

CelgeneRiskManagement.com

Login Page



The screenshot shows the Celgene REMS Program login page. At the top left is the Celgene logo. Below it, the text reads "Welcome to the Celgene REMS Program". A paragraph explains that REMS programs are mandatory for Celgene products THALOMID, REVLIMID, and POMALYST. Below this, a link is provided for more information: "If you would like to obtain more information about any of the Celgene REMS programs, please click on the program name below:". Three buttons are displayed: "RevlimidREMS™", "PomalystREMS™", and "THALOMIDREMS™". Each button has a corresponding URL below it: "Visit www.REVLIMIDREMS.com", "Visit www.POMALYSTREMS.com", and "Visit www.THALOMIDREMS.com". A section for prescribers follows, with instructions on how to login or create an account. A login form contains fields for "User Name" and "Password", a "Forgot Password?" link, and a "Login" button. Below the form are "Create User Account" and "Patient Surveys" buttons. At the bottom, there are links for "Contact Us", "Terms of Use", and "Privacy Policy", along with the phone number "1-829-234-2111" and the website "celgene.com".

Celgene

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.T.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:

RevlimidREMS™

Visit www.REVLIMIDREMS.com, to learn more about the REVLIMID REMS™ program.

PomalystREMS™

Visit www.POMALYSTREMS.com, to learn more about the POMALYST REMS™ program.

THALOMIDREMS™

Visit 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?](#)

[Contact Us](#) | [Terms of Use](#) | [Privacy Policy](#)
1-829-234-2111 | celgene.com

Home Page (after prescriber login)

first last [Home](#) [Help](#) [Logout](#)

 [Home](#)

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.

| | | |
|---|--|--|
| <p>For REVLIMID REMS™ (formerly known as the RevAssist® program)</p> <p>RevlimidREMS™</p> <p>Please see full Prescribing Information, including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.</p> | <p>For POMALYST REMS™</p> <p>PomalystREMS™</p> <p>Please see full Prescribing Information, including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.</p> | <p>For THALOMID REMS™ (formerly known as the S.T.E.P.S.® program)</p> <p>THALOMIDREMS™</p> <p>Please see full Prescribing Information, including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.</p> |
|---|--|--|

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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Pomalyst REMS module

The screenshot displays the Pomalyst REMS Main Menu. At the top left, the user name "John Doe" is visible. At the top right, there are three buttons: "Home", "Help", and "Logout". The main menu title "POMALYST REMS™ Main Menu" is centered at the top. Below the title, the Pomalyst REMS logo is on the left. The main content area features five teal buttons with white text and icons:

- New PPAF/
Patient Enrollment (document icon)
- Work with Saved/
Submitted PPAF Forms (document icon with a building)
- Prescriber Survey (document icon with a checklist)
- Standard
Prescription Form (pharmacist icon)
- Veterans Administration
Prescription Form (pharmacist icon)

At the bottom of the page, there are three links: [Prescribing information](#), [Terms of use](#), and [Privacy Policy](#). Below these links is the copyright notice: © 2005-2012, Celgene Corporation.

www.POMALYSTREMS.com Web site

Pomalyst REMS™

POMALYST REMS™ Home

About POMALYST REMS™

Important Safety Information

Full Prescribing Information

Patient Medication Guide

Prescriber Resources

Patient Resources

Pharmacist Resources

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

Welcome to the POMALYST REMS™ program

POMALYST® (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

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

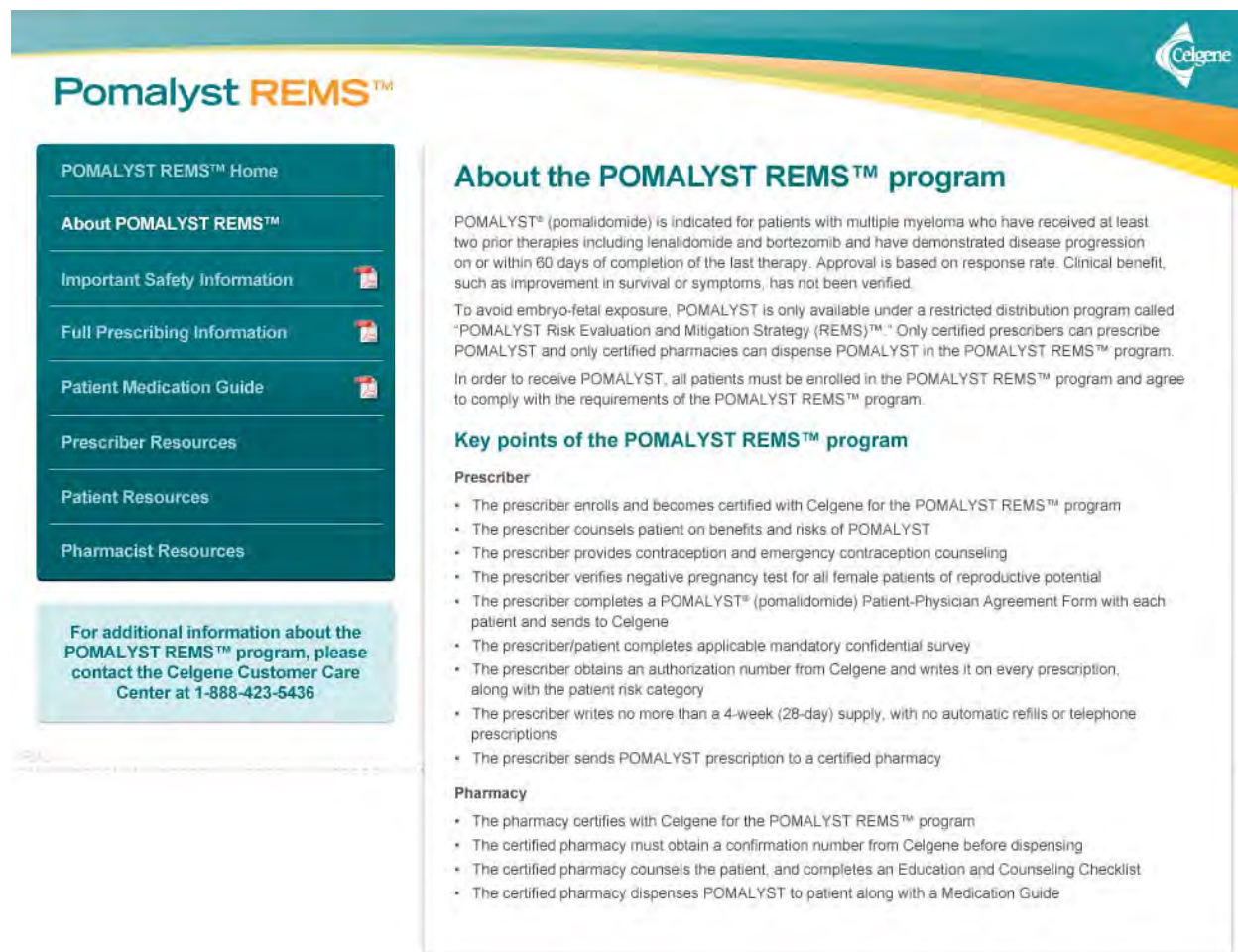
- POMALYST is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST provided adequate precautions are taken to avoid pregnancy.
- To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution 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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The image shows a webpage for the Pomalyst REMS™ program. At the top right is the Celgene logo. The main heading is "Pomalyst REMS™". On the left is a dark teal navigation menu with the following items: "POMALYST REMS™ Home", "About POMALYST REMS™", "Important Safety Information" (with a PDF icon), "Full Prescribing Information" (with a PDF icon), "Patient Medication Guide" (with a PDF icon), "Prescriber Resources", "Patient Resources", and "Pharmacist Resources". Below the menu is a light blue box with the text: "For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436". The main content area is titled "About the POMALYST REMS™ program" and contains the following text: "POMALYST® (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified." "To avoid embryo-fetal exposure, POMALYST 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." Below this is a section titled "Key points of the POMALYST REMS™ program" with two sub-sections: "Prescriber" and "Pharmacy". The "Prescriber" section lists seven bullet points: 1. The prescriber enrolls and becomes certified with Celgene for the POMALYST REMS™ program. 2. The prescriber counsels patient on benefits and risks of POMALYST. 3. The prescriber provides contraception and emergency contraception counseling. 4. The prescriber verifies negative pregnancy test for all female patients of reproductive potential. 5. The prescriber completes a POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene. 6. The prescriber/patient completes applicable mandatory confidential survey. 7. The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category. 8. The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions. 9. The prescriber sends POMALYST prescription to a certified pharmacy. The "Pharmacy" section lists four bullet points: 1. The pharmacy certifies with Celgene for the POMALYST REMS™ program. 2. The certified pharmacy must obtain a confirmation number from Celgene before dispensing. 3. The certified pharmacy counsels the patient, and completes an Education and Counseling Checklist. 4. The certified pharmacy dispenses POMALYST to patient along with a Medication Guide. At the bottom of the page are links for "Privacy policy", "Terms of Use", "Site map", and "Contact us". The Celgene logo is also present at the bottom right. Copyright information at the bottom left states: "POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation. ©2013 year of origin. Celgene Corporation, www.celgene.com. This website is intended for residents of the United States only."



Pomalyst REMS™

- POMALYST REMS™ Home
- About POMALYST REMS™
- Important Safety Information 
- Full Prescribing Information 
- Patient Medication Guide 
- Prescriber Resources**
- Patient Resources
- Pharmacist Resources


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

Prescriber Resources

POMALYST™ (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

Enrolling in POMALYST REMS™


In order to prescribe POMALYST, 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 Celgene Customer Care 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 and write prescriptions by downloading the Desktop Software and installing it on your computer.


Enroll Your Patients at CelgeneRiskManagement.com | **Desktop Software Installation** | **Installation User Guide** 

Patient Prescription Form 

Learning more about POMALYST REMS™

For a complete overview of the POMALYST REMS™ program, and a guide to the POMALYST REMS™ process, 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

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
300 Connell Dr.
Suite 6000
Berkeley Heights, NJ 07922

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: 1-800-332-1088

Fax: 1-800-332-0178

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

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The screenshot shows the Pomalyst REMS™ website. At the top right is the Celgene logo. The main heading is "Pomalyst REMS™". On the left is a vertical navigation menu with the following items: "POMALYST REMS™ Home", "About POMALYST REMS™", "Important Safety Information", "Full Prescribing Information", "Patient Medication Guide", "Prescriber Resources", "Patient Resources", and "Pharmacist Resources". The "Patient Resources" menu item is highlighted. The main content area is titled "Patient Resources" and contains the following text: "POMALYST® (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified." Below this is a section titled "What you need to know about the POMALYST REMS™ program" with the text: "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." There are four buttons: "Patient Guide to POMALYST REMS™ Program", "Patient Survey Reminder Card", "Patient Medication Guide", and "Visit Planned Parenthood site for Emergency Contraception Brochure". At the bottom left of the main content area is a box with the text: "For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436". At the bottom of the page is a footer with links for "Privacy policy", "Terms of Use", "Site map", and "Contact us". The Celgene logo is also present in the bottom right corner of the footer area.



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Pomalyst REMS™

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

Pharmacist Resources

POMALYST® (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.


POMALYST REMS™ information for certified pharmacies

POMALYST 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 

Education and Counseling Checklist for Pharmacies 

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

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
300 Connell Dr.
Suite 6000
Berkeley Heights, NJ 07922

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: 1-800-332-1088

Fax: 1-800-332-0178

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

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Site map

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The screenshot shows the Pomalyst REMS website interface. On the left is a navigation menu with links: POMALYST REMS™ Home, About POMALYST REMS™, Important Safety Information, Full Prescribing Information, Patient Medication Guide, Prescriber Resources, Patient Resources, and Pharmacist Resources. The main content area features a 'Welcome to the POMALYST REMS™ program' header, followed by a paragraph about the drug's indication for multiple myeloma. Below this is a 'POMALYST Risk Evaluation' section with a numbered list of points. A modal dialog box is centered on the screen, displaying the message 'You Are Now Leaving POMALYSTREMS.com' and instructions to click 'OK' or 'CANCEL'. The dialog box includes a 'Close' button in the top right corner and the Celgene logo in the bottom right corner. At the bottom of the page, there is a footer with trademark information and a copyright notice for 2013.

Pomalyst REMS™

Welcome to the POMALYST REMS™ program

POMALYST™ (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit,

You Are Now Leaving POMALYSTREMS.com

Click "OK" to proceed or "CANCEL" to return to POMALYSTREMS.com

OK CANCEL

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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