

# Pharmacy Guide

## Thalidomide Risk Evaluation and Mitigation Strategy (REMS)

**Thalidomide**  
REMS

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### Important Information About the Thalidomide REMS

- Thalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with thalidomide provided adequate precautions are taken to avoid pregnancy.
- To avoid embryo-fetal exposure, thalidomide is only available through a restricted distribution program called the Thalidomide Risk Evaluation and Mitigation Strategy (REMS).
- Only certified prescribers can prescribe thalidomide and only certified pharmacies can dispense thalidomide in the Thalidomide REMS.
- Dispensing pharmacists must be educated on the Thalidomide REMS and on dispensing procedures for thalidomide.
- Information about thalidomide and the Thalidomide REMS can be obtained by visiting [www.thalidomide-rems.com](http://www.thalidomide-rems.com), or by calling the REMS Coordinating Center at 1-877-770-7251.

# Guidelines for Ordering, Counseling, and Dispensing Thalidomide

Dispensing pharmacies must be certified in the Thalidomide REMS and must be educated in the following dispensing procedures.

## Step 1. Review Incoming Thalidomide Prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them
- 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 Patient

- A. Make sure a **certified Thalidomide REMS** counselor counsels the patient.
  - Thalidomide REMS counselors must:
    1. Be licensed healthcare professionals
    2. Complete the Thalidomide REMS training as provided by the certified pharmacy authorized representative
    3. Educate patient by telephone or in person before treatment can be dispensed
    4. Understand and counsel patients on the potential for birth defects or death to an unborn baby
    5. Counsel patients on possible side effects
  - Other pharmacy staff involved in dispensing treatment must:
    1. Be educated on the guidelines for dispensing
- B. Complete the corresponding section (based on the patient risk category) of the **Education and Counseling Checklist for Pharmacies** 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 thalidomide and any suspected pregnancy occurring during the treatment with thalidomide, make sure to document these experiences and notify the Thalidomide REMS.
- D. Report adverse drug experiences that are suspected to be associated with the use of thalidomide to the Thalidomide REMS within 24 hours.

## Step 3. Obtain a Confirmation Number from the Thalidomide REMS

- A. Prior to each prescription, ensure the patient and prescriber are enrolled in the Thalidomide REMS by obtaining a confirmation number from the REMS Coordinating Center (**1-877-770-7251**) or visiting the Thalidomide **REMS Website** ([www.thalidomide-rems.com](http://www.thalidomide-rems.com)).
- B. The pharmacy will confirm that both the patient and the prescriber have both completed the mandatory confidential survey prior to each prescription and a valid authorization number was received. Once there is confirmation that all REMS requirements have been met, the pharmacy will obtain a confirmation number from the Thalidomide REMS.
  - Authorization numbers are valid for 7 days from the date of last pregnancy test for females who can get pregnant and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
  - Confirmation numbers can be obtained:
    1. Search Certified Prescriber (name and National Provider Identifier (NPI))
    2. Search Enrolled Patient (name and date of birth)

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

3. Enter Authorization Number
  4. Enter Number of Capsules and Milligram Strength
  5. Generate Confirmation Number
  6. Document Confirmation Number
- C. Faxed prescriptions are permissible depending on state laws.
- D. If you do not obtain a confirmation number after confirming that all REMS requirements have been met, do not dispense thalidomide.

## 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, i.e., dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **you must generate a new confirmation number.** For female patients who can get pregnant, 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 for Pharmacies** (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 shipments and dispenses if picked up by patient.
- G. Pharmacies must submit records of thalidomide dispensing to the Thalidomide REMS.

## Step 5. Perform drug accountability

- A. Pharmacy shall keep an inventory log for thalidomide, by strength, reflecting its on-hand inventory at all times.
- B. Do not transfer thalidomide to another pharmacy without permission from the Thalidomide REMS.
- C. Accept unused thalidomide (previously dispensed) from a patient or patient caregiver.
- D. Return unused product from the patient or the prescriber to the Thalidomide REMS.

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

## Ensure your patients know the risks

Before you are able to fill a prescription for thalidomide, a checklist for each patient must be completed based on the patient risk category. 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:

**Pharmacy Name**

**Pharmacy Address (including City, State, ZIP Code)**

**Counselor Name**

**Work Phone Number Extension**

**Patient Name**

**Patient Date of Birth**

**Thalidomide REMS Education and Counseling Checklist for Pharmacies**

Pharmacy Information			Patient Information	
Pharmacy Name: <input type="text"/>			Patient Name: <input type="text"/>	
Street Address: <input type="text"/>				
City: <input type="text"/>	State: <input type="text"/>	Zip Code: <input type="text"/>	Date of Birth: <input type="text"/>	
Counselor Name: <input type="text"/>				
Work Phone Number: <input type="text"/>				
PEMS Confirmation				
Prescription Authorization Number: <input type="text"/>				
Patient Risk Category: <input type="checkbox"/> Adult Female Who Can Get Pregnant <input type="checkbox"/> Female Child Who Cannot Get Pregnant				
<input type="checkbox"/> Female Child Who Can Get Pregnant <input type="checkbox"/> Adult Male				
<input type="checkbox"/> Adult Female Who Cannot Get Pregnant <input type="checkbox"/> Male Child				
Authorization Date: <input type="text"/>				
Confirmation Prescriber is Certified, Patient is Enrolled and Not Pregnant (if applicable) and the Authorization Number Provided by the Prescriber is Valid: <input type="checkbox"/> Yes <input type="checkbox"/> No				
Confirmation Number: <input type="text"/>			Confirmation Date: <input type="text"/>	

**Checklist for Adult Female or Female Child Who Can Get Pregnant**

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

**I COUNSELED ADULT FEMALE OR FEMALE CHILD WHO CAN GET PREGNANT ON:**

- Potential embryo-fetal toxicity
- Not taking thalidomide if pregnant or breastfeeding
- Using at the **same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth controls 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
- 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 thalidomide, while taking thalidomide, during dose interruptions, and for at least 4 weeks after stopping thalidomide **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).
- Obtaining a pregnancy test—performed by their healthcare provider—at the required testing schedule:
  - Before treatment initiation (first prescription):
    - 10-14 days prior to initiation of thalidomide therapy
    - Within 24 hours of the initial prescription
  - During treatment:
    - Weekly during the first 4 weeks of use
    - Thereafter,
      - o Every 4 weeks for female patients who can get pregnant with regular menstrual cycles
      - o Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles

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Phone: 1-877-770-7251      www.thalidomide-rems.com      Fax: 1-877-770-7241

## Making sure before you release thalidomide

### **DO NOT DISPENSE OR SHIP THALIDOMIDE 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. For females who can get pregnant, the product must be shipped the same day the confirmation number is obtained. When shipping, the pharmacy must require a signature confirming receipt.
- 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 thalidomide prescription.

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

# Adverse Drug Experience Reporting Procedure for Healthcare Professionals

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

## REPORTING TO THALIDOMIDE REMS

- Telephone: **1-877-770-7251**

## REPORTING TO THE FDA

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

- Online at: **[www.fda.gov/medwatch](http://www.fda.gov/medwatch)**
- Telephone/Fax or Mail: **1-800-FDA-1088** Fax: **1-800-FDA-0178**  
MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information about thalidomide and the Thalidomide REMS, please visit **[www.thalidomide-rems.com](http://www.thalidomide-rems.com)**, or call the REMS Coordinating Center at **1-877-770-7251**.

Thalidomide is only available under a restricted distribution program, Thalidomide REMS.

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

**Thalidomide**  
**REMS**