program in order to prescribe a product with a REMS program for a patient
  - Prescribers must complete the REMS program enrollment and agree to comply with the program requirements
- Prescribers are required to enroll patients in a specific Celgene REMS program before starting a patient on a therapy with a REMS
  - Patients must enroll in the REMS program and agree to comply with the program requirements

# Patient risk categories



- There are 6 different patient risk categories for patients enrolled in Celgene REMS programs:
  - Adult female of reproductive potential
  - Female child of reproductive potential
  - Adult female not of reproductive potential
  - Female child not of reproductive potential
  - Adult male
  - Male child

# Definition of females of reproductive potential



**Females of reproductive potential** include all females who:

- Are menstruating
- Are amenorrheic from previous medical treatments
- Are under 50 years of age
- Are perimenopausal
- Do not qualify for the females not of reproductive potential category

The risk categories for **females of reproductive potential** are:

- Adult female of reproductive potential
- Female child of reproductive potential

# Definition of females not of reproductive potential



**Females not of reproductive potential** include females who:

- Have been in natural menopause for at least 24 consecutive months
- Have had a hysterectomy and/or bilateral oophorectomy
- Have not started menstruating

The risk categories for **females not of reproductive potential** are:

- Adult female not of reproductive potential
- Female child not of reproductive potential

# Definition of males



**Males** include adults and children (under 18 years of age)

The risk categories for **males** are:

- Adult Male
- Male Child

# Contraception requirements: Females of reproductive potential



- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 effective methods of contraception (at least one highly effective method and one effective method) at the same time
- The 2 effective contraceptive methods include using at the same time **at least 1 highly effective method and at least 1 additional method** of birth control every time they have sex with a male
- The 2 effective contraceptive methods must be started at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

## Highly effective methods

Tubal ligation

Intrauterine device (IUD)

Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)

Partner's vasectomy

+

## Additional effective methods

Male latex or synthetic condom

Diaphragm

Cervical cap

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

# Contraception requirements: Females of reproductive potential (continued)



- **Unacceptable contraception methods:**
  - Progesterone-only “mini-pills”
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield
    - A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

# Contraception requirements: Males



- Male patients must use a latex or synthetic condom:
  - Every time they have sexual intercourse with a female of reproductive potential even if they have undergone a successful vasectomy
  - During therapy (including dose interruptions)
  - For 4 weeks after discontinuation of therapy

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

# Pregnancy test requirements



- For females of reproductive potential, prescriber must obtain a negative pregnancy test:
  - 10 to 14 days before an initial prescription
  - Within 24 hours before an initial prescription
  - The pregnancy test must be sensitive to at least 50 mIU/mL
- Subsequent pregnancy testing should occur:
  - Weekly during the first 4 weeks of use, then
  - Every 4 weeks if patient has regular menses or no menses, or
  - Every 2 weeks if irregular menses

# Pregnancy test requirements (continued)



## If pregnancy does occur:

- Treatment must be **immediately** discontinued
- Any suspected embryo-fetal exposure must be reported **immediately** to Celgene Global Drug Safety and reported to the FDA
  - Celgene Global Drug Safety: 1-800-640-7854
  - FDA MedWatch number: 1-800-FDA-1088
- The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling

# Mandatory confidential surveys



- All patients must complete brief mandatory confidential surveys in order to obtain treatment
  - Surveys can be completed via [CelgeneRiskManagement.com](http://CelgeneRiskManagement.com), by accessing the Celgene REMS mobile app, or by calling the Celgene Customer Care Center at 1-888-423-5436

## Patient Mandatory Confidential Survey Schedule for Adults and Children

Risk category	Initial Prescription	Subsequent Prescriptions
Females of reproductive potential	Complete appropriate survey	Monthly survey
Females not of reproductive potential	Complete appropriate survey	Child: Monthly survey Adult: Survey every 6 months
Males	Do not need to take initial survey	Monthly survey

# Pharmacy staff knowledge check



- How many patient risk categories are there in the Celgene REMS programs?
  - A. 3
  - B. 5
  - C. 6

**Correct Answer: C. 6**

<b>Celgene REMS program patient risk categories</b>	
<b>Adult</b>	<b>Child (under 18)</b>
Adult female of reproductive potential	Female child of reproductive potential
Adult female not of reproductive potential	Female child not of reproductive potential
Adult male	Male child

## Pharmacy staff knowledge check (continued)



- For all Celgene REMS products, female patients of reproductive potential must take a pregnancy test:
  - A. 10-14 days before first prescription
  - B. Within 24 hours before first prescription
  - C. 10-14 days and within 24 hours before first prescription

**Correct Answer:**

**C. 10-14 days and within 24 hours before first prescription**

- Prescribers must obtain 2 negative pregnancy tests before the first prescription for females of reproductive potential:
  - 10 to 14 days before an initial prescription
  - Within 24 hours before an initial prescription

# Pharmacy staff knowledge check (continued)



- Which is a **highly effective** method of contraception?
  - A. Male latex or synthetic condom
  - B. IUD
  - C. Female condom

**Correct Answer: B. IUD**

<b>Highly effective methods</b>	<b>Additional effective methods</b>
Tubal ligation	Male latex or synthetic condom
Intrauterine device (IUD)	Diaphragm
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Cervical cap
Partner's vasectomy	

# Celgene REMS Programs Pharmacy Training: THALOMID REMS®

## Section 3: Program Requirements for Pharmacies

# In this section



- Training and certification requirements
- Pharmacy compliance
- Pharmacy staff knowledge check

# Training and certification requirements



- Celgene REMS program certified counselors must:
  - Be licensed healthcare professionals
  - Complete the Celgene-sponsored training on all required modules **annually** and pass certification exam **with 100% accuracy**
  - Educate patient by telephone or in person before treatment can be dispensed
  - Understand and counsel patients on the potential for birth defects or death to an unborn baby
  - Counsel patients on possible side effects
- Other pharmacy staff involved in dispensing treatment must:
  - Be educated on the guidelines for dispensing

- Pharmacy manager responsibilities
  - Educate all staff regarding dispensing guidelines
    - Includes floater pharmacists, pharmacy technicians, or anyone else handling the product
  - Make sure counselors are registered and certified in ComplianceWire<sup>®</sup> and advise Celgene of inactive counselors
  - Complete and return all documentation that pertains to non-compliance

**Did you know?** Pharmacy managers can call the Celgene Customer Care Center at **1-888-423-5436** with questions. Ask for Risk Compliance.



- Pharmacy deviations
  - The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
  - Celgene will work with the pharmacy to implement appropriate corrective actions and a timeframe for those actions
  - If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy



- A High Risk Deviation is:
  - Any action taken by the pharmacy that is inconsistent or non-compliant with the Celgene REMS program that increases the risk of embryo-fetal exposure
  - Any action that occurs on a consistent basis that shows a pharmacy's negligent or willful disregard to the Celgene REMS program requirements
- For any additional occurrence of a High Risk Deviation beyond 2 High Risk Deviations, the pharmacy may be deactivated and no longer permitted to dispense product

# Pharmacy staff knowledge check



- Celgene REMS program certified counselors must complete the Celgene-sponsored training:
  - A. Annually
  - B. Every 6 months
  - C. Every 2 years

**Correct Answer: A. Annually**

- Counselors must complete the Celgene-sponsored training annually

# Pharmacy staff knowledge check (continued)



- All counselors must pass the certification test with an accuracy of:
  - A. 100%
  - B. 90%
  - C. 95%

**Correct Answer: A. 100%**

- Counselors must pass the certification exam with 100% accuracy

# Pharmacy staff knowledge check (continued)



- Celgene may deactivate pharmacies for deviations.
  - A. True
  - B. False

**Correct Answer: A. True**

- The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
- If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy

# Celgene REMS Programs Pharmacy Training: THALOMID REMS®

## Section 4: Guidelines for Counseling

# In this section

- Counseling for female patients of reproductive potential
- Counseling for female patients not of reproductive potential
- Counseling for male patients
- Additional counseling for all patients taking THALOMID® (thalidomide)
- Pharmacy staff knowledge check

**THALOMID REMS®**  
**Education and Counseling Checklist for Pharmacies**

THALOMID Risk Evaluation and Mitigation Strategy (REMS) program education and prescribing safety

Authorization No. \_\_\_\_\_ Confirmation No. \_\_\_\_\_ Confirmation Date \_\_\_\_\_  
 Pharmacy Name \_\_\_\_\_  
 Pharmacy Address \_\_\_\_\_  
 Counselor Name \_\_\_\_\_ Work Phone \_\_\_\_\_ Ext. \_\_\_\_\_  
 Patient Name \_\_\_\_\_ Date of Birth \_\_\_\_\_  
 Risk Category \_\_\_\_\_

**Checklist for female patients of reproductive potential**

I will make sure that patients are aware that they will receive the Medication Guide along with their prescription.

**FOUNDED ADULTS AND DRUG USE:**

Potential embryo-fetal toxicity

Not taking THALOMID (thalidomide) if pregnant or breastfeeding

Using at the same time at least 1 highly effective method—tubal ligation, IUD, hormonal birth control pill, hormonal patches, injections, vaginal rings, or implants, or partner's vasectomy—and at least 1 additional effective method of birth control—male or synthetic condom, diaphragm, or cervical cap—every time they have sex with a male, or abstaining from sex with a male

Unacceptable methods of birth control are progesterone-only "mini-pill," IUD Progesterone I, female condoms, natural family planning rhythm method or breastfeeding, fertility awareness, withdrawal, and cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception)

Continuing to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking THALOMID, while taking THALOMID, during dose interruptions, and for at least 4 weeks after stopping THALOMID every time they have sex with a male, or abstaining from sex with a male

Obtaining a pregnancy test—performed by their healthcare provider—monthly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks

The need to stop taking THALOMID right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately

Possible side effects include deep vein thrombosis and pulmonary embolism

Not sharing THALOMID capsules with anyone—especially with females who can get pregnant

Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

Not breaking, chewing, or opening THALOMID capsules

Instructions on THALOMID dose and administration

Mg (mg) Strength \_\_\_\_\_ Number of Capsules Dispensed \_\_\_\_\_

**FEMALE DRUG USE (16 YEARS OF AGE):**

Parent or legal guardian must have read the THALOMID REMS® education material and agreed to ensure compliance

**Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)**

I will make sure that patients are aware that they will receive the Medication Guide along with their prescription.

**FOUNDED ADULTS AND DRUG USE:**

Possible side effects include deep vein thrombosis and pulmonary embolism

Not sharing THALOMID capsules with anyone—especially with females who can get pregnant

Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

Not breaking, chewing, or opening THALOMID capsules

Instructions on THALOMID dose and administration

Mg (mg) Strength \_\_\_\_\_ Number of Capsules Dispensed \_\_\_\_\_

**FEMALE DRUG USE (16 YEARS OF AGE):**

Parent or legal guardian must have read the THALOMID REMS® education material and agreed to ensure compliance

Parent or legal guardian must inform the child's healthcare provider when the child begins menses

1 of 2 (continued on next page)

The sequence of this section is based on the Education and Counseling Checklist for Pharmacies.

**Remember to fill out this checklist for every patient for every prescription.**

# Counseling for female patients of reproductive potential



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

## COUNSEL ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity
- Not taking treatment if pregnant or breastfeeding
- Using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time they have sex with a male**, or abstaining from sex with a male
  - **Highly effective** methods of contraception: Tubal ligation, intrauterine device (IUD), hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy
  - **Additional effective** methods of contraception: Male latex or synthetic condom, diaphragm, or cervical cap

# Counseling for female patients of reproductive potential (continued)



## COUNSEL ADULTS AND CHILDREN ON:

- Unacceptable methods of birth control are:
  - Progesterone-only “mini-pills”
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception)

# Counseling for female patients of reproductive potential (continued)



## COUNSEL ADULTS AND CHILDREN ON:

- Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
  - Beginning at least 4 weeks before treatment
  - During treatment
  - During dose interruptions
  - For at least 4 weeks after stopping treatment
  - **Every time they have sex with a male**, or abstaining from sex with a male

# Counseling for female patients of reproductive potential (continued)



## COUNSEL ADULTS AND CHILDREN ON:

- Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use
- Pregnancy testing should be repeated:
  - Every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all
  - If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- The need to stop treatment right away **in the event of becoming pregnant, or if they think for any reason they may be pregnant,** and to call their healthcare provider immediately

# Counseling for female patients of reproductive potential (continued)



## **COUNSEL ADULTS AND CHILDREN ON:**

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

## **FOR FEMALE CHILDREN (<18 YEARS OF AGE):**

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance

# Counseling for female patients not of reproductive potential



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

## COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

# Counseling for female patients not of reproductive potential (continued)



## FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance
- Parent or legal guardian must inform the child's doctor when the child begins menses

# Counseling for male patients



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

## **COUNSEL ADULTS AND CHILDREN ON:**

- Potential embryo-fetal toxicity and contraception
  - Wearing a latex or synthetic condom every time when engaging in sexual intercourse with a female who can get pregnant, even if they have undergone a successful vasectomy
- Female partners of males receiving treatment must call their healthcare provider right away if they get pregnant

# Counseling for male patients (continued)



## **COUNSEL ADULTS AND CHILDREN ON:**

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood or sperm during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

## **FOR MALE CHILDREN (<18 YEARS OF AGE):**

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance

# Additional counseling for all patients taking THALOMID® (thalidomide)



## COUNSEL ADULTS AND CHILDREN ON:

- Possible side effects include deep vein thrombosis and pulmonary embolism

Counsel patient to **contact healthcare provider** if experiencing any side effects.

# Pharmacy staff knowledge check



- Which of these is **not** something patients need to be counseled on?
  - A. Not sharing capsules
  - B. Not breaking, chewing, or opening capsules
  - C. Wearing gloves while taking capsules

**Correct Answer: C. Wearing gloves while taking capsules.**

- Patients must be counseled on:
  - Not sharing capsules with anyone—especially with females who can get pregnant
  - Not breaking, chewing, or opening capsules

# Pharmacy staff knowledge check (continued)



- Female patients of reproductive potential must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control for 4 weeks after stopping treatment.
  - A. True
  - B. False

**Correct Answer: A. True**

- Female patients of reproductive potential must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
  - Beginning at least 4 weeks before treatment
  - During treatment
  - During dose interruptions
  - For at least 4 weeks after stopping treatment
  - **Every time they have sex with a male**, or abstaining from sex with a male

## Pharmacy staff knowledge check (continued)



- All patients must receive a Medication Guide along with their prescription.
  - A. True
  - B. False

Correct Answer: A. True

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

# Celgene REMS Programs Pharmacy Training: THALOMID REMS®

## Section 5: Guidelines for Dispensing

# In this section



- Pharmacy and prescription requirements
- Dispensing guidelines
- Steps for dispensing
- Pharmacy staff knowledge check

# Pharmacy and prescription requirements



- Dispensing pharmacies must be certified in the applicable Celgene REMS program and educated on the program and on dispensing procedures for the treatment
- Pharmacy must ensure that every prescription includes:
  - Patient and prescriber demographics and contact information
  - Patient risk category
  - Dosing information and instructions
  - Authorization number
  - Prescriber signature
- 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

# Dispensing guidelines



- Dispense **no more than a 4-week (28-day) supply** with the Medication Guide. A new prescription is required for further dispensing
- **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription**
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product **must be shipped the same day** confirmation number is obtained **or picked-up within 24 hours** of obtaining confirmation
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame
  - Pharmacy must obtain a new confirmation number by calling the Celgene Customer Care Center at 1-888-423-5436 when ready to ship or have the product picked up

# Dispensing guidelines (continued)



- When shipping, pharmacy must require a signature confirming receipt
- Pharmacy shall keep an inventory log for the drug, by strength, reflecting its on-hand inventory at all times
- Do not transfer the drug to another pharmacy without prior authorization from Celgene
- Accept unused capsules (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal

## Review incoming prescriptions

- Only accept prescriptions with all of the following information:
  - Patient and prescriber demographics and contact information
  - Patient risk category
  - Dosing information and instructions
  - Authorization number
  - Prescriber signature
- Make sure the prescription is signed and dated
- Confirm the prescription is written for a 4-week (28-day) supply or less
- For subsequent prescriptions, verify there are 7 days or less of therapy remaining on the existing prescription

# Steps for dispensing (continued)



## Counsel patient

- Patients must receive counseling from a Celgene REMS program certified pharmacy counselor
- Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist
  - Make sure form is signed and dated by the counselor and appropriate boxes are checked off
  - Keep a copy of the checklist and the associated prescription
- Please report adverse drug experiences that are suspected to be associated with the use of the drug and any suspected pregnancy occurring during the treatment

# Steps for dispensing (continued)



## Obtain confirmation number from Celgene

- Prior to each prescription, contact the Celgene Customer Care Center 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.
  1. Enter the pharmacy NABP number or DEA number
  2. Enter the authorization number written on the prescription
  3. Enter the number of capsules and milligram strength being dispensed
  4. Write the **confirmation number** and **date** on the prescription. Note: the confirmation number is **only valid for 24 hours**
- If you do not obtain a confirmation number, you are not permitted to dispense the product to the patient

If you have questions about the validity of the authorization or confirmation numbers, call the Celgene Customer Care Center.

# Steps for dispensing (continued)



## Dispense prescription

- Include a Medication Guide with each prescription
- Document the dispense date on either the shipping receipt or pharmacy dispensing log
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product **must be shipped the same day** confirmation number is obtained **or handed to the patient within 24 hours**

# Pharmacy staff knowledge check



- A confirmation number is valid for:
  - A. 24 hours
  - B. 7 days
  - C. 30 days

**Correct Answer: A. 24 hours**

- The confirmation number is **only valid for 24 hours**
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame

# Pharmacy staff knowledge check (continued)



- Each prescription must have both an authorization number and a patient risk category written on it.
  - A. True
  - B. False

**Correct Answer: A. True**

- Only accept prescriptions with all of the following information:
  - Patient and prescriber demographics and contact information
  - Patient risk category
  - Dosing information and instructions
  - Authorization number
  - Prescriber signature

## Pharmacy staff knowledge check (continued)



- The pharmacy must dispense no more than a 4-week (28-day) supply.
  - A. True
  - B. False

**Correct Answer: A. True**

- Dispense **no more than a 4-week (28-day) supply** with the Medication Guide
- A new prescription is required for further dispensing

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/s/  
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BARRY W MILLER  
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