

## 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®” (formerly known as the *S.T.E.P.S.*® program)
- 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**

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 at **1-888-423-5436**.

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

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

## 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 use. 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](http://www.CelgeneRiskManagement.com), accessing the Celgene REMS mobile app, using the CD-ROM software, 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](http://www.CelgeneRiskManagement.com), the Celgene REMS mobile app, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**.
5. Instruct female patients to complete a brief initial mandatory confidential survey by visiting [www.CelgeneRiskManagement.com](http://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](http://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.

## Subsequent prescriptions (for all patients unless otherwise noted)

1. 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.
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open THALOMID capsules and to maintain storage of capsules in blister packs until ingestion.
3. Instruct patient to complete a brief mandatory confidential survey **as scheduled**, prior to prescriber obtaining an authorization number and filling the prescription.
  - 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**
4. 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)
5. 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.
6. Send the prescription to a certified pharmacy.

THALOMID® is a registered trademark of Celgene Corporation. THALOMID REMS® is a trademark of Celgene Corporation.