

POMALYST REMS module

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For additional information about the POMALYST REMS® program, please contact the Celgene Customer Care Center at 1-888-423-5436

Download the Celgene REMS mobile app to your iPad by clicking here:



Welcome to the POMALYST REMS® program

Important information about POMALYST® (pomalidomide) and the POMALYST Risk Evaluation and Mitigation Strategy (REMS) program

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

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

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

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About the POMALYST REMS® program

To avoid embryo-fetal exposure, POMALYST® (pomalidomide) is only available under a restricted distribution program called "POMALYST Risk Evaluation and Mitigation Strategy (REMS)." Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST in the POMALYST REMS® program.

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

Key points of the POMALYST REMS® program

Prescriber

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

Pharmacy

- The pharmacy certifies with Celgene for the POMALYST 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 POMALYST to patient along with a Medication Guide

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Prescriber Resources

Enrolling in POMALYST REMS®

In order to prescribe POMALYST® (pomalidomide), you must enroll in the POMALYST 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 1-888-432-9325.

[Prescriber Enrollment Form](#)



Prescribing POMALYST for your patients

In order to receive POMALYST, your patients must also be enrolled in the POMALYST 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.

Additionally, you can also enroll your patients by accessing the Celgene REMS mobile app for your iPad.

[Enroll Your Patients at CelgeneRiskManagement.com](#)

[Download the Celgene REMS Mobile App](#)

[Patient Prescription Form](#)



Learning more about POMALYST REMS®

For additional information about the POMALYST REMS® program, please see the educational materials below.

[Prescriber Guide to POMALYST REMS® Program](#)



[POMALYST REMS® At-A-Glance](#)



[Full Prescribing Information](#)



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

REPORTING TO CELGENE

Online: www.celgene.com/contact-us/

Email: drugsafety@celgene.com

Telephone: 1-908-673-9667

Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or
1-888-423-5436 (Celgene Customer Care Center)

Fax: 1-908-673-9115

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 POMALYST and any suspected pregnancy occurring during the treatment with POMALYST 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-0178

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

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For additional information about the POMALYST REMS® program, please contact the Celgene Customer Care Center at 1-888-423-5436

Download the Celgene REMS mobile app to your iPad by clicking here:



Patient Resources

What you need to know about the POMALYST REMS® program

Your doctor will enroll you in the POMALYST REMS® program so that you can receive your medication. Use the materials below to learn more about the POMALYST REMS® program, and what you need to do.

[Patient Guide to POMALYST REMS® Program](#)



[Guía para el paciente de POMALYST REMS®](#)



[Patient Medication Guide](#)



[Visit Planned Parenthood Site for Emergency Contraception Brochure](#)

[Patient Survey Reminder Card](#)



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](#)



You can also complete your survey by using the Celgene REMS mobile app for your iPad. Please download the app to your iPad by clicking here:



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

POMALYST REMS® information for certified pharmacies

POMALYST® (pomalidomide) is only dispensed from POMALYST REMS® program certified pharmacies. To learn more about how to become a certified pharmacy, please contact the Celgene Customer Care Center at 1-888-423-5436.

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

[Pharmacy Guide to POMALYST REMS® Program](#)



[Full Prescribing Information](#)



[Education and Counseling Checklist for Pharmacies](#)



[Lista de verificación de educación y asesoramiento para farmacias](#)



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](#)

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REPORTING TO CELGENE

Online: www.celgene.com/contact-us/

Email: drugsafety@celgene.com

Telephone: 1-908-673-9667

Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)

Fax: 1-908-673-9115

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 POMALYST and any suspected pregnancy occurring during the treatment with POMALYST 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-0178

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

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/s/

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