Home Page (after prescriber logon)

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.

For REVlimid REMS™
(formerly known as the RevAssist® program)

Please see full Prescribing Information, including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

For Pomalyset REMS™

Please see full Prescribing Information, including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

For ThALOMID REMS™
(formerly known as the S.T.E.M.A.P® program)

Please see full Prescribing Information, including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

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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Reference ID: 3838532
THALOMID REMS module
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™” (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.

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.

Announcing the new Celgene REMS mobile app for CelgeneRiskManagement.com! Download to your iPad here:

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THALOMID REMS™ is a trademark of Celgene Corporation.
This website is intended for residents of the United States only.
About the THALOMID REMS™ program

THALOMID® (thalidomide) in combination with dexaexamethasone 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 neutropia.

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)™" (formerly known as the S.T.E.P.S.™ program). 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

- The prescriber enrolls and becomes certified with Celgene for the THALOMID REMS™ program.
- The prescriber counsels the 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 it 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’s name.
- The prescriber writes for a 4-week 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 submission 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.
THALOMID REMS™

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 moderate to severe erythema nodosum lipoïdæ (ENL).

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

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 (formerly known as the 3.T.E.P.® 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.

For additional information about the THALOMID REMS™ program, please contact the Celgene Customer Care Center at 1-800-423-5435.

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[App Store]

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Pharmacist 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 moderate to severe erythema nodosum leprosum (ENL).

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

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

THALOMID REMS® information for certified pharmacies

THALOMID® is only dispensed from THALOMID REMS® program (formerly known as the S.T.E.P.S.® program) certified pharmacies. To learn more about how to become a certified pharmacy, please contact the Celgene Customer Care Center at 1-866-423-5430.

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.

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

REPORTING TO CELGENE

Email: drugsafety@celgene.com
Telephone: 1-988-673-9667
Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-866-423-5430 (Celgene Customer Care Center)
Fax: 1-988-673-9115
Mail to: Global Drug Safety & Risk Management
Celgene Corporation
300 Connell Dr.
Suite 6000
Burlington Heights, NJ 07822

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: 1-800-332-1088
Fax: 1-800-332-0178
Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787