Welcome to the THALOMID REMS® program

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.

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®

For additional information about the THALOMID REMS® program, please contact the Celgene Customer Care Center at 1-888-422-5436.

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About the THALOMID REMS® program

To avoid embryofetal exposure, THALOMID® (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® 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 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
Prescriber Resources

Enrolling in THALOMID REMS®
In order to prescribe THALOMID® (thalidomide), you must enroll in the THALOMID REMS® program and agree to follow the requirements of the program. You can enroll by visiting CelgeneRiskManagement.com, a website that allows prescribers to handle the REMS process for all of the Celgene REMS programs. You can also download the Prescriber Enrollment Form below and fax it to the Celgene Customer Care Center at 1-888-442-5426.

Prescribing THALOMID for your patients
In order to receive THALOMID, your patients must also be enrolled in the THALOMID REMS® program. You can enroll your patients and fill out a prescription form using CelgeneRiskManagement.com. You and your patients can also complete your mandatory confidential surveys there.

Remind your patients to download the REMS Companion app on their smartphones
The REMS Companion app lets your patients complete their mandatory surveys on their smartphones. They can also get reminders when it’s time to complete the surveys by allowing notifications in the app.

Learning more about THALOMID REMS®
For additional information about the THALOMID REMS® program, please see the educational materials below.

REPORTING TO CELGENE

Online: www.celgene.com/contact-us/
Email: drugsafety@celgene.com
Telephone: 1-800-673-9667
Toll-free: 1-800-649-7654 (Global Drug Safety & Risk Management) or
1-888-442-5426 (Celgene Customer Care Center)
Fax: 1-800-673-9115
Mail to: Global Drug Safety & Risk Management
Celgene Corporation
86 Morris Avenue
Summit, New Jersey 07901

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-678
Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-7787

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Patient Resources

What you need to know about the THALOMID REMS® program

Your doctor will enroll you in the THALOMID REMS® program so that you can take 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
- Guía para el paciente de THALOMID REMS®
- Patient Medication Guide
- Visit Planned Parenthood Site for Emergency Contraception Brochure
- Patient Survey Reminder Card

Take your survey from your smartphone

Download the REMS Companion app to take your surveys anywhere. Once the app has been downloaded, allow notifications to get a reminder when it's time to complete your survey.

You can take your mandatory confidential patient survey at CelgeneRiskManagement.com in English or Spanish by clicking one of the buttons below.

- Patient Survey
- Encuesta del paciente

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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Pharmacist Resources

THALOMID® REMS® information for certified pharmacies

THALOMID® (thalidomide) is only dispensed from THALOMID® REMS® program certified pharmacies. To learn more about how to become a certified pharmacy, please contact the Celgene Customer Care Center at 1-888-423-5438.

As a THALOMID® REMS® certified pharmacy, you must follow the requirements of the THALOMID® REMS® program. You may download a guide to the program, a checklist for counseling patients, and the Full Prescribing Information below.

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 CelgeneREMSPharmacyPortal.com. Contact your Celgene Account Manager to see if your pharmacy is eligible.

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/
Email:  drugsafety@celgene.com
Telephone:  1-800-673-9667
Toll-free:  1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5438 (Celgene Customer Care Center)
Fax:  1-800-673-9115
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-ov.htm
Telephone:  1-800-FDA-1998
Fax:  1-800-FDA-0178
Mail to:  MedWatch
5600 Fishers Lane
Rockville, MD 20852-9777

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