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 (formerly known as the S.E.E.P.S.® program), REVLIMID REMS™ program (formerly known as the RevAssist® 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:

- **Revlimid REMS™**
  - Visit [www.REVLIIDREMS.com](http://www.REVLIIDREMS.com) to learn more about the REVLIID REMS™ program.

- **Pomalyst REMS™**
  - Visit [www.POMALYSTREMS.com](http://www.POMALYSTREMS.com) to learn more about the POMALYST REMS™ program.

- **THALOMID REMS™**
  - 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?  Login

Create User Account  Patient Surveys

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Reference ID: 3838478
Home Page (after prescriber logon)
REVLIMID REMS module

![REVLIMID REMS Main Menu](image-url)
www.REVLIMIDREMS.com Web site

Welcome to the REVLIMID REMS™ program

REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM).

REVLIMID® is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate 1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID® is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Important information about REVLIMID and the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program

- REVLIMID® is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID® provided adequate precautions are taken to avoid pregnancy.
- To avoid embryo-fetal exposure, REVLIMID® is only available under a restricted distribution program called “REVLIMID REMS™” (formerly known as the RevAssist® program).
- Only prescribers and pharmacies certified by the REVLIMID REMS™ program can prescribe and dispense REVLIMID® to patients who are enrolled and meet all the conditions of the REVLIMID REMS™ program.

The goals of the REVLIMID REMS risk evaluation and mitigation strategy are as follows:
1. To prevent the risk of embryo-fetal exposure to REVLIMID®
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for REVLIMID®
About the REVLIMID REMS™ program

REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM).

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomb.

To avoid embryofetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™" (formerly known as the RevAssist™ program). Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID in the REVLIMID REMS™ program.

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

Key points of the REVLIMID REMS™ program

Prescriber
- The prescriber enrolls and becomes certified with Celgene for the REVLIMID REMS™ program
- The prescriber counsels patient on benefits and risks of REVLIMID
- 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 REVLIMID® (lenalidomide) 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 refills no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends REVLIMID prescription to certified pharmacy

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

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REVLIMID REMS™ is a trademark of Celgene Corporation.
This website is intended for residents of the United States only.
Prescriber Resources

REVIMOD® is indicated in combination with dexamethasone in the treatment of patients with multiple myeloma (MM).

REVIMOD is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVIMOD is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Enrolling in REVIMOD REMS™

In order to prescribe REVIMOD, you must enroll in the REVIMOD REMS™ program, formerly known as the Revsyst® program and agree to follow the requirements of the program. You can enroll by visiting CelgeneRisksManagement.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 Celgene Customer Care at 1-888-423-9320.

Prescribing REVIMOD for your patients

In order to prescribe REVIMOD, your patients must also be enrolled in the REVIMOD REMS™ program. You can enroll your patients, and fill out a prescription form using CelgeneRisksManagement.com. You and your patients can also complete your mandatory confidential surveys here.

Additionally, you can also enroll your patients and write prescriptions by downloading the Desktop Software and installing it on your computer.

Learning more about REVIMOD REMS™

For a complete overview of the REVIMOD REMS™ program, and a guide to the REVIMOD REMS™ process, please see the educational materials below.

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

REPORTING TO CELGENE

Email: drugsafety@celgene.com
Telephone: 1-908-673-9867
Toll-free: 1-800-649-7084 (Global Drug Safety & Risk Management) or 1-888-423-5435 (Celgene Customer Care Center)
Fax: 1-908-673-9116
Mail to: Global Drug Safety & Risk Management
Celgene Corporation
340 Conwell Dr.
Suite 6000
Berkeley Heights, NJ 07082

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVIMOD and any suspected pregnancy occurring during the treatment with REVIMOD 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

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Prescriber Resources

REVlimid® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM).

REVlimid® is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1 risk cytogenetic abnormality myelodysplastic/myeloproliferative neoplasms (MDS/MPN), whose disease has progressed.

REVlimid® program (formerly known as the REVA program) You can enroll by visiting the eREMS portal. You can also enroll your patients and write prescriptions by downloading the Desktop Software and installing it on your computer.

Enroll Your Patients for the eREMS portal.

Download the eREMS Mobile App.

Patient Prescription Form

Desktop Software Setup

Installation User Guide

Learning more about REVlimid REMS™

For a complete overview of the REVlimid REMS™ program and a guide to the REVlimid REMS™ process, please see the educational materials below.

Prescriber Guide to REVlimid REMS™ Program

REVlimid REMS™ At-A-Glance

Full Prescribing Information

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

REPORTING TO CELGENE

Email: drugsafety@celgene.com
Telephone: 1-800-677-9667
Toll-free: 1-800-646-7854 (Global Drug Safety & Risk Management) or 1-888-425-5436 (Celgene Customer Care Center)
Fax: 1-800-671-9115

Mail to:
Global Drug Safety & Risk Management
Celgene Corporation
390 Coventry Dr.
Suite 6000
Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVlimid® and any suspected pregnancy occurring during the treatment with REVlimid 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-lookup.htm
Telephone: 1-800-332-1088
Fax: 1-800-332-0078

Mail to:
MedWatch
5600 Fishers Lane
Rockville, MD 20852-8717
Pharmacist Resources

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

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermedium-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

REVLIMID REMS™ information for certified pharmacies

REVLIMID is only dispensed from REVOLUTION REMS™ program (formerly known as the RevAssist® program) certified pharmacies. To learn more about how to become a certified pharmacy please contact the Celgene Customer Care at 1-888-423-5400.

As a REVOLUTION REMS™ certified pharmacy, you must follow the requirements of the REVOLUTION REMS™ program. You may download a guide to the program, a checklist for counseling patients, and the full prescribing information below.

Pharmacy Guide to REVOLUTION REMS™ Program

Education and Counseling Checklist for Pharmacists

Full Prescribing Information

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.

Celgene REMS Pharmacy Portal

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

REPORTING TO CELGENE

Email: drugsafety@celgene.com

Telephone: 1-800-673-9667

Toll-free: 1-800-445-7664 (Global Drug Safety & Risk Management) or 1-888-423-5400 (Celgene Customer Care Center)

Fax: 1-800-673-9115

Mail to: Global Drug Safety & Risk Management

Celgene Corporation

300 Cossitt Dr.

Suite 600

Berkeley Heights, NJ 07922

REPORTING TO THE FDA

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

Online: https://www.accessdata.fda.gov/scripts/medwatch/trmedwatch-online.htm

Telephone: 1-800-332-1088

Fax: 1-800-332-0788

Mail to: MedWatch

8000 Fishers Lane

Rockville, MD 20852-0787

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Welcome to the REVLIMID REMS™ program

REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM).

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or high-risk myelo-fibrosis (MF) associated with deletion 5q cytogenetic abnormality.

REVLIMID is indicated to reduce the risk of death for patients with refractory multiple myeloma whose disease has progressed following prior therapy with at least two prior therapies, including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 monoclonal antibody.

REVLIMID is indicated as a single agent for the treatment of relapsed or refractory mycosis fungoides (MF) and Sézary syndrome (SS) whose disease has progressed following at least two prior therapies, including a bruton tyrosine kinase (BTK) inhibitor.

REVLIMID Risk Evaluation and Mitigation Strategy (REMS) Overview

REVLIMID is a pregnancy category X drug. The following REMS programs are required for all patients receiving REVLIMID. For additional information about the REVLIMID REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-6436.

You Are Now Leaving REVLIMIDREMS.com

Click “OK” to proceed or “CANCEL” to return to REVLIMIDREMS.com

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

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

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Reference ID: 3838478