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 approved 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.
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 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 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
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 1-866-430-1025.

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 online.

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

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

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: 1-800-673-9667
Toll-free: 1-866-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)
Fax: 1-866-673-9115
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
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®
- Patient Medication Guide
- Patient Survey Reminder Card
- Visit Planned Parenthood Site for Emergency Contraception Brochure

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

If you are able to become pregnant, you are required to use 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 label 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
Pharmacist Resources

POMALYST® 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 1-888-423-6436.

As a POMALYST® 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® 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: 1-908-673-9657
Toll-free: 1-800-640-7654 (Global Drug Safety & Risk Management) or 1-888-423-6436 (Celgene Customer Care Center)
Fax: 1-908-673-9115
Mail to: Global Drug Safety & Risk Management
       Celgene Corporation
       96 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: 1-888-FDA-0170
Mail to: MedWatch
       5600 Fishers Lane
       Rockville, MD 20852-7797

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