

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204026Orig1s000

REMS

POMALYST[®] (pomalidomide)

NDA # 204026

Celgene Corporation

86 Morris Avenue

Summit, NJ 07901

Contact Information:

1-908-673-9000

www.celgene.com

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

1. GOALS

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.

2. REMS ELEMENTS

2.1. Elements to Assure Safe Use

2.1.1. Healthcare providers who prescribe POMALYST are specially certified.

Celgene will ensure that healthcare providers who prescribe POMALYST are specially certified in the POMALYST REMS[™] program. POMALYST[®] (pomalidomide) is available only through a restricted distribution program, POMALYST REMS[™].

To become certified, each prescriber must complete the Prescriber Enrollment Form and agree to do the following:

- a. Provide patient counseling on the benefits and risks of POMALYST therapy, including risks described in the BOXED WARNINGS.
- b. Enroll each patient by completing and submitting to the Celgene Customer Care Center via mail (86 Morris Avenue, Summit, NJ 07901), email (customer care@celgene.com), fax (1-888-432-9325), or online (www.celgeneriskmanagement.com), a signed Patient-Physician Agreement Form (PPAF) identifying the patient's risk category (see PPAFs for all six risk categories) for each new patient. In signing the PPAF, each prescriber acknowledges that they understand that POMALYST is available only through the POMALYST REMS[™] program, and that they must comply with program requirements.

- c. Provide contraception and emergency contraception counseling with each new prescription prior to and during POMALYST treatment.
- d. Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions.
- e. Report any pregnancies in female patients or female partners of male patients prescribed POMALYST immediately to Celgene Drug Safety (or Celgene Customer Care Center (1-888-423-5436)).
- f. Complete a prescriber survey (phone or online) for every patient (new and follow-up), obtain a unique prescription authorization number for each prescription written, and include this authorization number on the prescription. The authorization number can be obtained by contacting the Celgene Customer Care Center, using the automated IVR system, or via the www.CelgeneRiskManagement.com website.
 - o For females of reproductive potential, authorization numbers are valid only for 7 days from date of last pregnancy test.
 - o Authorization numbers are valid for 30 days from the date it is issued for all other patients.
- g. Facilitate compliance with the mandatory POMALYST REMS™ patient survey by instructing patients to complete the mandatory surveys (phone or online) at program specified frequencies.
- h. Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions.
- i. Contact a pharmacy certified by the POMALYST REMS™ program to fill the POMALYST prescription.
- j. Return all unused POMALYST brought in by patients to Celgene Customer Care.
- k. Re-enroll patients in the POMALYST REMS™ program if POMALYST is required and previous therapy with POMALYST has been discontinued for 12 consecutive months.

Celgene will:

1. Ensure that the POMALYST REMS™ program materials including prescriber enrollment are available on the CelgeneRiskManagement.com website or can be obtained by contacting Celgene Customer Care Center at 1-888-423-5436
2. Maintain a secure database of all POMALYST REMS™ certified prescribers.
3. Monitor to ensure that only POMALYST REMS™ certified prescribers are prescribing POMALYST.
4. Monitor and ensure that patients have been assigned correctly to one of the following patient risk categories. Confirm risk category when completing the PPAFs during the patient enrollment process:
 - a. **Adult female of reproductive potential:** all females who are menstruating, amenorrheic from previous medical treatments, under 50 years, and/or perimenopausal.
 - b. **Female child of reproductive potential:** all females under 18 years who are menstruating.
 - c. **Adult female NOT of reproductive potential:** females who have had a natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy.

- d. **Female child NOT of reproductive potential:** all females under 18 years who are not menstruating.
 - e. **Adult males 18 years or older**
 - f. **Male child under 18 years**
5. Monitor certified prescriber compliance with the POMALYST REMS™ program, including patient risk categorization and the appropriate corresponding counseling requirements, contraception requirements, pregnancy testing, and survey completion for all patients treated with POMALYST.
6. Institute corrective action and prevent the certified prescriber from prescribing POMALYST if the prescriber is found to be non-compliant with the POMALYST REMS™ program.
7. Train POMALYST REMS™ program certified prescribers in adverse experience reporting procedures, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to POMALYST if a pregnancy occurs.
8. Ensure that once the prescriber submits the completed PPAF, the prescriber will receive a confirmation letter via fax or online to confirm the patient's enrollment and signify that the prescriber and patient surveys can be taken to receive an authorization number for the POMALYST prescription (for all males, the PPAF is considered the initial survey). The authorization number is written on the POMALYST prescription.
9. Ensure that, for subsequent prescriptions, the prescriber completes a telephone or online survey designed to look for signals of at-risk behavior (e.g., pending or outdated pregnancy test), report the patient's pregnancy test results, correct assignment of risk category, and confirm or re-enforce patient understanding of contraceptive requirements. The completion of the survey will allow the prescriber to obtain a new authorization number every time a prescription for POMALYST is written.

The following materials are part of the REMS, and are appended:

- [Prescriber Enrollment Form](#)
- [Patient Prescription Form](#)
- [Patient Prescription Form \(Veterans Administration\)](#)
- [Prescriber Guide to POMALYST REMS™ program](#)
- [POMALYST REMS™ At-A-Glance](#)
- [Welcome Letter](#)
- [CelgeneRiskManagement.com website](#)

2.1.2. POMALYST will only be dispensed by pharmacies that are specially certified.

Celgene will ensure that POMALYST is only dispensed from POMALYST REMS™ program certified pharmacies. To become a certified pharmacy, the pharmacy must agree to do the following before filling a POMALYST prescription:

- a. Only accept prescriptions with a prescription authorization number. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients.

- b. Dispense no more than a 4-week (28-day) supply, and require a new prescription from the patient prior to dispensing additional POMALYST.
- c. Dispense subsequent prescriptions only if there are 7 days or less remaining on an existing POMALYST prescription.
- d. Obtain a POMALYST REMS™ confirmation number from the Celgene Customer Care Center (phone or online) and write this confirmation number on the prescription. The POMALYST REMS™ confirmation number may be obtained using the following procedure:
 1. Enter the pharmacy identification number (NABP or DEA);
 2. Enter the prescription authorization number written on the prescription;
 3. Enter the number of capsules and milligram (mg) strength being dispensed;
 4. Dispense or ship the prescribed POMALYST within 24 hours of obtaining and recording the POMALYST REMS™ confirmation number and confirmation date.
- e. Dispense POMALYST only after a POMALYST REMS™ confirmation number is obtained. If no confirmation is obtained, then no POMALYST is dispensed. Contact the patient's physician and Celgene for further instruction.
- f. Accept unused POMALYST (previously dispensed) from a patient or patient caregiver and return to Celgene Corporation for proper disposal.
- g. For each patient receiving treatment, retain a record of each POMALYST prescription dispensed and the corresponding completed Education and Counseling Checklist.
- h. Complete the checklist that applies to the patient risk category written on the front of the Education and Counseling Checklist for Pharmacies.
- i. Provide counseling to patients and/or guardians of patients under 18 years of age receiving POMALYST treatment.
 - a. Counsel all patients and guardians of patients under 18 years of age on the following:
 1. The benefits and risks of POMALYST therapy.
 2. Not sharing POMALYST medication.
 3. Not donating blood while taking POMALYST, during dose interruptions, and for 4 weeks after stopping POMALYST.
 4. Not to break, chew, or open POMALYST capsules.
 5. Instructions on POMALYST dose and administration.
 6. To read the POMALYST REMS™ program education materials and encourage compliance with the requirements.
 - b. In addition to above, counsel **Females of Reproductive Potential** on the following:
 1. The potential for embryo-fetal toxicity with exposure to POMALYST.
 2. Using 2 forms of effective birth control at the same time or abstaining from heterosexual sexual intercourse.
 3. Continuing to use 2 forms of birth control if POMALYST therapy is interrupted and for at least 4 weeks after therapy is discontinued.
 4. Obtaining a pregnancy test weekly during the first 4 weeks of POMALYST use, then a repeat pregnancy test every 4 weeks in females with regular menstrual cycles, and every 2 weeks in females with irregular menstrual cycles.

5. The need to stop taking POMALYST and notify their POMALYST prescriber immediately if they become pregnant or suspect they may be pregnant.
- c. In addition to items listed for all patients above, counsel **Males** receiving POMALYST treatment about the potential for embryo-fetal toxicity with exposure to POMALYST and the importance of using barrier contraception by wearing a latex or synthetic condom when engaging in sexual intercourse with a female of reproductive potential even if the male receiving POMALYST has had a successful vasectomy.
 1. The need to not donate sperm while taking POMALYST, during dose interruptions, and for 4 weeks after stopping POMALYST.
- d. Counsel the **Parent or legal guardian of Female Child NOT of reproductive potential** who is receiving POMALYST treatment about the need to inform their POMALYST prescriber when the child begins menses.

Before a certified pharmacy dispenses POMALYST, Celgene will train the appropriate pharmacy staff:

1. About the POMALYST REMS™ program
2. About the procedures for reporting adverse experiences to Celgene, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to POMALYST if a pregnancy occurs.

The following materials are part of the REMS and are appended:

- [Pharmacy Guide to the POMALYST REMS™ Program](#)
- [Education and Counseling Checklist for Pharmacies](#)
- [Celgene REMS Programs Pharmacy Training: the POMALYST REMS™ Program](#)
- [Pharmacy Certification Quiz \(the POMALYST REMS™ Program\)](#)

2.1.3. Celgene will ensure that POMALYST will only be dispensed to patients enrolled in the POMALYST REMS™ program with evidence or other documentation of safe-use conditions.

Celgene will ensure that all patients treated with POMALYST are enrolled by a certified prescriber. The prescriber will enroll the patient by completing Patient-Physician Agreement Form and submitting the form via mail (86 Morris Avenue, Summit, NJ 07901), fax (1-888-432-9325), email (customer@celgene.com) or online (www.celgeneriskmanagement.com) for each patient who receives POMALYST. Each patient and/or guardian of patients under 18 years of age consents to participate in the program by:

- a. acknowledging that he or she understands that:
 - i. severe birth defects or death to an unborn baby may occur if a female becomes pregnant while she is receiving POMALYST;
 - ii. POMALYST must not be shared with anyone, even someone with similar symptoms;

- iii. POMALYST must be kept out of the reach of children and should NEVER be shared with females who are able to have children;
- iv. they cannot donate blood while receiving POMALYST, including dose interruptions, and for 4 weeks after stopping POMALYST;
- v. they might be asked to participate in the POMALYST Pregnancy Exposure Registry; and
- vi. they may be contacted by Celgene about following the rules of the REMS.

In addition, each patient and/or guardian of patients under 18 years of age consents to participate in the program by:

- i. agreeing to return unused POMALYST to Celgene or their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them;
- ii. agreeing to participate in a monthly (telephone or online) survey while on POMALYST (with the exception of Adult Females Not of Reproductive Potential who are required to take a survey once every six months); and
- iii. reviewing the POMALYST REMS™ program educational materials and asking their prescriber any questions that have not been answered.

In addition, **Females and guardians of female children** must attest to their understanding of their/their child's reproductive potential, as categorized by the prescribing physician.

Females of Reproductive Potential and guardians of Female Children of Reproductive Potential will attest that they/their child:

- a. is not currently pregnant, and will try to refrain from becoming pregnant while receiving POMALYST therapy and for at least 4 weeks after completely stopping POMALYST therapy;
- b. must not take POMALYST if pregnant, breastfeeding a baby, or not using birth control as defined in the REMS;
- c. will, unless abstinent, use contraception as defined within the REMS: for at least 4 weeks before starting POMALYST, while receiving POMALYST, during dose interruptions, and for at least 4 weeks after stopping POMALYST;
- d. will have pregnancy testing done as ordered by the certified prescriber within 10 to 14 days and 24 hours prior to starting POMALYST, every week for at least the first 4 weeks of POMALYST therapy, and then every 4 weeks if the Female of Reproductive Potential has regular menstrual cycles, or every 2 weeks if the Female of Reproductive Potential has irregular menstrual cycles, while receiving POMALYST;
- e. will immediately stop taking POMALYST and inform the certified prescriber if the patient becomes pregnant, misses a menstrual period, experiences unusual menstrual bleeding, stops using contraception, or thinks for any reason that she might be pregnant; if the prescriber is not available, the Female of Reproductive Potential or guardian of a Female Child of Reproductive Potential can call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information on emergency contraception.

Males or guardians of Males will attest that they/their child will:

- a. never have unprotected sexual contact with a female who can become pregnant;
- b. wear a latex or synthetic condom every time the male patient has sexual contact with a female who is or who can become pregnant; continue condom use with sexual contact while the male patient is receiving POMALYST treatment, during dose interruptions, and for 4 weeks after the male patient stops taking POMALYST, even if the patient has had a successful vasectomy; and
- c. inform their certified prescriber if the male patient has unprotected sexual contact with a female who can become pregnant, or if they think for any reason that the male patient's sexual partner might be pregnant; the male patient or guardian of an underage male patient can call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information on emergency contraception;
- d. not donate sperm while taking (including dose interruptions) and for 4 weeks after stopping POMALYST.

The following appended materials are part of the REMS:

- [Patient-Physician Agreement Form for Adult Male](#)
- [Patient-Physician Agreement Form for Male Child](#)
- [Patient-Physician Agreement Form for Adult Female Who Can Not Get Pregnant](#)
- [Patient-Physician Agreement Form for Adult Female Who Can Get Pregnant](#)
- [Patient-Physician Agreement Form for a Female Child Who Can Not Get Pregnant](#)
- [Patient-Physician Agreement Form for a Female Child Who Can Get Pregnant](#)
- [Patient Guide to POMALYST REMS™ program](#)
- [Emergency Contraception Brochure](#)
- [Patient Survey Reminder Card](#)
- [POMALYST Risk Evaluation and Mitigation Strategy \(REMS\)™ program education and prescribing safety kit](#)
- [POMALYST REMS™ Patient Resource Pack Envelope](#)

2.1.4. Female patients or female partners of male patients receiving POMALYST who report a pregnancy that occurred during POMALYST therapy will be enrolled in the POMALYST Pregnancy Exposure Registry.

Upon receiving a report of pregnancy from the POMALYST REMS™ program, Celgene Pregnancy Prevention Plan programs in the rest of the world, clinical trials, or directly from a prescriber, a pharmacy, or a patient, Celgene will enroll the female patient or female partner of the male patient taking POMALYST into the POMALYST Pregnancy Exposure Registry. The objectives of the registry are to monitor pregnancy outcomes in female patients of reproductive potential and male patients' female partners who are exposed to POMALYST and to understand why the POMALYST REMS™ program was unsuccessful.

The following materials are part of the REMS and are appended:

- 1) [POMALYST Pregnancy Exposure Registry Protocol, including letter and questionnaires](#)

2.2. Implementation System

The implementation system will include the following:

- 1) Celgene will maintain a secure database of all certified entities, including enrolled patients and certified prescribers and pharmacies to monitor and evaluate implementation of the elements provided for in Sections 2.1.1, 2.1.2, and 2.1.3.
- 2) Celgene will monitor pharmacy certification compliance and address deviations by monitoring real time dispensing activity and conducting pharmacy audits.
 - a. The Celgene Customer Care Center will monitor the certified pharmacies in the manner described in the REMS supporting document to ensure only enrolled and authorized patients are receiving POMALYST. If a certified pharmacy is found to be non-compliant with the POMALYST REMS™ program, Celgene will institute corrective action and may de-activate pharmacies for which re-training has proven ineffective, removing them from the POMALYST REMS™ program.
 - b. Celgene will perform regular on-site audits of contract pharmacies participating in the POMALYST REMS™ program. For pharmacies that have been in the program for more than two years, Celgene will perform a risk-based assessment to select which pharmacies will be audited. The POMALYST REMS™ program compliance audits will be performed by internal auditors of Celgene and/or outside auditors contracted and trained by Celgene.
- 3) Celgene will monitor and ensure that the prescriptions are filled within the allowed timeframes.
- 4) Celgene Customer Care Center will address customer complaints received that are related to the POMALYST REMS™ program and distribution and dispensing of POMALYST.
- 5) Celgene will maintain a reporting and collection system for safety information that includes a process to monitor pregnancy testing results and pregnancy outcomes (should one occur) through the POMALYST Pregnancy Exposure Registry and to understand why the POMALYST REMS™ program was unsuccessful for the pregnancy case in question.
- 6) Based on monitoring and evaluation of these elements to assure safe use, Celgene will take reasonable steps to work to improve implementation of these elements as applicable.
- 7) Celgene will develop and follow written procedures related to the implementation of the REMS.

2.3. Timetable for Submission of Assessment Reports

Assessment Reports will be submitted annually from the date of the initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment will conclude no earlier than 60 days before the submission date for that assessment. Celgene will submit each assessment so it will be received by the FDA on or before the due date.

POMALYST® (pomalidomide) Patient Prescription Form

<p>Today's Date _____ Date Rx Needed _____</p> <p>Patient Last Name _____ Patient First Name _____</p> <p>Phone Number (____) _____</p> <p>Shipping Address _____</p> <p>City _____ State _____ Zip _____</p> <p>Date of Birth _____ Patient ID# _____</p> <p>Language Preference: <input type="checkbox"/> English <input type="checkbox"/> Spanish <input type="checkbox"/> Other _____</p> <p>Best Time to Call Patient: <input type="checkbox"/> AM _____ <input type="checkbox"/> PM _____</p> <p>Patient Diagnosis (ICD-9 Code) _____</p> <p>Patient Allergies _____</p> <p>Other Current Medications _____</p>	<p>Prescriber Name _____</p> <p>State License Number _____</p> <p>Prescriber Phone Number (____) _____ Ext. _____</p> <p>Fax Number (____) _____</p> <p>Prescriber Address _____</p> <p>City _____ State _____ Zip _____</p> <p>Patient Type From PPAF (Check one)</p> <p><input type="checkbox"/> Adult Female – NOT of Reproductive Potential</p> <p><input type="checkbox"/> Adult Female – Reproductive Potential</p> <p><input type="checkbox"/> Adult Male</p> <p><input type="checkbox"/> Female Child – Not of Reproductive Potential</p> <p><input type="checkbox"/> Female Child – Reproductive Potential</p> <p><input type="checkbox"/> Male Child</p>
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PRESCRIPTION INSURANCE INFORMATION

(Fill out entirely and fax a copy of patient's insurance card, both sides)

Primary Insurance _____

Insured _____

Policy # _____

Group # _____

Phone # _____

Rx Drug Card # _____

Secondary Insurance _____

Insured _____

Policy # _____

Group # _____

Phone # _____

Rx Drug Card # _____

For further information on POMALYST, please refer to the full Prescribing Information

TAPE PRESCRIPTION HERE PRIOR TO FAXING REFERRAL, OR COMPLETE THE FOLLOWING:

Recommended Starting Dose: See below for dosage

Multiple Myeloma: The recommended starting dose of POMALYST is 4 mg/day orally for Days 1 – 21 of repeated 28-day cycles. Dosing is continued or modified based upon clinical and laboratory findings

POMALYST

Dose	Quantity	Directions
<input type="checkbox"/> 1 mg _____	_____	
<input type="checkbox"/> 2 mg _____	_____	
<input type="checkbox"/> 3 mg _____	_____	
<input type="checkbox"/> 4 mg _____	_____	
<input type="checkbox"/> Dispense as Written		<input type="checkbox"/> Substitution Permitted

NO REFILLS ALLOWED (Maximum Quantity = 28 days)

Prescriber Signature _____ Date _____

Authorization # _____ Date _____

(To be filled in by healthcare provider)

Pharmacy Confirmation # _____ Date _____

(To be filled in by pharmacy)

How to Fill a POMALYST® (pomalidomide) Prescription

1. Healthcare provider (HCP) instructs female patients to complete initial patient survey
2. HCP completes survey
3. HCP completes patient prescription form
4. HCP obtains POMALYST REMS™ authorization number
5. HCP provides authorization number on patient prescription form
- 6. HCP faxes form, including prescription, to one of the Celgene Certified Pharmacy Network participants (see below)**
7. HCP advises patient that a representative from the certified pharmacy will contact them
8. Certified pharmacy conducts patient education
9. Certified pharmacy obtains confirmation number
10. Certified pharmacy ships POMALYST to patient with MEDICATION GUIDE

Please see www.Celgene.com/PharmacyNetwork for the list of pharmacy participants

Information about POMALYST and the POMALYST REMS™ program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.CelgeneRiskManagement.com



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1/13

REMS-POM12150

POMALYST® (pomalidomide)

Patient Prescription Form – Veterans Administration (VA) ONLY

Today's Date _____ Date Rx Needed _____
Patient Last Name _____ Patient First Name _____
Phone Number (____) _____
Shipping Address _____
City _____ State _____ Zip _____
Date of Birth _____ Patient ID# _____
Language Preference: English Spanish Other _____
Best Time to Call Patient: AM _____ PM _____
Patient Diagnosis (ICD-9 Code) _____
Patient Allergies _____

Other Current Medications _____

Prescriber Name _____
State License Number _____
Prescriber Phone Number (____) _____ Ext. _____
Fax Number (____) _____
Prescriber Address _____

City _____ State _____ Zip _____

Patient Type From PPAF (Check one)

- Adult Female – NOT of Reproductive Potential
- Adult Female – Reproductive Potential
- Adult Male
- Female Child – Not of Reproductive Potential
- Female Child – Reproductive Potential
- Male Child

VA Pharmacy Information (Fill out entirely)

VA Name _____
Address _____

City _____ State _____ Zip _____
VA Pharmacist Name _____
Phone # _____
Fax # _____
McKesson Specialty Distribution Account # _____

Shipping Information

Check below for direct delivery to patient. If any information is omitted, product will be shipped to the VA Pharmacy.

Patient
Name _____
Address _____
City _____ State _____ Zip _____
Phone _____

For further information on POMALYST, please refer to the full Prescribing Information

TAPE PRESCRIPTION HERE PRIOR TO FAXING REFERRAL, OR COMPLETE THE FOLLOWING:

Recommended Starting Dose: See below for dosage

Multiple Myeloma: The recommended starting dose of POMALYST is 4 mg/day orally for Days 1 – 21 of repeated 28-day cycles. Dosing is continued or modified based upon clinical and laboratory findings

POMALYST

Dose	Quantity	Directions
------	----------	------------

- | | | |
|-------------------------------|-------|-------|
| <input type="checkbox"/> 1 mg | _____ | _____ |
| <input type="checkbox"/> 2 mg | _____ | _____ |
| <input type="checkbox"/> 3 mg | _____ | _____ |
| <input type="checkbox"/> 4 mg | _____ | _____ |

Dispense as Written Substitution Permitted

NO REFILLS ALLOWED (Maximum Quantity = 28 days)

Prescriber Signature _____ Date _____

Authorization # _____ Date _____
(To be filled in by healthcare provider)

Pharmacy Confirmation # _____ Date _____
(To be filled in by pharmacy)

How to Fill POMALYST® (pomalidomide)

Prescription in the Veterans Administration (VA)

1. Healthcare Provider (HCP) instructs female patients to complete initial patient survey
2. HCP completes survey
3. HCP completes patient prescription form (include cell number for patient if possible)
4. HCP obtains POMALYST REMS™ authorization number
5. HCP provides authorization number on patient prescription form
6. HCP sends prescription to the VA Pharmacy
The following information must be filled in:
 - **Rx must include McKesson Specialty Distribution account number**
 - **Rx must include VA address** (Name, Street, City, State, ZIP)
 - **Rx must include VA Pharmacist contact information** (Name, Phone and Fax #)
7. VA Pharmacist faxes the form, including prescription, to:
The POMALYST REMS™ certified Walgreens Specialty at 1-888-591-8482
8. HCP advises patient that a representative from POMALYST REMS™ certified pharmacy will be in contact
9. The POMALYST REMS™ certified Walgreens Specialty Pharmacist conducts patient education
10. The POMALYST REMS™ certified Walgreens Specialty Pharmacist obtains confirmation number
11. The POMALYST REMS™ certified Walgreens Specialty Pharmacist ships POMALYST to the VA Pharmacy or directly to the patient with MEDICATION GUIDE
12. VA Pharmacist gives POMALYST to VA patient with MEDICATION GUIDE

POMALYST REMS™ Veterans Administration (VA) Pharmacy

Walgreens Specialty

Phone: 1-877-865-9396

Fax: 1-888-591-8482

Information about POMALYST and the POMALYST REMS™ program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.CelgeneRiskManagement.com.



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1/13

REMS-POM12151

Prescriber Guide to

((POMALYST REMS™ logo))

Risk Evaluation and Mitigation Strategy (REMS)™ Program

Due to its structural similarity to thalidomide, a known teratogen, POMALYST® (pomalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program.

This guide contains important information for prescribers about:

- The risks of POMALYST, including a boxed warning for
 - Embryo-fetal toxicity
 - Venous thromboembolism

- The POMALYST REMS™ program
 - Prescriber Certification
 - Patient Enrollment
 - Contraceptive Requirements and Counseling for Patients
 - Initial and Subsequent Prescription Requirements

POMALYST REMS™ Resources for Prescribers Include:

- Prescriber Guide to POMALYST REMS™ Program
- CD-ROM, including Patient-Physician Agreement Form and Patient Prescription Form Software and Installation Instructions
- Full Prescribing Information for POMALYST

Table of contents

About POMALYST® (pomalidomide).....	3
The POMALYST REMS™ program.....	4
Key points of the POMALYST REMS™ program.....	4
Patient enrollment into POMALYST REMS™ program.....	5
Initial prescription requirements.....	7
• All patients.....	7
• Female patients.....	7
○ Females of reproductive potential.....	8
○ Females not of reproductive potential.....	10
• Male patients.....	10
Initial mandatory confidential survey.....	11
• Additional information for the prescriber.....	11
Subsequent prescription requirements	12
After the last dose of POMALYST.....	13
Ordering English and non-English materials.....	14
Adverse drug experience reporting procedure for healthcare professionals.....	15

About POMALYST® (pomalidomide)

POMALYST 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.

Risks of POMALYST

POMALYST has a Boxed Warning for embryo-fetal toxicity and venous thromboembolism.

Due to the fact that it is an analogue of thalidomide, a known teratogen, POMALYST is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST if they take adequate precautions to avoid pregnancy.

Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE) occurred in patients with multiple myeloma treated with pomalidomide. The decision to take prophylactic measures should be done carefully after an assessment of an individual patient's underlying risk factors.

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 POMALYST REMS™ and agree to comply with the requirements of the POMALYST REMS™ program. Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**.

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 a certified pharmacy

Pharmacy

- The pharmacy certifies with Celgene for POMALYST REMS™
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy dispenses POMALYST to patient along with a Medication Guide

POMALYST REMS™ patient enrollment

- Obtain, review, and complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**
- Prescribers who do not have access to a computer, or whose computer systems are not compatible with the software, will be provided with POMALYST REMS™ program materials. For additional assistance, please contact the Celgene Customer Care Center or your Celgene Hematology Oncology Consultant
- Patient, parent/legal guardian, and/or authorized representative must read the POMALYST® (pomalidomide) Patient-Physician Agreement Form in the language of their choice

Help Ensure Timely Processing of Each Prescription

Fill Out Form as Directed

- Write only in the designated areas on the POMALYST® (pomalidomide) Patient-Physician Agreement Form
- The box next to each statement must be marked (with an “X”) to indicate understanding
- The form must be completed and signed by both prescriber and patient

Instructions for Female Patients

- For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

Instructions for Minors

- If the patient is under 18 years of age, his or her legal guardian must read this material, mark the statement in each block of the form (with an “X”) and agree to ensure compliance by signing and dating the form

Instructions for Incompetent Adult Patients

- For an incompetent adult patient, an authorized representative must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form

POMALYST REMS™ patient enrollment (continued)

- An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient's behalf
- The authorized representative must read the material, mark the statements, and agree to ensure compliance by signing and dating the form
- If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the POMALYST® (pomalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the POMALYST REMS™ program and is authorized to consent to treatment with POMALYST on behalf of the patient

Send in Completed Forms

- Send the completed POMALYST® (pomalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**
- You will receive confirmation electronically or via fax to your office once the patient is enrolled
- Once the POMALYST® (pomalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys
- In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

Note: If therapy with POMALYST is discontinued for 12 consecutive months, the patient must enroll again in the POMALYST REMS™ program. Follow the above procedures to re-enroll the patient.

Initial prescription requirements

ALL PATIENTS

- Provide comprehensive counseling on the benefits and risks of therapy with POMALYST® (pomalidomide)
- Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with POMALYST
- Provide counseling not to share POMALYST capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of POMALYST, as well as counseling on appropriate contraceptive use, including emergency contraception
- Provide patients with education materials provided in the POMALYST REMS™ Patient Resource Pack
- Patients should be instructed to not extensively handle or open POMALYST capsules
- Instruct patients to return unused POMALYST capsules for disposal to Celgene or to their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them

FEMALE PATIENTS

Determine if female patient is of reproductive potential

Two categories:
1. Females of Reproductive Potential <ul style="list-style-type: none">• All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
2. Females Not of Reproductive Potential <ul style="list-style-type: none">• Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating

1. Females of Reproductive Potential

Pregnancy test requirements

- Obtain a **negative** pregnancy test 10 to 14 days prior to writing an initial prescription for POMALYST® (pomalidomide) and again within 24 hours prior to writing an initial prescription for POMALYST even if continuous abstinence is the chosen method of birth control
 - The pregnancy test must be sensitive to at least 50 mIU/mL
 - Pregnancy testing should occur weekly during the first 4 weeks of use
 - Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
 - If a patient misses her period or if there is any abnormality in menstrual bleeding, POMALYST should be discontinued immediately. Obtain a pregnancy test and counsel the patient
- **If pregnancy does occur during treatment, POMALYST must be immediately discontinued.** Any suspected embryo-fetal exposure to POMALYST must be reported immediately to the FDA via the MedWatch number at **1-800-332-1088** and also to the Celgene Customer Care Center at **1-888-423-5436**. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling
- The patient must not breastfeed a baby while being treated with POMALYST

Patient Counseling on Contraception Requirements

Contraception requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before POMALYST® (pomalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Effective Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	Male latex or synthetic condom + Diaphragm Cervical cap
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	
Tubal ligation (having your tubes tied)	
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	

Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.

- **Unacceptable forms of contraception:**
 - Progesterone-only “mini-pills”
 - IUD Progesterone T
 - Female condoms
 - Natural family planning (rhythm method) or breastfeeding
 - Fertility awareness
 - Withdrawal
 - Cervical shield*

- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

2. Females Not of Reproductive Potential

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy

- The parent or guardian must confirm that a prepubertal female child is not now pregnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before POMALYST® (pomalidomide) therapy, during therapy, and for at least 4 weeks after stopping therapy

MALE PATIENTS

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking POMALYST therapy is unknown
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of POMALYST

Initial mandatory confidential survey

Females

- Instruct the female patient to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**. See page 12 for subsequent prescription requirements

Males

- Males do not need to take the initial survey

Prescribers

- Prescriber will complete a brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted

Additional Information for the Prescriber

- Healthcare provider must send the prescription to a POMALYST REMS™ certified pharmacy. To locate a certified pharmacy, please visit **www.Celgene.com/PharmacyNetwork**
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

Subsequent prescription requirements

The prescriber must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for POMALYST® (pomalidomide) is written.

No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

FEMALE PATIENTS

- Provide counseling as outlined in the “FEMALE PATIENTS” section on pages 7-10
- Follow pregnancy test requirements as outlined in the “Pregnancy test requirements” section on page 8
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
 - Before prescription is obtained
 - Monthly
 - Adult females of reproductive potential
 - All female children
 - Every 6 months
 - Adult females not of reproductive potential

MALE PATIENTS

- Provide patient counseling as outlined in the “MALE PATIENTS” section on page 10
- Male patients must complete a brief mandatory confidential survey once a month
 - Males do not complete an initial survey

After the last dose of POMALYST® (pomalidomide)

After patients have stopped taking POMALYST, they must do the following:

ALL PATIENTS

- Must not share POMALYST capsules—especially with females of reproductive potential
- Must return any unused POMALYST capsules for disposal to Celgene or their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them
- Must not donate blood for 4 weeks after stopping POMALYST

FEMALE PATIENTS

- Must not get pregnant for at least 4 weeks after stopping POMALYST by using the appropriate contraceptives each time engaging in sexual activity with a male

MALE PATIENTS

- Must use a latex or synthetic condom for 4 weeks after stopping POMALYST
- Must not donate sperm for 4 weeks after stopping POMALYST

Ordering English and non-English materials

CALL CELGENE CUSTOMER CARE CENTER AT 1-888-423-5436

- Materials are available in 16 languages and include:
 - POMALYST® (pomalidomide) Patient-Physician Agreement Forms
 - Patient Guide to POMALYST REMS™ Program
 - Mandatory confidential survey forms

Available languages:

Arabic	French	Japanese	Portuguese
Cambodian	German	Korean	Russian
Chinese	Greek	Laotian	Spanish
English	Italian	Polish	Vietnamese

- POMALYST® (pomalidomide) Patient-Physician Agreement Forms, Patient Guide to POMALYST REMS™ Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

Prescriber's:

Name

Identification Number

Full Address

Fax Number

Patient's:

Name

Full Address

Phone Number

Date of Birth

Identification Number

Diagnosis (most recent version of ICD code)

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of POMALYST® (pomalidomide).

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

[Back Cover]

For more information about POMALYST[®] (pomalidomide) and the POMALYST REMS[™] program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation

86 Morris Ave

Summit, NJ 07901

POMALYST is only available under a restricted distribution program, POMALYST REMS[™].

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

((Celgene logo)) ((POMALYST REMS logo)) ((POMALYST logo))

POMALYST[®] is a registered trademark of Celgene Corporation. POMALYST REMS[™] is a trademark of Celgene Corporation.

((POMALYST REMS™ logo))

At-A-Glance

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
- Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

For more information about POMALYST and the POMALYST REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

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

((Celgene logo)) ((POMALYST REMS logo)) ((POMALYST logo))

Initial prescription (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for POMALYST® (pomalidomide).
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open POMALYST capsules.
3. Obtain, review, and complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**.
 - **Males (adults and children)**
 - **Females of reproductive potential include all females who are menstruating**, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
 - **Females not of reproductive potential include females who have been in natural menopause for at least 24 consecutive months**, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating
4. Send the completed and signed POMALYST® (pomalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**.
5. Instruct female patients to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**, prior to prescriber obtaining an authorization number.
 - Males do not need to complete the initial survey
6. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written.
 - You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7

days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.

8. Send the prescription to a certified pharmacy.

Subsequent prescriptions (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open POMALYST capsules.
3. Instruct patient to complete a brief mandatory confidential survey **as scheduled**, prior to prescriber obtaining an authorization number and filling the prescription.
 - Monthly:
 - **Males (adults and children)**
 - **Females of reproductive potential (adults and children)**
 - **Female children not of reproductive potential**
 - Every 6 months:
 - **Adult females not of reproductive potential**
4. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for every patient before each prescription is written.
 - You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
5. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
6. Send the prescription to a certified pharmacy.

POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation.

((POMALYST REMS™ logo)) Prescriber Enrollment Form

All prescribers **must** be certified to prescribe POMALYST® (pomalidomide). To become certified the prescriber must:

1. Complete the Prescriber Enrollment Form, which is required for POMALYST REMS™ certification.
2. Agree to steps below that **must** be followed with every patient.

To submit this form electronically, please go to www.CelgeneRiskManagement.com.

To submit this form via fax, please complete all required fields below and fax all pages to 1-888-432-9325.

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.

Please review the steps below that must be followed with every patient.

When prescribing POMALYST, I agree to:

- Provide patient counseling on the benefits and risks of POMALYST therapy, including Boxed Warnings
- Submit a completed POMALYST® (pomalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during POMALYST treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed POMALYST immediately to Celgene Drug Safety (or Celgene Customer Care Center)
- Complete a mandatory and confidential prescriber survey online or by telephone for all patients and obtain a new authorization number for each prescription written and include this authorization number on the prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone

- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a POMALYST REMS™ certified pharmacy to fill the prescription
- Return to Celgene all POMALYST capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Remind patients to return all POMALYST capsules to Celgene Corporation or their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them
- Re-enroll patients in the POMALYST REMS™ program if POMALYST is required and previous therapy with POMALYST has been discontinued for 12 consecutive months

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

((POMALYST logo))

Please fill out the spaces below completely.

Prescriber Name _____

Degree: MD/DO/PA/NP/Fellow/Medical Resident

Specialty _____

Prescriber Identification Number _____

Please indicate which office(s) will receive POMALYST REMS™ materials and updates:

• Primary Office Name _____

Attention _____

Address _____

City _____ State _____ ZIP Code _____

Phone _____ Ext. _____ Fax _____

Email Address _____

• Secondary Office Name _____

Attention _____

Address _____

City _____ State _____ ZIP Code _____

Phone _____ Ext. _____ Fax _____

Email Address _____

I understand that if I fail to comply with all requirements of the POMALYST REMS™ program, my prescriptions for POMALYST® (pomalidomide) will not be honored at certified pharmacies.

Prescriber Signature _____ Date _____

Return this form to the Celgene Customer Care Center via fax or mail.

Mail to: Celgene Customer Care Center, 86 Morris Avenue, Summit, NJ 07901

Phone: **1-888-423-5436**

Fax: **1-888-432-9325**

www.CelgeneRiskManagement.com

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((POMALYST REMS logo))

((POMALYST logo))

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REMS-POM12154

POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed POMALYST for you. POMALYST is available only through a restricted distribution program called POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, you must read and agree to all of the instructions in the POMALYST REMS™ program.

If you are pregnant or become pregnant while taking POMALYST, it is important for you to know that your unborn baby can have severe birth defects or even die.

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

INSTRUCTIONS

Before starting your treatment with POMALYST, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the POMALYST® (pomalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the POMALYST REMS™ program and is authorized to consent to treatment with POMALYST on behalf of the patient.

For more information, visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

BAR CODE HERE

POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- POMALYST can cause severe birth defects or death to my unborn baby if I am pregnant or become pregnant during treatment
- I am not pregnant now and will not get pregnant while being treated with POMALYST
- It is possible for me to get pregnant if:
 - I am having my period (am menstruating), or
 - My period has stopped because of my treatment
 - And I have sex with a male
- Not having sex is the only birth control method that is 100% effective
- I am not breastfeeding now and will not breastfeed while being treated with POMALYST
- My POMALYST prescription is **only** for me and is not to be shared with others
- I have read and understood the POMALYST Patient Guide to POMALYST REMS™ program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- My healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by Celgene to assist with the POMALYST REMS™ program
- I will NOT donate blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

BAR CODE HERE

POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

- I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male unless otherwise recommended by my doctor. My doctor may recommend that I use **at the same time** 2 different birth control methods **every time** I have sex with a male if I cannot use a hormonal or intrauterine device (IUD) method

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	Male latex or synthetic condom + Diaphragm Cervical cap
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	
Tubal ligation (having your tubes tied)	
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	

- I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male:
- Starting at least 4 weeks before taking POMALYST
 - While taking POMALYST
 - During breaks (dose interruptions)
 - For at least 4 weeks after stopping POMALYST

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

- I will have pregnancy tests—performed by my healthcare provider—according to the schedule listed below:
- 10 to 14 days before receiving my first prescription for POMALYST, and again 24 hours before receiving my first prescription for POMALYST
 - Every week during the first 4 weeks of my treatment with POMALYST
 - Every 4 weeks during the rest of my treatment if I have a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if I have an irregular menstrual cycle
- I will have these pregnancy tests even if I do not get my period because of my treatment
- I will need to take another pregnancy test performed by my healthcare provider if my medication is not dispensed within 7 days of taking my pregnancy test
- I will stop taking POMALYST and call my doctor right away if I:
- Become pregnant while taking POMALYST, or
 - Miss my period or have unusual menstrual bleeding, or
 - Stop using birth control, or
 - Think—**for any reason**—that I am pregnant or may be pregnant
- If I become pregnant or think I may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my doctor is not available
- I will complete the mandatory confidential monthly survey while taking POMALYST
- I will keep my POMALYST prescription out of the reach of children
- I will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused POMALYST capsules can also be returned to my POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to me

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Section 2. Authorization

I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
 - Analyze data for internal business purposes on the use of POMALYST
 - Evaluate the effectiveness of the POMALYST REMS™ program
 - Use in any other manner as required or permitted by law
 - Provide me with information about POMALYST or my condition
- This authorization will remain in effect for 12 months after I stop POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the POMALYST REMS™ program
- Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want to participate in POMALYST REMS™ program. I understand that by refusing to participate in POMALYST REMS™ program, I will not be able to receive POMALYST. However, I understand that I can speak with my doctor about other treatment options for my condition
- Upon signing this form, **I authorize my healthcare provider to begin my treatment with POMALYST**



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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the POMALYST REMS™ program, I will not be able to receive POMALYST. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with POMALYST (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category Menstruating: Surgical Menopause: Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the patient.

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed POMALYST for you. POMALYST is available only through a restricted distribution program called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, you must read and agree to all of the instructions in the POMALYST REMS™ program.

Any unborn baby of a female taking POMALYST can have severe birth defects or even die.

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

INSTRUCTIONS

Before starting your treatment with POMALYST, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 5.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the POMALYST® (pomalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the POMALYST REMS™ program and is authorized to consent to treatment with POMALYST on behalf of the patient.

For more information, visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- POMALYST can cause severe birth defects or death to unborn babies of females taking POMALYST
- I am not pregnant
- I am not able to get pregnant because:
 - I have had both of my ovaries and/or my uterus removed, or
 - I have been in natural menopause for at least 2 years
- My POMALYST prescription is **only** for me and is not to be shared with others
- I have read and understood the POMALYST Patient Guide to the POMALYST REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- My healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by Celgene to assist with the POMALYST REMS™ program

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

I will:

- I will complete the mandatory confidential survey every 6 months while taking POMALYST
- I will keep my POMALYST prescription out of the reach of children
- I will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused POMALYST capsules can also be returned to my POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to me

I will not:

- I will **not** share my POMALYST capsules with anyone even if they have symptoms like mine
- I will **not** donate blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Section 2. Authorization

I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
 - Analyze data for internal business purposes on the use of POMALYST
 - Evaluate the effectiveness of the POMALYST REMS™ program
 - Use in any other manner as required or permitted by law
 - Provide me with information about POMALYST or my condition
- This authorization will remain in effect for 12 months after I stop POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the POMALYST REMS™ program
- Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want to participate in the POMALYST REMS™ program. I understand that by refusing to participate in POMALYST REMS™ program, I will not be able to receive POMALYST. However, I understand that I can speak with my doctor about other treatment options for my condition
- Upon signing this form, **I authorize my healthcare provider to begin my treatment with POMALYST**



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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the POMALYST REMS™ program, I will not be able to receive POMALYST. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with POMALYST and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category Menstruating: Surgical Menopause: Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the patient.

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed POMALYST for your child.* POMALYST is available only through a restricted distribution program called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, patients must read and agree to all of the instructions in the POMALYST REMS™ program.

If your child is pregnant or becomes pregnant while taking POMALYST, it is important to know that the unborn baby can have severe birth defects or even die.

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

INSTRUCTIONS

Before your child starts treatment with POMALYST, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- POMALYST can cause severe birth defects or death to the unborn baby if my child is pregnant or becomes pregnant during treatment
- My child is not pregnant and will not get pregnant while being treated with POMALYST
- It is possible for my child to get pregnant if:
 - She has her period (is menstruating) or has shown any sign of puberty, or
 - Her period has stopped because of treatment
 - And she has sex with a male
- Not having sex is the only birth control method that is 100% effective
- My child is not breastfeeding and will not breastfeed while being treated with POMALYST
- My child's POMALYST prescription is **only** for her and is not to be shared with others
- We have read and understood the POMALYST Patient Guide to the POMALYST REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- We may be contacted by Celgene to assist with the POMALYST REMS™ program
- My child will NOT donate blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

I will tell my child that:

- She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male unless otherwise recommended by her doctor. Her doctor may recommend that she use **at the same time** 2 different birth control methods **every time** she has sex with a male if she cannot use a hormonal or intrauterine device (IUD) method

Unless she chooses not to have sexual intercourse with a male at any time (abstinence), she must always use acceptable birth control

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom
Tubal ligation (having your tubes tied)	Diaphragm
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Cervical cap

- She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male:
- Starting at least 4 weeks before taking POMALYST
 - While taking POMALYST
 - During breaks (dose interruptions)
 - For at least 4 weeks after stopping POMALYST

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

- She must have pregnancy tests—performed by her healthcare provider—according to the schedule listed below:
 - 10 to 14 days before receiving her first prescription for POMALYST, and again 24 hours before receiving her first prescription for POMALYST
 - Every week during the first 4 weeks of her treatment with POMALYST
 - Every 4 weeks during the rest of her treatment if she has a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if she has an irregular menstrual cycle
- She must have these pregnancy tests even if she does not get her period because of her treatment
- She must take another pregnancy test performed by her healthcare provider if her medication is not dispensed within 7 days of taking her pregnancy test
- She must stop taking POMALYST and I will call her doctor right away if she:
 - Becomes pregnant while taking POMALYST, or
 - Misses her period or has unusual menstrual bleeding, or
 - Stops using birth control, or
 - Thinks—**for any reason**—that she is pregnant or may be pregnant
- If she becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my child's doctor is not available
- We will complete the mandatory confidential monthly survey while she is taking POMALYST
- We will keep her POMALYST prescription out of the reach of other children
- We will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused POMALYST capsules can also be returned to my child's POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to my child

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Section 2. Authorization

I understand and confirm that:

- By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
- Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
 - Analyze data for internal business purposes on the use of POMALYST
 - Evaluate the effectiveness of the POMALYST REMS™ program
 - Use in any other manner as required or permitted by law
 - Provide me and my child with information about POMALYST or my child's condition
- This authorization will remain in effect for 12 months after my child stops POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the POMALYST REMS™ program
- Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want my child to participate in the POMALYST REMS™ program. I understand that by refusing to have my child participate in the POMALYST REMS™ program, she will not be able to receive POMALYST. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with POMALYST**



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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the POMALYST REMS™ program, she will not be able to receive POMALYST. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with POMALYST (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category Menstruating: Surgical Menopause: Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed POMALYST for your child.* POMALYST is available only through a restricted distribution program called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, patients must read and agree to all of the instructions in the POMALYST REMS™ program.

Any unborn baby of a girl taking POMALYST can have severe birth defects or even die.

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

INSTRUCTIONS

Before your child starts treatment with POMALYST, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 5.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- POMALYST can cause severe birth defects or death to unborn babies of females taking POMALYST
- My child is not pregnant
- My child is not able to get pregnant because she has not yet started her period (is not menstruating)
- My child's POMALYST prescription is **only** for her and is not to be shared with others
- We have read and understood the POMALYST Patient Guide to the POMALYST REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- We may be contacted by Celgene to assist with the POMALYST REMS™ program

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Female Child Who Can Not Get Pregnant

I will tell my child that:

- We will complete the mandatory confidential monthly survey while my child is taking POMALYST
- We will keep my child's POMALYST prescription out of the reach of other children
- We will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused POMALYST capsules can also be returned to my child's POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to my child
- She must **not** share her POMALYST capsules with anyone even if they have symptoms like hers
- She must **not** donate blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

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POMALYST® (pomalidomide) Patient-Physician Agreement

Female Child Who Can Not Get Pregnant

Section 2. Authorization

I understand and confirm that:

- By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
- Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of POMALYST
 - Evaluate the effectiveness of the POMALYST REMS[™] program
 - Use in any other manner as required or permitted by law
 - Provide me and my child with information about POMALYST or my child's condition
- This authorization will remain in effect for 12 months after my child stops POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the POMALYST REMS[™] program
- Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want my child to participate in the POMALYST REMS[™] program. I understand that by refusing to have my child participate in the POMALYST REMS[™] program, she will not be able to receive POMALYST. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with POMALYST**



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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the POMALYST REMS™ program, she will not be able to receive POMALYST. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with POMALYST and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category Menstruating: Surgical Menopause: Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

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Confidential and Proprietary

57

POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Male

Please read the following statements carefully.

Your doctor has prescribed POMALYST for you. POMALYST is available only through a restricted distribution program called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, you must read and agree to all of the instructions in the POMALYST REMS™ program.

If a female you have sex with is pregnant or becomes pregnant by you while you are taking POMALYST, it is important for you to know that your unborn baby can have severe birth defects or even die.

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

INSTRUCTIONS

Before starting your treatment with POMALYST, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the POMALYST® (pomalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the POMALYST REMS™ program and is authorized to consent to treatment with POMALYST on behalf of the patient.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Male

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- POMALYST can cause severe birth defects or death to my unborn baby if I have sex with a female who is pregnant or who is able to get pregnant during my treatment
- My semen may contain POMALYST even after I stop treatment. I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST
- Not having sex is the only birth control method that is 100% effective
- My POMALYST prescription is **only** for me and is not to be shared with others
- I have read and understood the POMALYST Patient Guide to the POMALYST REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- My healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by Celgene to assist with the POMALYST REMS™ program

BAR CODE HERE

POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Male

- I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant, even if I have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- I will use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant:
 - While taking POMALYST
 - During breaks (dose interruptions)
 - For 4 weeks after stopping POMALYST
- I will call my doctor right away if I:
 - Have unprotected sex with a female who is pregnant or who is able to get pregnant
 - Think—**for any reason**—that my sexual partner is pregnant or may be pregnant
- If my partner becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my doctor is not available
- I will complete the mandatory confidential monthly survey while taking POMALYST
- I will keep my POMALYST prescription out of the reach of children
- I will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused POMALYST capsules can also be returned to my POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to me

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Male

- I will **not** share my POMALYST capsules with anyone even if they have symptoms like mine
- I will **not** donate blood or sperm while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST

Section 2. Authorization

I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
 - Analyze data for internal business purposes on the use of POMALYST
 - Evaluate the effectiveness of the POMALYST REMS™ program
 - Use in any other manner as required or permitted by law
 - Provide me with information about POMALYST or my condition

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Male

- This authorization will remain in effect for 12 months after I stop POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the POMALYST REMS™ program
- Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want to participate in the POMALYST REMS™ program. I understand that by refusing to participate in the POMALYST REMS™ program, I will not be able to receive POMALYST. However, I understand that I can speak with my doctor about other treatment options for my condition
- Upon signing this form, **I authorize my healthcare provider to begin my treatment with POMALYST**



Pomalyst REMS™



POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation.

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Adult Male

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the POMALYST REMS™ program, I will not be able to receive POMALYST. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if he has any questions regarding his treatment with POMALYST (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.

Patient	Prescriber
Name	Name
Identification Number	Identification Number
Address	Address
Telephone Number	Telephone Number
Date of Birth	Fax Number
Sex	
Diagnosis	
Patient or Authorized Representative's Signature:	Prescriber's Signature:
Signature Date:	Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the patient.

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Male Child

Please read the following statements carefully.

Your doctor has prescribed POMALYST for your child.* POMALYST is available only through a restricted distribution program called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, patients must read and agree to all of the instructions in the POMALYST REMS™ program.

If a female your child has sex with is pregnant or becomes pregnant by your child while he is taking POMALYST, it is important to know that the unborn baby can have severe birth defects or even die.

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

INSTRUCTIONS

Before your child starts treatment with POMALYST, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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POMALYST® (pomalidomide) Patient-Physician Agreement

Male Child

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- POMALYST can cause severe birth defects or death to the unborn baby if my child has sex with a female who is pregnant or who is able to get pregnant during his treatment
- My child's semen may contain POMALYST even after he stops treatment. He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST
- Not having sex is the only birth control method that is 100% effective
- My child's POMALYST prescription is **only** for him and is not to be shared with others
- We have read and understood the POMALYST Patient Guide to the POMALYST REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- We may be contacted by Celgene to assist with the POMALYST REMS™ program

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Male Child

I will tell my child that:

- He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant, even if he has had a successful vasectomy (tying of the tubes to prevent passing of sperm)
- He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant:
 - While taking POMALYST
 - During breaks (dose interruptions)
 - For 4 weeks after stopping POMALYST
- I will call his doctor right away if he:
 - Has unprotected sex with a female who is pregnant or who is able to get pregnant
 - Thinks—**for any reason**—that his sexual partner is pregnant or may be pregnant
- If my child's partner becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my child's doctor is not available
- We will complete the mandatory confidential monthly survey while my child is taking POMALYST
- We will keep his POMALYST prescription out of the reach of other children
- We will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give us a refund for the capsules my child did not take. Unused POMALYST capsules can also be returned to my child's POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to my child

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Male Child

- He must **not** share his POMALYST capsules with anyone even if they have symptoms like his
- He must **not** donate blood or sperm while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST

Section 2. Authorization

I understand and confirm that:

- By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
 - Analyze data for internal business purposes on the use of POMALYST
 - Evaluate the effectiveness of the POMALYST REMS™ program
 - Use in any other manner as required or permitted by law
 - Provide me and my child with information about POMALYST or my child's condition

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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Male Child

- This authorization will remain in effect for 12 months after my child stops POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the POMALYST REMS™ program
- Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want my child to participate in the POMALYST REMS™ program. I understand that by refusing to have my child participate in the POMALYST REMS™ program, he will not be able to receive POMALYST. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with POMALYST**



Pomalyst REMS™



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POMALYST® (pomalidomide) Patient-Physician Agreement Form

Male Child

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the POMALYST REMS™ program, he will not be able to receive POMALYST. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and his parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and his parent/guardian if they have any questions regarding the child's treatment with POMALYST (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.

Patient	Prescriber
Name	Name
Identification Number	Identification Number
Address	Address
Telephone Number	Telephone Number
Date of Birth	Fax Number
Sex	
Diagnosis	
Patient or Authorized Representative's Signature:	Prescriber's Signature:
Signature Date:	Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

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[Housing Unit Front Cover Flap]

((POMALYST REMS™ logo))

POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety kit

[Housing Unit Front Cover]

Risks of POMALYST® (pomalidomide)

- POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or embryo-fetal death. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST
- POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

POMALYST 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 logo))

[Housing Unit Spine]

**POMALYST Risk Evaluation and Mitigation Strategy (REMS)[™] program
education and prescribing safety kit**

[Housing Unit Back Cover]

((POMALYST REMS™ logo))

Prescriber quick reference guide

1. The prescriber provides comprehensive counseling.
2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
3. The prescriber completes POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
4. Female patients complete initial mandatory confidential survey by:
 - Visiting **www.CelgeneRiskManagement.com**, or
 - Calling Celgene Customer Care Center at **1-888-423-5436**Male patients do not need to complete the initial survey.

All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to POMALYST REMS™ Program.

5. The prescriber completes mandatory confidential survey and receives authorization number by:
 - Visiting **www.CelgeneRiskManagement.com**, or
 - Calling Celgene Customer Care Center at **1-888-423-5436**
6. The prescriber writes POMALYST prescription and includes authorization number and patient risk category.
7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the POMALYST REMS™ procedures.

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

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

((Celgene logo)) ((POMALYST REMS™ logo)) ((POMALYST logo))

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Dear Prescriber:

Enclosed are your POMALYST REMS™ program education materials

Celgene Corporation is pleased to provide you with the enclosed materials for use in the POMALYST REMS™ program.

Important Information about the POMALYST REMS™ program

- To avoid embryo-fetal exposure, POMALYST® (pomalidomide) is only available under a restricted distribution program called “POMALYST REMS™”
- Pomalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with pomalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of pomalidomide in human semen. Male patients taking POMALYST should not donate sperm. Males receiving POMALYST must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with POMALYST REMS™ can prescribe and dispense POMALYST to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program

As a prescriber certified with the POMALYST REMS™ program, please review and familiarize yourself with the contents of the enclosed POMALYST REMS™ Kit:

Prescriber Materials

- POMALYST REMS™ software and Installation Guide
- Prescriber Guide to POMALYST REMS™ Program
- POMALYST Full Prescribing Information

Patient Materials (Patient Resource Pack)

- Patient Guide to POMALYST REMS™ Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,

Jerome B. Zeldis, MD, PhD

Chief Medical Officer

Enclosures

Risks of POMALYST® (pomalidomide)

- POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or embryo-fetal death. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST
- POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

POMALYST 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.

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

((Celgene logo)) ((POMALYST REMS™ logo)) ((POMALYST logo))

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[Front Cover]

**Pharmacy Guide to
((POMALYST REMS™ logo))
Risk Evaluation and Mitigation Strategy (REMS)™ Program**

**Important information about POMALYST® (pomalidomide) and the
POMALYST 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 pharmacists certified with the POMALYST REMS™ program can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program
- Dispensing pharmacists must be educated on the POMALYST REMS™ program and on dispensing procedures for POMALYST
- Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

((POMALYST logo))

Table of contents

Guidelines for ordering, counseling, and dispensing POMALYST® (pomalidomide)	3
POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ education and counseling checklist for pharmacies.....	6
Rules for dispensing and shipping	6
Adverse drug experience reporting procedure for healthcare professionals.....	7

Guidelines for ordering, counseling, and dispensing POMALYST® (pomalidomide)

Dispensing pharmacies must be certified in the POMALYST REMS™ program with Celgene and must be educated in the following dispensing procedures.

Step 1. Review incoming POMALYST prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them.
 - Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted
 - Faxed prescriptions are permissible depending on state laws
- B. Make sure the prescription is signed and dated.
- C. Confirm the prescription is written for a 4-week (28-day) supply or less.
- D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription.

Step 2. Counsel patient

- A. Make sure a **certified POMALYST REMS™** counselor counsels the patient.
- B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.
- C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST, make sure to document these experiences using acceptable documentation as noted on the checklist.
 - **Acceptable documentation examples:**
 1. Celgene ADE form and fax confirmation
 2. Pharmacy log
- D. Report adverse drug experiences that are suspected to be associated with the use of POMALYST to Celgene Drug Safety within 24 hours. See the Adverse Drug Experience Reporting Procedure on page 7 for more information.

Step 3. Obtain confirmation number from Celgene Customer Care

- A. Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week.
 - Enter the pharmacy NABP number or DEA number
 - Enter the authorization number written on the prescription
 - Enter the number of capsules and milligram strength being dispensed
- B. Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.
- C. If you do not obtain a confirmation number, do not dispense POMALYST.

Step 4. Dispensing

- A. No Refills. A new prescription is required for each dispense. **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.**
- B. Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.
- C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.
 - **Acceptable documentation examples:**
 1. Signed Education and Counseling checklist (if counseling pharmacist and dispensing pharmacist are the same)
 2. Pharmacy log
- D. Document the dispense date and maintain a record on acceptable documentation.
 - **Acceptable documentation examples:**
 1. Shipping receipt
 2. Pharmacy dispensing log
- E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.
- F. A signature is required for all shipping and dispense if picked up by patient.

Step 5. Perform drug accountability

- A. Pharmacy shall keep an inventory log for POMALYST, by strength, reflecting its on-hand inventory at all times.
- B. Do not transfer POMALYST to another pharmacy without prior authorization from Celgene.
- C. Accept unused POMALYST (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal.

POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ education and counseling checklist for pharmacies

Ensure your patients know the risks

Before you are able to fill a prescription for POMALYST® (pomalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off ([✓]) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.

Be prepared to provide the following information for each checklist:

((IMAGE OF CHECKLIST))

Authorization Number	Confirmation Number	Confirmation Date
Pharmacy Name	Pharmacy Address (including City, State, ZIP Code)	
Counselor Name	Work Phone Number	Extension
Patient Name	Patient Date of Birth	Patient Identification Number

Rules for dispensing and shipping

Making sure before you release POMALYST

DO NOT DISPENSE OR SHIP POMALYST TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing POMALYST prescription

For further information about POMALYST, please refer to the full Prescribing Information, enclosed.

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of POMALYST® (pomalidomide).

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 at: **<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

[Back Cover]

For more information about POMALYST® (pomalidomide) and the POMALYST REMS™ program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

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

((Celgene logo))

((POMALYST REMS™ logo))

((POMALYST logo))

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((POMALYST REMS™ logo))

Education and counseling checklist for pharmacies

POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety

Authorization No.: Confirmation No.: Confirmation Date:

Pharmacy Name:

Pharmacy Address:

Counselor Name: Work Phone: Ext.:

Patient Name: Date of Birth: Patient I.D. No.:

Risk Category:

Checklist for female patients of reproductive potential

- I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity

- Not taking POMALYST if pregnant or breastfeeding

- Using **at the same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth controls pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic

condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male

Continuing to use at the **same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking POMALYST, while taking POMALYST, during dose interruptions, and for at least 4 weeks after stopping POMALYST **every time they have sex with a male**, or abstaining from sex with a male

Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks

1 of 4

(continued on next page)

- The need to stop taking POMALYST® (pomalidomide) right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately

 - Possible side effects include deep vein thrombosis and pulmonary embolism

 - Not sharing POMALYST capsules with anyone—especially with females who can get pregnant

 - Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

 - Not breaking, chewing, or opening POMALYST capsules

 - Instructions on POMALYST dose and administration
- Milligram (mg) Strength_____ Number of Capsules Dispensed_____

FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

- I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- Possible side effects include deep vein thrombosis and pulmonary embolism

- Not sharing POMALYST capsules with anyone—especially with females who can get pregnant

Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

Not breaking, chewing, or opening POMALYST capsules

Instructions on POMALYST dose and administration

Milligram (mg) Strength_____ Number of Capsules Dispensed_____

FEMALE CHILDREN (<18 YEARS OF AGE):

Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

Parent or legal guardian must inform the child's doctor when the child begins menses

2 of 4

(continued on next page)

Checklist for male patients

I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant)

Female partners of males taking POMALYST® (pomalidomide) must call their healthcare provider right away if they get pregnant

Possible side effects include deep vein thrombosis and pulmonary embolism

Not sharing POMALYST capsules with anyone—especially with females who can get pregnant

Not donating blood or sperm while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

Not breaking, chewing, or opening POMALYST capsules

Instructions on POMALYST dose and administration

Milligram (mg) Strength_____ Numbers of Capsules Dispensed_____

MALE CHILDREN (<18 YEARS OF AGE):

Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

Rules for dispensing and shipping

DO NOT DISPENSE OR SHIP POMALYST® (pomalidomide) TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- Prescription has an authorization number and patient risk category written on it

- You have counseled the patient

- You have obtained a confirmation number and a confirmation date

- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained

- The Medication Guide is included with the prescription

- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing POMALYST prescription

All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.

Counselor Signature: _____ **Date:** _____

For more information about POMALYST and the POMALYST REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

86 Morris Ave
Summit, NJ 07901

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

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

((Celgene logo)) ((POMALYST REMS™ logo)) ((POMALYST logo))

POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation.

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Questions for POMALYST REMS™ Pharmacy Certification Quiz

1. Authorization numbers for females of reproductive potential are valid for up to ____ days:
(Mandatory Question)
 - a. **7 days**
 - b. 10 days
 - c. 14 days
 - d. 28 days
2. It is not necessary to obtain a confirmation number to dispense. *(Mandatory Question)*
 - a. True
 - b. **False**
3. Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for each treatment. *(Mandatory Question)*
 - a. **True**
 - b. False
4. It is not required to retain the prescription with the authorization and confirmation numbers for each filled prescription. It is not necessary to complete the Education and Counseling Checklist.
 - a. True
 - b. **False**
5. According to the package insert's boxed warnings and warnings and precautions, venous thromboembolism have been reported in patients receiving POMALYST *(Mandatory Question)*
 - a. **True**
 - b. False
6. POMALYST can cause serious birth defects. *(Mandatory Question)*
 - a. **True**
 - b. False
7. What pregnancy precautions are required for a female of reproductive potential with respect to heterosexual sexual contact?
 - a. **Must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time she has sex with a male, beginning at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks after stopping therapy**
 - b. Abstain from having any heterosexual sexual contact only while taking therapy
 - c. After stopping therapy it is okay to get pregnant at any time
 - d. Use 2 forms of birth control 2 weeks before taking therapy
8. What precautions are required for a male with respect to sexual contact with his female partner of reproductive potential?
 - a. **Use of a latex or synthetic condom every time he has sexual intercourse with a female of reproductive potential during therapy (including dose interruptions) and for 4 weeks after stopping therapy, even if he has undergone a successful vasectomy**
 - b. Abstain from having any sexual contact with a females of reproductive potential only while taking therapy

- c. Use latex or synthetic condoms while taking therapy. No precautions are necessary once treatment has stopped
 - d. Males taking therapy who have had a vasectomy do not need to use latex or synthetic condoms
9. For all Celgene REMS programs, female patients of reproductive potential must have a negative pregnancy test: *(Mandatory Question)*
- a. Prior to initial prescription
 - b. Prior to subsequent prescription
 - c. **All of the above**
 - d. None of the above
10. Adverse drug experiences that are suspected to be associated with the use of therapy, and any suspected pregnancy occurring during treatment, must be reported to Celgene. *(Mandatory Question)*
- a. **True**
 - b. False
11. The Medication Guide must be provided every time POMALYST is dispensed. *(Mandatory Question)*
- a. **True**
 - b. False
12. A certified Celgene REMS pharmacy cannot dispense more than a _____ supply of POMALYST.
- a. **28 day**
 - b. 3 month
 - c. 2 week
 - d. 1 year
13. Authorization numbers for patient risk categories other than females of reproductive potential are valid for up to _____ days. *(Mandatory Question)*
- a. **30 days**
 - b. 10 days
 - c. 7 days
 - d. 28 days
14. A male patient can donate sperm at any time during therapy.
- a. True
 - b. **False**

REMS-POM12165

((POMALYST REMS™ logo))

Patient Resource Pack

POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program

The Patient Resource Pack contains:

- Patient Guide to POMALYST REMS™ Program
- Emergency Contraception Brochure
- Medication Guide

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

((Celgene logo))

((POMALYST logo))

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Patient Guide to

((Pomalyst REMS™ logo))

Risk Evaluation and Mitigation Strategy (REMS)™ Program

This guide provides you important information about:

- The risks of POMALYST® (pomalidomide)
 - Birth defects (deformed babies) or death of an unborn baby
 - Blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)
- The POMALYST REMS™ Program
 - What females who can get pregnant need to know
 - Birth control options
 - What females who can not get pregnant need to know
 - What males need to know

((POMALYST logo))

Table of contents

Risks of POMALYST® (pomalidomide).....	4
What is the POMALYST REMS™ program?	4
What do all patients need to know about the POMALYST REMS™ program?.....	5
What do females who can get pregnant need to know about the POMALYST REMS™ program?.....	6
What do females who can not get pregnant need to know about the POMALYST REMS™ program?.....	12
What do males need to know about the POMALYST REMS™ program?.....	14
Mandatory confidential patient surveys.....	16
Warning to patients taking POMALYST.....	18

Risk of POMALYST® (pomalidomide)

POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or death to unborn babies. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST.

POMALYST causes higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

What is the POMALYST REMS™ program?

To avoid serious risks to unborn babies, POMALYST is only available under a restricted distribution program called the “POMALYST Risk Evaluation and Mitigation Strategy (REMS)™.” Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST. In order to receive POMALYST, patients must be enrolled in the POMALYST REMS™ program and agree to follow the requirements.

For more information about POMALYST and the POMALYST REMS™ program, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center toll-free at **1-888-423-5436**.

What do all patients need to know about the POMALYST REMS™ program?

General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects
- POMALYST® (pomalidomide) must be kept out of the reach of children
- Do not open or unnecessarily handle POMALYST capsules
- Keep POMALYST in a cool, dry place
- Do **not** donate blood while you are taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST
- Unused POMALYST capsules should be returned for disposal to Celgene by calling **1-888-423-5436**, or to your POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to you

What do females who can get pregnant need to know about the POMALYST REMS™ program?

A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says you understand that POMALYST should not be used during pregnancy, and that you agree not to become pregnant while taking POMALYST
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking POMALYST
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for POMALYST, and again within 24 hours before you receive your first prescription for POMALYST. If you are pregnant, you cannot take POMALYST
- You will have pregnancy tests before starting POMALYST and while taking POMALYST, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for POMALYST, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing POMALYST® (pomalidomide), your POMALYST REMS™ certified pharmacy will contact you to discuss treatment
- Your healthcare provider will talk with you about your birth control options

1. Choose at least 1 highly effective method and at least 1 additional effective method of birth control. Talk to your healthcare provider about the following acceptable birth control methods. See below.

Reliable Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	Male latex or synthetic condom + Diaphragm + Cervical cap
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	
Tubal ligation (having your tubes tied)	
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	

2. Use the 2 methods of birth control at the same time

- Remember:** You must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons

**What do females who can get pregnant need to know about the POMALYST REMS™ program?
(continued)**

- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- **Remember, not having sex is the only method of birth control that is 100% effective**

3. Unacceptable methods of birth control

- Progesterone-only “mini-pills”
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield*

4. Take pregnancy tests

- You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for POMALYST® (pomalidomide) and again within 24 hours before receiving your first prescription for POMALYST. Both pregnancy tests must have a negative result

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

B. While taking POMALYST® (pomalidomide)

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use
- You will have a pregnancy test performed by your healthcare provider:
 - Every week during the first 4 weeks of treatment, then
 - Every 4 weeks if your menstrual cycles are regular, or
 - Every 2 weeks if your cycles are irregular
 - If you miss your period or have unusual menstrual bleeding, or
 - If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control, stop taking POMALYST immediately and call your healthcare provider right away

**What do females who can get pregnant need to know about the POMALYST REMS™ program?
(continued)**

- If you get pregnant, or think you may be pregnant, you must **immediately** stop taking POMALYST® (pomalidomide). Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must not breastfeed a baby while you are taking POMALYST
- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking POMALYST® (pomalidomide)

- You must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
 - For at least 4 weeks after stopping POMALYST, or
 - Do not have any sex with a male for 4 weeks after stopping POMALYST

See also “General guidelines” on page 5 for requirements for all patients.

What do females who can not get pregnant need to know about the POMALYST REMS™ program?

A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
 - You have been in natural menopause for at least 2 years, or
 - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting POMALYST
- Before your healthcare provider can write your prescription for POMALYST, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing POMALYST® (pomalidomide), your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

B. While taking POMALYST

- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

See also “General guidelines” on page 5 for requirements for all patients.

What do males need to know about the POMALYST REMS™ program?

- You must use a latex or synthetic condom **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form. You must agree that while taking POMALYST you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant
- Before dispensing POMALYST, your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

B. While taking POMALYST

- You must use a latex or synthetic condom **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must **not** donate sperm while taking POMALYST® (pomalidomide) (including during breaks [dose interruptions])
- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking POMALYST

- For 4 weeks after receiving your last dose of POMALYST, you must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping POMALYST

See also “General guidelines” on page 5 for requirements for all patients.

Mandatory confidential patient surveys

As a patient who is enrolled in the POMALYST REMS™ program for POMALYST® (pomalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

Adult females who can get pregnant

- Initial survey before first prescription
- Monthly

Adult females who can not get pregnant

- Initial survey before first prescription
- Every six months

Female children

- Initial survey before first prescription
- Monthly

Males

- No initial survey
- Monthly

Mandatory confidential survey process

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a POMALYST REMS™ certified pharmacy. The POMALYST REMS™ certified pharmacy will contact you to discuss your POMALYST® (pomalidomide) therapy. You will not receive your medication until you speak with the POMALYST REMS™ certified pharmacy

- For more information, contact the Celgene Customer Care Center at **1-888-423-5436**

Warning to patients taking POMALYST® (pomalidomide)

Attention females:

Do **not** take POMALYST if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

Attention males:

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST.

Attention all patients:

You must **not** donate blood while taking POMALYST® (pomalidomide), during breaks (dose interruptions), and for 4 weeks after stopping POMALYST.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects.

POMALYST must be kept out of the reach of children. Return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**, or to your POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to you.

[Back Cover]

For more information about POMALYST® (pomalidomide) and the POMALYST REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation

86 Morris Ave

Summit, NJ 07901

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

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((POMALYST REMS logo))

((POMALYST logo))

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REMS-POM12146

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107

Reference ID: 3258521

Celgene logo

REMS Patient Survey Reminder

Patient Name _____ Date Survey Available _____

Doctor Office Contact and Phone # _____

Product _____ Pharmacy Name _____

Telephone Survey

OR

Website Survey



From a touchtone phone dial **1-888-423-5436**

Para español, oprime el numero dos

to identify that you are a patient

to take a survey

Enter your 9-digit patient identification number (the number you provided during the enrollment process – for example your Social Security Number).

From the menu provided, select the drug that you have been prescribed



Your survey will then begin. Please answer all of the questions. Confirmation that the survey has been completed will be provided at the end of your survey.

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Access the internet and type in the website address

www.CelgeneRiskManagement.com

You are not required to have a User Name or Password to complete a survey. To take your survey, left click your mouse on the button



You will be asked for the following information. Please enter the information exactly as it was provided during your enrollment process

A screenshot of a web form titled 'Please enter your details in the form below to continue with the patient survey.' It has three input fields: 'Patient Last Name', 'Patient First Name', and 'Patient Identification Number'. Below the third field is a note: 'Social Security Number e.g. 123456789'. At the bottom, it says 'Please be sure to complete the survey in its entirety and upon completion send to Celgene.'

After entering the information above, click



Survey questions will be displayed 1 per page. Please be sure to complete the survey in its entirety. A summary page displaying your survey answers will be displayed at the end of your survey. Upon completion, send the survey to Celgene by clicking

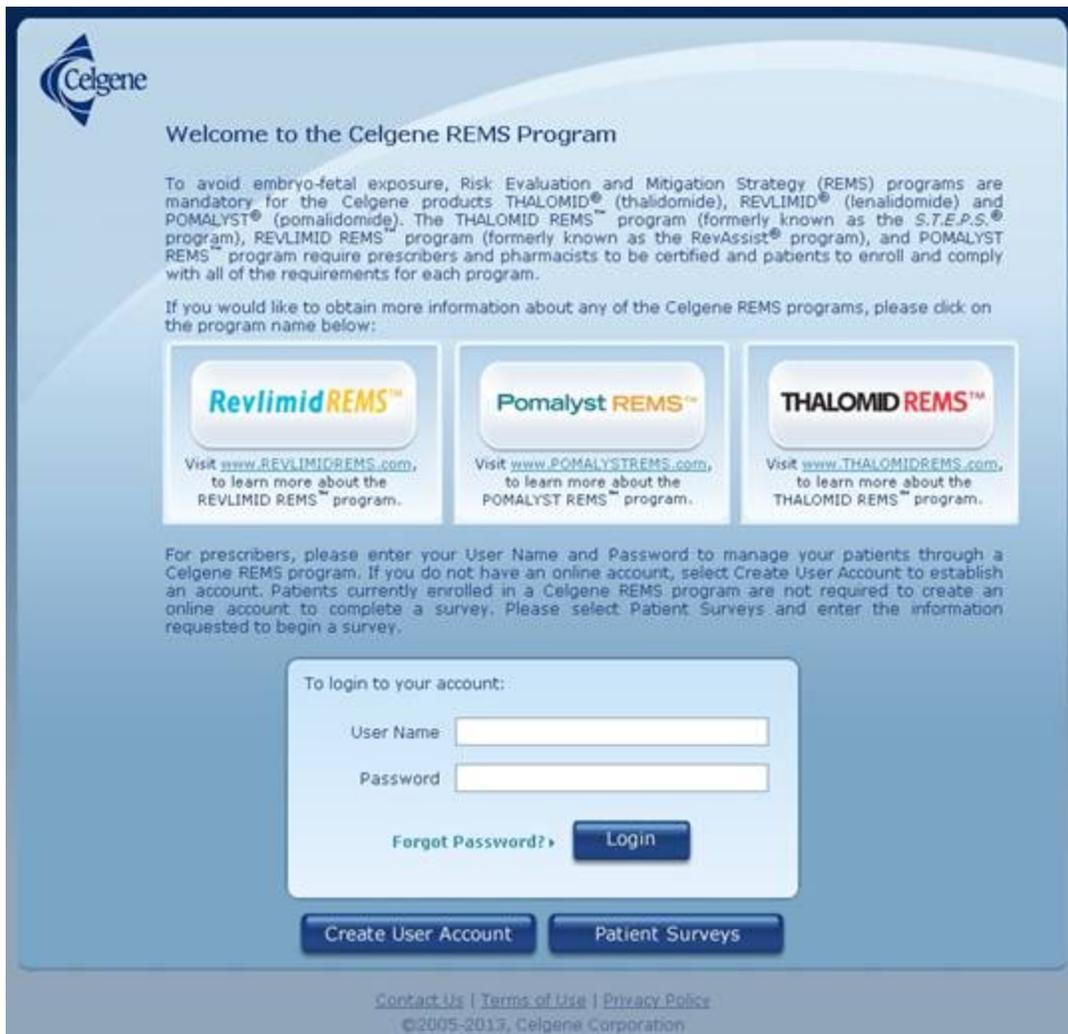


1/13 REMS-GEN12169

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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 and a brief description. Below these buttons, a paragraph explains the login process for prescribers. A login form is provided with fields for "User Name" and "Password", a "Forgot Password?" link, and a "Login" button. At the bottom of the form are "Create User Account" and "Patient Surveys" buttons. The footer contains links for "Contact Us", "Terms of Use", and "Privacy Policy", along with the copyright notice "©2005-2013, Celgene Corporation".

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](#)
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Home Page (after prescriber login)

The screenshot shows the Celgene Home Page for prescribers after login. At the top left, there is a text input field labeled "first last" and three buttons: "Home", "Help", and "Logout". The Celgene logo is in the top left corner, and the word "Home" is in the top right corner. The main content area features a central instruction: "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." Below this are three columns, each for a different product: 1. **REVLIMID REMS™** (formerly known as the RevAssist® program). It includes a button for "RevlimidREMS™" and text: "Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS." 2. **POMALYST REMS™**. It includes a button for "PomalystREMS™" and text: "Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS." 3. **THALOMID REMS™** (formerly known as the S.T.E.P.S.® program). It includes a button for "THALOMIDREMS™" and text: "Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS." Below these columns, a text block states: "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." At the bottom of this section are two buttons: "Prescriber Dashboard" and "Manage My Account". The footer contains links for "Contact Us", "Terms of Use", and "Privacy Policy", along with the copyright notice "©2005-2013, Celgene Corporation".

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". Below the user name and navigation buttons, the "Pomalyst REMS™" logo is on the left, and "POMALYST REMS™ Main Menu" is on the right. The main content area features five teal buttons with icons and text:

-  New PPAF/
Patient Enrollment
-  Work with Saved/
Submitted PPAF Forms
-  Prescriber Survey
-  Standard
Prescription Form
-  Veterans Administration
Prescription Form

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.



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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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Pomalyst REMS™

POMALYST REMS™ Home

About POMALYST REMS™

Important Safety Information 

Full Prescribing Information 

Patient Medication Guide 

Prescriber Resources

Patient Resources

Pharmacist Resources

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About 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.

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.

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 a 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 an Education and Counseling Checklist
- The certified pharmacy dispenses POMALYST to patient along with a Medication Guide

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Pomalyst REMS™

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

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Field

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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- [POMALYST REMS™ Home](#)
- [About POMALYST REMS™](#)
- [Important Safety Information !\[\]\(0c25d1004bd94b54acd60024e81ec010_img.jpg\)](#)
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For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

Patient 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.

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  | Patient Survey Reminder Card  |
| Patient Medication Guide  | Visit Planned Parenthood site for Emergency Contraception Brochure |

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Pomalyst REMS™

POMALYST REMS™ Home

About POMALYST REMS™

Important Safety Information 

Full Prescribing Information 

Patient Medication Guide 

Prescriber Resources

Patient Resources

Pharmacist Resources

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Fold

Pharmacist Resources

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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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[POMALYST REMS™ Home](#)

[About POMALYST REMS™](#)

[Important Safety Information](#)



[Full Prescribing Information](#)



[Patient Medication Guide](#)



[Prescriber Resources](#)

[Patient Resources](#)

[Pharmacist Resources](#)

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Site map

[POMALYST REMS™ Home](#)

[About POMALYST REMS™](#)

[Prescriber Resources](#)

[Patient Resources](#)

[Pharmacist Resources](#)

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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

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

OK CANCEL 

POMALYST Risk Evaluation

able of becoming pregnant.
provided adequate precautions are taken
a restricted distribution program called
™ program can prescribe and dispense
of the POMALYST REMS™ program
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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TITLE PAGE



POMALYST® (POMALIDOMIDE) PREGNANCY EXPOSURE REGISTRY

Version 2

Celgene Corporation
86 Morris Ave.
Summit, NJ 07901

TABLE OF CONTENTS

TITLE PAGE 120

1.	INTRODUCTION.....	123
1.1.	POMALYST Pregnancy Prevention Program	123
1.2.	Full Prescribing Information.....	124
2.	OBJECTIVE.....	125
3.	METHODS.....	126
3.1.	Pregnancy/Pregnancy Background.....	127
3.1.1.	Health Care Providers.....	127
3.1.2.	Patient and Male Patient of Pregnant Partner	127
3.2.	Pregnancy Follow-up	128
3.3.	Pregnancy Outcome.....	129
3.3.1.	Health Care Providers.....	129
3.3.2.	Patient and Male Patient of Pregnant Partner	129
3.4.	Infant Follow-up	130
4.	DATA ANALYSIS.....	131
5.	INDIVIDUAL CASE REPORTS	132
6.	STATUS REPORTS.....	132
7.	REGISTRY DISCONTINUATION.....	134
8.	REFERENCES.....	135
	APPENDIX 1: PREGNANCY LETTERS AND QUESTIONNAIRES	139
	APPENDIX 2: DEFINITIONS.....	157

LIST OF FIGURES

Figure 1:	Pregnancy Background and Follow-Up Process Flow - HCP	136
Figure 2:	Pregnancy Outcome and Infant Follow-Up Process Flow - HCP.....	137
Figure 3:	Pregnancy/Pregnancy Outcome Process Flow - Patient and Male Patient of Pregnant Partner.....	138

1. INTRODUCTION

The goal of the program is to prevent the risk of embryo-fetal exposure to POMALYST due to the potential of embryo-fetal toxicity. The drug is contraindicated in female patients who are or may become pregnant.

POMALYST (pomalidomide) is structurally related to thalidomide and lenalidomide. Thalidomide is a known human teratogen with an active pharmaceutical ingredient that causes severe life-threatening birth defects. POMALYST was found to be teratogenic in a developmental study in rats and rabbits. The teratogenic effect of POMALYST in humans cannot be ruled out.

1.1 POMALYST Pregnancy Prevention Program

Because of the potential teratogenic effects of POMALYST and to avoid embryo-fetal exposure, POMALYST is available only under a restricted distribution program called “the POMALYST Risk Evaluation and Mitigation Strategy (REMS)”™ for POMALYST education and prescribing safety. Under this program, only prescribers and pharmacies certified with the program are able to prescribe and dispense the product.

In addition, POMALYST must be dispensed only to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program. Certified pharmacies and/or pharmacists are the only authorized healthcare providers allowed to dispense prescriptions of POMALYST to patients and are required to educate and direct the patient to POMALYST educational materials and the Medication Guide.

Prescribers must complete a mandatory survey through Celgene to obtain an authorization number for each prescription written. Patients must periodically take part in a mandatory, confidential survey to help ensure that they receive, understand and can follow information on preventing embryo-fetal exposure. In the POMALYST REMS™ program, a female of reproductive potential (FRP) is defined as a female who is menstruating, amenorrheic from previous medical treatments, under 50 years, and/or perimenopausal. Enrolled FRP need to complete a brief, confidential survey monthly before a prescription can be written for the medication. A POMALYST REMS™ certified pharmacy will contact the patient by phone to discuss POMALYST therapy. The patient will not receive the medication unless she speaks with the POMALYST REMS™ certified pharmacy. The FRP must have a thorough understanding of the need for 2 of the recommended forms of birth control at the same time beginning at least 4 weeks before therapy, and continuing during therapy (including any necessary dose interruptions) and for at least 4 weeks following discontinuation of therapy with POMALYST. The FRP must have negative pregnancy tests (1) within 10 to 14 days and (2) within 24 hours prior to receiving an initial prescription for POMALYST. Pregnancy tests must be sensitive to at least 50 mIU/mL. A pregnancy test is to be performed weekly during the first 4 weeks, and then repeated every 4 weeks among FRP with regular menstrual cycles. If menstrual cycles are irregular, testing should occur every 2 weeks. In the event of pregnancy, the FRP should discontinue POMALYST. Pregnancy testing and counseling should be performed if a patient misses her period or if there is any abnormality in her pregnancy test or in her menstrual bleeding. All

cases of pregnancy should be reported to FDA MedWatch at 1-800-FDA-1088 and to Celgene at 1-888-423-5436.

1.2 Full Prescribing Information

The full prescribing information states that pregnancy test results should be verified by the prescriber and the pharmacist prior to dispensing any prescription. If a pregnancy does occur during treatment, POMALYST must be discontinued immediately. Any suspected embryo-fetal exposure to POMALYST should be reported to the FDA via the MedWatch number at 1-800-FDA-1088 and also to Celgene Corporation at 1-888-423-5436.

The Medication Guide (Information for Patients and Caregivers), which is a part of the prescribing information, noted that female partners of males taking POMALYST should call their health care provider right away if they get pregnant and patients who get pregnant should stop taking POMALYST right away and call their health care provider. Health care providers and patients should report all cases of pregnancy to FDA MedWatch at 1-800-FDA-1088 and to Celgene Corporation at 1-888-423-5436.

2. OBJECTIVE

Celgene is committed to investigating any reports of possible embryo-fetal exposure to POMALYST whether it is the patient or the male patient's partner.

The objectives of the POMALYST Pregnancy Exposure Registry are:

- to monitor pregnancy outcomes (should one occur) in female patients of reproductive potential and female partners of male patients who are exposed to POMALYST and
- to understand the root cause for the pregnancy.

3. METHODS

Pregnancy is identified as any of the following:

- Pregnancy of a patient
- Pregnancy of a female partner of a male patient taking POMALYST

Reports of pregnancy may be received from the POMALYST REMS[™] program in the United States, Celgene Pregnancy Prevention Plan programs in the rest of the world (ROW) as applicable, company representatives, clinical trials (US and ROW), or directly from consumer and health care professionals. Specifications for handling pregnancy reports are included in every Celgene study protocol. All reports of pregnancy in a female patient or partner of patient will be actively monitored. Contact information of health care providers and patients will be retrieved from the United States Risk Evaluation and Mitigation Strategies (US REMS) database for reports from the commercial environment and from the repository of study information for reports from clinical trials. Health care providers (HCP, clinical trial investigator, prescriber, obstetrician, neonatologist, pediatrician) will be contacted to obtain pregnancy background, pregnancy outcome, pregnancy follow-up and infant outcome information; patients and male patients of pregnant partners will be contacted (when appropriate) to obtain pregnancy information to the extent permitted by local regulations/laws will permit. A letter with the Pregnancy Background Form will be sent initially to the health care provider (prescriber, clinical trial investigator, and obstetrician) and a letter with the Pregnancy Follow-up Form will be sent every trimester or until the outcome is known. A letter with the Pregnancy Form for patient or male patient of pregnant partner will be sent (when appropriate) within 30 days after a report of a confirmed pregnancy. A letter with the Pregnancy Outcome Form for HCP (prescriber, clinical trial investigator, obstetrician, neonatologist, and pediatrician) will be sent within 30 days after expected delivery. A letter with the Pregnancy Outcome Form for patient/male patient of partner will be sent (when appropriate) within 30 days after expected delivery. A letter with the Infant Follow-up Form will be sent to the pediatrician or primary care physician every quarter until the infant is a year old.

All pregnancy cases are entered in the Global Drug Safety database. The Drug Safety Specialist (DSS) or designee will process the completed forms and follow-up with the HCP and patient or male patient of pregnant partner.

The following forms will be used to monitor the pregnancy and pregnancy outcome:

- Pregnancy Background Form for HCP,
- Pregnancy Follow-up Form for HCP,
- Pregnancy Outcome Form for HCP,
- Pregnancy Background Form for Patient or Male Patient of Pregnant Partner
- Pregnancy Outcome Form for Patient or Male Patient of Pregnant Partner, and
- Infant Follow-up Form for Primary Care Physician or Pediatrician.

The Pregnancy Background Form for Patient or Male Patient of Pregnant Partner will be utilized for the root cause analysis of pregnancy. The letters and the forms are found in [Appendix 1](#) and the definition of terms is found in [Appendix 2](#).

The processes are presented in [Figure 1](#), [Figure 2](#) and [Figure 3](#).

3.1 Pregnancy/Pregnancy Background

3.1.1 Health Care Providers

- When a pregnancy is reported, the Drug Safety Specialist (DSS) or designee will make an outbound call to the reporter to verify the pregnancy. If there is no response, the DSS or designee will make another outbound call to the reporter to verify the pregnancy.
- If the pregnancy is verified, the DSS will generate a letter and a Pregnancy Background Form that will be sent to the health care provider (HCP; prescriber, clinical investigator, obstetrician, primary care physician).
- If no response is received within 30 days, the letter and Pregnancy Background Form will be resent.
- If there is no response to the second letter within 30 days, an outbound call will be made to the HCP (prescriber, clinical investigator, obstetrician, primary care physician) requesting that the Pregnancy Background Form be completed.
- If there is no response to the outbound call from the obstetrician/primary care physician within 30 days, all contacts and attempts will be documented in the case.
- If there is no response to the outbound call from the clinical investigator, the clinical study manager will be contacted to assist in obtaining the response from the clinical investigator.
- If there is no response to the outbound call from the prescriber within 30 days, he or she will be flagged. When the flagged prescriber request for a prescription authorization, the call will be directed to the DSS or designee who will remind the prescriber to complete the Pregnancy Background Form.
- If there is no response within 30 days, the DSS or designee will document all contacts and attempts. If the completed Pregnancy Background Form is received, the DSS or designee will unflag the Prescriber.
- The DSS or designee will process the completed Pregnancy Background Form.

3.1.2 Patient and Male Patient of Pregnant Partner

- A letter and a Pregnancy Background Form for patient and male patient of pregnant partner will be sent (when appropriate) within 30 days after a report of confirmed pregnancy to patients enrolled in the POMALYST REMS™ program. The letter and the form for patient and male patient of pregnant partner will be sent to the clinical investigator for completion of the

study subject at the next study visit. The Pregnancy Background Form will collect information for the root cause analysis of pregnancy.

- If no response is received within 30 days, the letter and Pregnancy Background Form will be resent.
- If there is no response to the second letter within 30 days, an outbound call will be made to the patient/male patient of pregnant partner for patients enrolled in the POMALYST REMS™ program requesting that the Pregnancy Background Form be completed and to the clinical investigator to remind the study subject to complete the form at the next study visit.
- If there is no response to the outbound call from the patient/male patient of pregnant partner within 30 days, the study manager will be contacted to assist in obtaining the response.
- If there is no response to the outbound call from the patient/male patient of pregnant partner within 30 days, all contacts and attempts will be documented in the case.
- The DSS or designee will process the completed Pregnancy Background Form.

3.2 Pregnancy Follow-up

- A Pregnancy Follow-up Form will be sent to the obstetrician/primary care physician every trimester or until the outcome is known.
- If the obstetrician/primary care physician does not respond within 30 days, the letter and Pregnancy Follow-up Form will be resent.
- If there is no response to the second letter, an outbound call will be made to the obstetrician/primary care physician requesting the completion of the Pregnancy Follow-up Form.
- If no response is received within 30 days, all contacts and attempts will be documented in the case.
- The DSS or designee will process the completed Pregnancy Follow-up Form.

3.3 Pregnancy Outcome

3.3.1 Health Care Providers

- For confirmed pregnancies, Pregnancy Outcome Form for HCP (prescriber, clinical investigator, obstetrician, neonatologist, pediatrician, primary care physician) will be sent within 30 days after the expected date of delivery.
- If the HCP (prescriber, clinical investigator, obstetrician, neonatologist, pediatrician, primary care physician) does not respond within 30 days, the letter and Pregnancy Outcome Form will be resent.
- If there is no response to the second letter, an outbound call will be made to the HCP (prescriber, clinical investigator, obstetrician, neonatologist, pediatrician, primary care physician) requesting the completion of the Pregnancy Outcome Form.
- If there is no response from the clinical investigator, the study manager will be contacted to assist in obtaining the response.
- If there is no response from the obstetrician/neonatologist/pediatrician/primary care physician/clinical investigator within 30 days, all contacts and attempts will be documented in the case.
- If there is no response from the Prescriber within 30 days, the prescriber will be flagged. When the flagged prescriber request for a prescription authorization, the call will be directed to the DSS or designee who will remind the prescriber to complete the Pregnancy Outcome Form.
- If there is no response within 30 days, the DSS or designee will document all contacts and attempts. If the completed Pregnancy Outcome Form is received, the DSS or designee will unflag the Prescriber.
- The DSS or designee will process the completed Pregnancy Outcome Form.

3.3.2 Patient and Male Patient of Pregnant Partner

- A Pregnancy Outcome Form for patient and male patient of pregnant partner will be sent (when appropriate) within 30 days after the expected date of delivery.
- If the patient and male patient of pregnant partner do not respond within 30 days, the letter and Pregnancy Outcome Form will be resent.
- If there is no response to the second letter, an outbound call will be made to the patient and male patient of pregnant partner requesting the completion of the Pregnancy Outcome Form.

- If no response is received within 30 days, all contacts and attempts will be documented in the case.
- The DSS or designee will process the completed Pregnancy Outcome Form.

3.4 Infant Follow-up

- The DSS or designee will send a letter and an Infant Follow-up Form to the primary care physician or pediatrician quarterly until the infant is a year old. The first letter will be sent 3 months after birth.
- If there is no response within 30 days, the DSS or designee will re-send the letter and the Infant Follow-up Form.
- If there is no response to the second letter, an outbound call will be made to the primary care physician or pediatrician requesting the completion of the Infant Follow-up Form.
- If no response is received within 30 days, all contacts and attempts will be documented in the case.
- The DSS or designee will process the completed Infant Follow-up Form.

4. DATA ANALYSIS

Descriptive statistics will be the primary approach for summarizing data from the pregnancy exposure registry.

Subjects' age, duration of POMALYST treatment, and weeks of gestational age at exposure will be summarised using descriptive statistics for continuous variables, while gender, indication for POMALYST use, concomitant medications, type of delivery, pregnancy outcome, obstetrical history, adverse events during pregnancy, embryo-fetal outcome, infant status, and cytogenetic abnormalities will be summarised with descriptive statistics appropriate for categorical data. The information will be separately provided for female patients and pregnant partners of male patients as appropriate for the variable of interest.

The pregnancy proportion among female patients of reproductive potential (FRP) will be determined by dividing the total number of FRP experiencing at least one pregnancy over the total FRP population. The pregnancy proportion will be stratified by prescribing environment (e.g., patients exposed to commercially marketed POMALYST, patients exposed to POMALYST in clinical trials under IND applications]. Because of the unique denominator data available in the United States, these analyses will be conducted separately for patients in the POMALYST REMS™ program. Patients with more than one exposed pregnancy will be tabulated.

The Pregnancy Background Form completed by the patient or male patient of pregnant partner will be utilized to analyze root cause for the pregnancy. The forms of birth control; unprotected sex; reasons for unprotected sex; receipt, reading, and understanding of the medication guide, source of knowledge about contraception, and understanding of the risk of pregnancy during POMALYST use will be summarized with descriptive statistics.

The CDC birth defects code list will be used for classifying any reported congenital anomalies.

5. INDIVIDUAL CASE REPORTS

Initial pregnancy cases must be reported (notification) to the FDA within 24 hours of receipt followed by a 15-day alert report. Any follow-up information received must be submitted as a follow-up 15-day alert report.

For all Celgene products where there is a regulatory commitment for 24-hour notification (i.e., pomalidomide, thalidomide) or a requirement in the clinical study protocol for immediate notification, all Celgene personnel, including affiliates and licensed partners, shall inform Global Drug Safety or the appropriate Celgene Drug Safety department worldwide **IMMEDIATELY** by a telephone call followed by electronic transmission (email or facsimile) of a serious adverse event report of any possible exposure of a pregnant woman to the Celgene product.

6. Status Reports

The status report will be included in the POMALYST periodic safety report. The status report will include the following:

- Number of pregnancies in patients and partners of male patients with outcome known (stratified by live birth, spontaneous abortions, elective terminations, fetal deaths/stillbirths)
- Number of pregnancies with outcome pending
- Number of pregnancies lost to follow-up
- Pregnancy proportions for FRP patients and for male patients, stratified by prescribing environment
- Number of females of reproductive potential exposed for postmarketing and clinical trials (US and ROW*) during the time period
- Number of males exposed for postmarketing and clinical trials (US and ROW*) during the time period

*Note: The POMALYST REMS™ program is unique to the United States. In other countries where POMALYST is marketed, such controlled distribution may not be possible because of legal restraints. Hence, accurate data on patient demographics will not be available.

For pregnancies with known outcome, the status report will include line listings and summaries of:

- Demographics, obstetrical and medical history of mothers
- Weeks of gestational age at exposure
- Type, dose and duration of exposure
- Weeks of gestational age at completion or termination of pregnancy
- For live births and deaths/stillbirths, whether multiple birth, small for gestational age, pre-term delivery and congenital anomalies or other embryo-fetal abnormalities
- For spontaneous abortions and elective terminations, abnormalities in products of conception

7. REGISTRY DISCONTINUATION

The pregnancy registry will be evaluated annually to determine if the feasibility of collecting information has diminished to unacceptable levels because of low exposure rates or loss to follow-up.

8. REFERENCES

CDC. Metropolitan Atlanta Congenital Defects Program Procedure Manual, 1993; A32-A100(77):488-7160.

EMA Committee for Medicinal Products for Human Use: Guideline on the Exposure to Medicinal Products During Pregnancy: Need for Post-Authorisation Data. London, UK. 14Nov2005.

Food and Drug Administration. Guidance for Industry Establishing Pregnancy Exposure Registries. Rockville, MD. August 2002.

Investigator's Brochure for Pomalidomide ver 15. Summit, NJ: Celgene Corporation, 10May2011.

POMALYST[®] [Full Prescribing Information and the Medication Guide]. Summit, NJ: Celgene Corporation; 2012.

Figure 1: Pregnancy Background and Follow-Up Process Flow - HCP

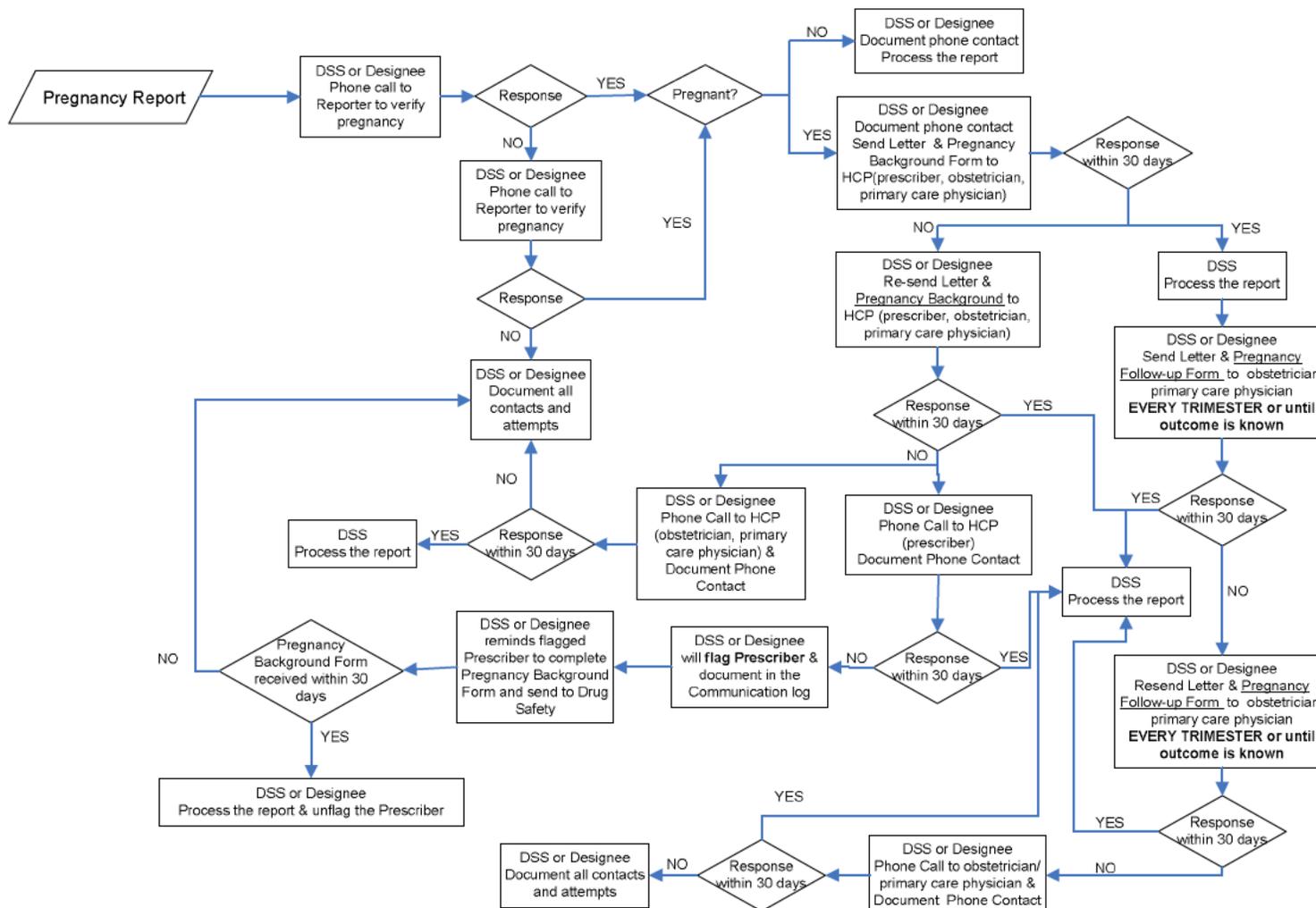


Figure 2: Pregnancy Outcome and Infant Follow-Up Process Flow - HCP

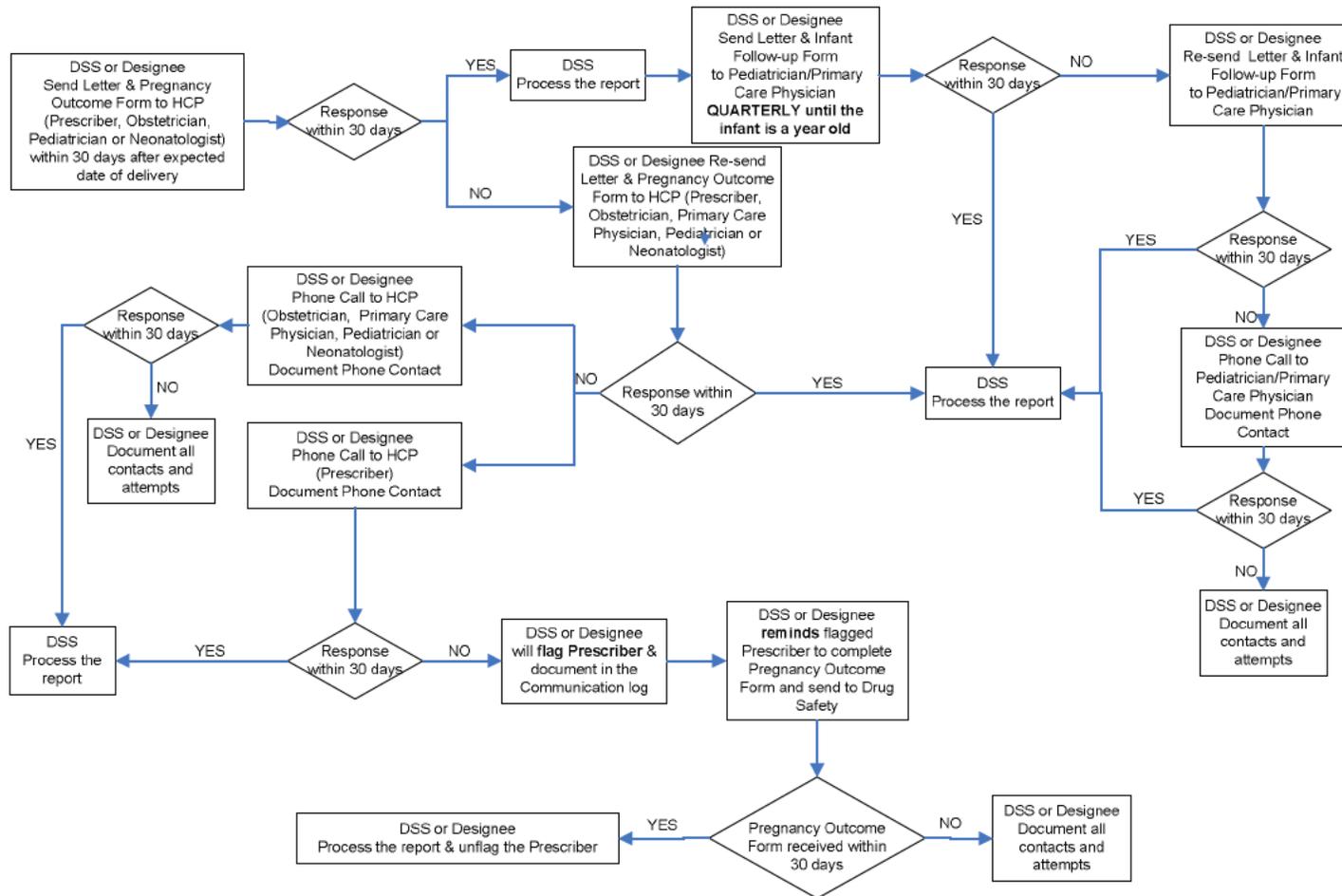
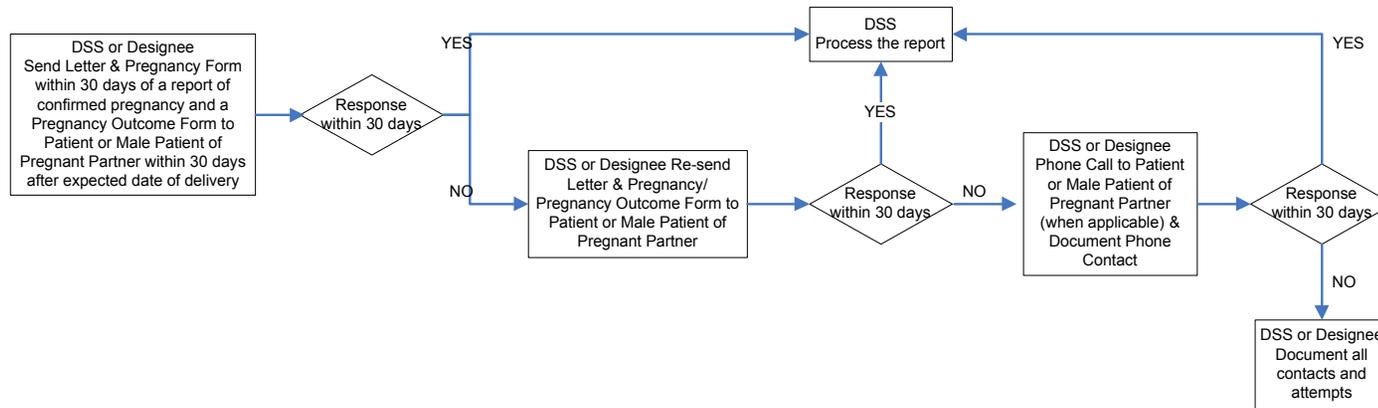


Figure 3: Pregnancy/Pregnancy Outcome Process Flow - Patient and Male Patient of Pregnant Partner



APPENDIX 1: PREGNANCY LETTERS AND QUESTIONNAIRES

Name, MD [Prescriber/Clinical Investigator/Obstetrician/Pediatrician/Neonatologist/Primary Care Physician]

Attn: Name

Address:

DDMMYYYY

Re: Patient Identifier: [patient identifier]

Patient DOB, Patient sex

Drug: [Primary Suspect Product Name]

Our Manufacturer Control No (MCN): [MCN]

Dear Dr. [Selected Reporter]

The Celgene Corporation Global Drug Safety Department has received a report of a pregnancy regarding your patient [patient identifier].

Celgene is committed to investigating any reports of possible embryo-fetal exposure to our products whether it be the patient or patient's partner. In order to perform a thorough evaluation and to meet our regulatory reporting requirements throughout the world, we are interested in obtaining additional details regarding this patient. Please be assured that all information will be treated in the strictest of confidence.

Please complete the enclosed Event-Specific Questionnaire for HCP – Pregnancy Background (Patient or Partner of Patient)/ Event-Specific Questionnaire for HCP - Pregnancy Outcome (Patient or Partner of Patient)/ Event-Specific Questionnaire for HCP - Pregnancy Follow-up (Patient or Partner of Patient)/ Event-Specific Questionnaire for Primary Care Physician or Pediatrician Infant Follow-up Form, date and sign the form(s) and return to Celgene Drug Safety via mail (self-addressed envelope provided), or FAX to (908) 673-9115. Please provide our Manufacturer Control No. as stated above in all communications regarding this case.

If you are aware that further information will not be available, it would be helpful if you could indicate that to us, including the reason if complete information cannot be provided.

If you have any questions, please do not hesitate to contact me at 1-800-640-7854.

Thank you in advance for your assistance.

Name of Specialist

Title

Name of Patient

Address:

DDMMYYYY

Re: Patient Identifier: [patient identifier]

Patient DOB, Patient sex

Drug: [Primary Suspect Product Name]

Our Manufacturer Control No (MCN): [MCN]

Dear [Patient's Name]

The Celgene Corporation Global Drug Safety Department has received a report of your [your partner's pregnancy].

Celgene is committed to investigating any reports of possible embryo-fetal exposure to our products whether it be the patient or patient's partner. In order to perform a thorough evaluation and to meet our regulatory reporting requirements throughout the world, we are interested in obtaining additional details regarding your [your partner's] pregnancy. Please be assured that all information will be treated in the strictest of confidence.

Please complete the enclosed Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner – Pregnancy Background/ Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner – Pregnancy Outcome Form and return to Celgene Drug Safety via mail (self-addressed envelope provided), or FAX to (908) 673-9115.

If you have any questions, please do not hesitate to contact me at 1-800-640-7854.

Thank you in advance for your assistance.

Name of Specialist

Title

Event-Specific Questionnaire for HCP – Pregnancy Background

(Patient or Partner of Patient)

Telephone: (908) 673-9667

Fax: (908) 673-9115

Email: Drugsafety@celgene.com

Reporter Information				
REPORTER NAME:				
ADDRESS:			CITY, STATE, ZIP, COUNTRY:	
PHONE NO.:			FAX NO.:	
Obstetrician Information (Please provide)				
OBSTETRICIAN NAME:				
ADDRESS:			CITY, STATE, ZIP, COUNTRY:	
PHONE NO.:			FAX NO.:	
Patient Information				
PATIENT ID:	DATE OF BIRTH:	ETHNICITY: <input type="checkbox"/> WHITE <input type="checkbox"/> AFRICAN-AMERICAN <input type="checkbox"/> ASIAN <input type="checkbox"/> OTHER, SPECIFY:		
Partner of Patient Information <input type="checkbox"/> Not applicable				
DATE OF BIRTH:		ETHNICITY: <input type="checkbox"/> WHITE <input type="checkbox"/> AFRICAN-AMERICAN <input type="checkbox"/> ASIAN <input type="checkbox"/> OTHER, SPECIFY:		
Patient Treatment Information: POMALYST®				
LOT NO.	EXPIRY DATE:	DOSE:	FREQUENCY:	ROUTE:
START DATE			STOP DATE	
INDICATION FOR USE				

CYTOGENETIC ABNORMALITIES: <input type="checkbox"/> No <input type="checkbox"/> Yes, IF YES, SPECIFY:					
Current Pregnancy					
Date of last menstrual period:			Estimated Delivery Date:		
<i>Pregnancy Test</i>	<i>REFERENCE RANGE</i>	<i>DATE</i>			
Urine Qualitative					

Serum quantitative					
Prenatal Tests					
	<i>Date</i>	<i>Result</i>			
Ultrasound					
Ultrasound					
Ultrasound					
Amniocentesis					
Maternal Serum AFP					
Pregnancy History					
No. of previous pregnancies:		No. of Full term deliveries:		No. of Pre-term births:	
Date of last pregnancy:					
No. of fetal deaths:		No. of living children:		No. of abortions:	
				Elective Spontaneous	
Type of delivery: Vaginal:		C-section:	Other:, specify		
Did birth defect occur in any previous pregnancy? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown					
If Yes, specify					

MCN:

Pregnancy History			
Did a stillbirth or miscarriage occur in any previous pregnancy? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown			
1) If Yes, in what week of pregnancy did the stillbirth or miscarriage occur? _____ week			
2) Was there any birth defect noted? Specify: _____			
Relevant Medical History			
	<i>DATE OF DIAGNOSIS</i>		<i>DATE OF DIAGNOSIS</i>
CANCER <input type="checkbox"/> No <input type="checkbox"/> YES, IF YES, SPECIFY			

Social History			
ALCOHOL <input type="checkbox"/> No <input type="checkbox"/> YES, IF YES, AMOUNT/UNIT CONSUMED PER DAY:			
TOBACCO <input type="checkbox"/> No <input type="checkbox"/> YES		IV OR RECREATIONAL DRUG USE <input type="checkbox"/> No <input type="checkbox"/> YES, SPECIFY	
Family History: CONGENITAL ABNORMALITIES <input type="checkbox"/> No <input type="checkbox"/> YES, SPECIFY:			
Medications/Treatments (including herbal, alternative and over the counter medicines and dietary supplements) During Pregnancy			
<i>DRUG</i>	<i>START DATE</i>	<i>STOP DATE/ CONTINUING</i>	<i>INDICATION</i>
Adverse Event(s) During Pregnancy			

Event(s)	SERIOUS		SERIOUS CRITERIA ¹	START DATE	STOP DATE	CAUSAL RELATIONSHIP TO CELGENE PRODUCT		
	N	Y				YES	NO	If No, what medications, disease states etc played a role in the event.
	O	E						
		S						

¹ Serious Criteria: 1) death, 2) life-threatening, 3) required inpatient hospitalization or prolongation of existing hospitalization, 4) a persistent or significant disability/incapacity, 5) a congenital anomaly/birth defect, 6) medically significant

SIGNATURE OF PERSON COMPLETING THIS FORM

DATE

.....

MCN:

**Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner-
Pregnancy Background****Telephone: (908) 673-9667****Fax: (908) 673-9115****Email: Drugsafety@celgene.com**

Date _____

Name of Patient or Name of Male Patient of Partner _____

For a better understanding of pregnancy among patients or partners of patients on POMALYST® and for further improvement of the POMALYST REMS™ program, please complete the following questions.

1. What forms of birth control have you been using while on POMALYST before you/your partner got pregnant? Please check all that applies.

- Tubal ligation
- IUD
- Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)
- Partner's vasectomy
- Male Latex or synthetic condom
- Diaphragm
- Cervical cap or shield
- Spermicide or sponge
- Withdrawal

2. Were you or your partner at any time during use of POMALYST without contraception for even one day?

- No, please proceed to Q5
- Yes, please answer Q3, Q4, Q5, and Q6

3. How often did you have unprotected sexual intercourse?

- multiple times
- once a week
- once every 2 weeks
- once a month
- not at all
- other, specify _____

4. Why did you or your partner interrupt or stop using contraception?

- wanted a child
- partner disapproved
- side effects
- health concerns
- inconvenient to use
- other, specify _____

5. Did you receive the POMALYST Medication Guide?

- No, please proceed to Q6

Yes, please answer the following question

5.1 Did you read the POMALYST Medication Guide?

No, please proceed to Q6

Yes, please answer the following question

5.2 Did you understand the information in the POMALYST Medication Guide?

No

Yes

6. Where did most of your knowledge about contraception during POMALYST use come from?

Physician who prescribed POMALYST

Patient Guide to the POMALYST REMS™ Program

POMALYST Medication Guide

Other, specify _____

7. Do you feel you and/or your partner had good understanding of the risk of pregnancy during POMALYST use?

Yes

No

Don't know

Event-Specific Questionnaire for HCP – Pregnancy Follow-up

(Patient or Partner of Patient)

Telephone: (908) 673-9667

Fax: (908) 673-9115

Email: Drugsafety@celgene.com

Date:		Period Covered: [Date] to [Date]		
Reporter Information				
REPORTER NAME:				
ADDRESS:		CITY, STATE, ZIP, COUNTRY:		
PHONE NO.:		FAX NO.:		
Name of Patient or Pregnant Partner of Male Patient				
Current Pregnancy				
Prenatal Tests				
	<i>Date</i>	<i>Result</i>		
Ultrasound				
Ultrasound				
Ultrasound				
Amniocentesis				
Maternal Serum AFP				
Other tests, specify				
Medications/Treatments (including herbal, alternative and over the counter medicines and dietary supplements) During Pregnancy				
<i>DRUG</i>	<i>START DATE</i>	<i>STOP DATE/ CONTINUING</i>	<i>INDICATION</i>	

Adverse Event(s) During Pregnancy								
Event(s)	SERIOUS		SERIOUS CRITERIA ¹	START DATE	STOP DATE	CAUSAL RELATIONSHIP TO CELGENE PRODUCT		
	N	Y				YES	NO	If No, what medications, disease states etc played a role in the event.
	O	E						
		S						

¹ Serious Criteria: 1) death, 2) life-threatening, 3) required inpatient hospitalization or prolongation of existing hospitalization, 4) a persistent or significant disability/incapacity, 5) a congenital anomaly/birth defect, 6) medically significant

SIGNATURE OF PERSON COMPLETING THIS FORM

DATE

.....

MCN:

Event-Specific Questionnaire for HCP – Pregnancy Outcome

(Patient or Partner of Patient)

Telephone: (908) 673-9667

Fax: (908) 673-9115

Email: Drugsafety@celgene.com

Reporter Information			
REPORTER NAME:			
ADDRESS:		CITY, STATE, ZIP, COUNTRY:	
PHONE No.:		FAX No.:	
Patient Information			
PATIENT ID:	DATE OF BIRTH:	ETHNICITY: <input type="checkbox"/> WHITE <input type="checkbox"/> AFRICAN-AMERICAN <input type="checkbox"/> OTHER, SPECIFY:	
Partner of Patient Information <input type="checkbox"/> Not applicable			
DATE OF BIRTH:		ETHNICITY: <input type="checkbox"/> WHITE <input type="checkbox"/> AFRICAN-AMERICAN <input type="checkbox"/> OTHER, SPECIFY:	
Pregnancy Outcome			
DATE OF DELIVERY:		GESTATION AGE AT DELIVERY:	
	No	Yes	
Normal	<input type="checkbox"/>	<input type="checkbox"/>	
C-section	<input type="checkbox"/>	<input type="checkbox"/>	
Induced	<input type="checkbox"/>	<input type="checkbox"/>	
Ectopic pregnancy	<input type="checkbox"/>	<input type="checkbox"/>	
Elective termination	<input type="checkbox"/>	<input type="checkbox"/>	Date:

Spontaneous abortion (≤20 weeks)	<input type="checkbox"/>	<input type="checkbox"/>	Weeks from LMP:
Fetal death/stillbirth (>20 weeks)	<input type="checkbox"/>	<input type="checkbox"/>	
Were the products of conception examined?	<input type="checkbox"/>	<input type="checkbox"/>	If yes, was the fetus normal? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If no, describe:
Obstetrics Information			
	No	Yes	
Complications during pregnancy	<input type="checkbox"/>	<input type="checkbox"/>	If yes, please specify
Complications during labor/delivery	<input type="checkbox"/>	<input type="checkbox"/>	If yes, please specify
Post-partum maternal complications	<input type="checkbox"/>	<input type="checkbox"/>	If yes, please specify
Fetal Outcome			
	No	Yes	
LIVE NORMAL INFANT	<input type="checkbox"/>	<input type="checkbox"/>	
FETAL DISTRESS	<input type="checkbox"/>	<input type="checkbox"/>	
INTRA-UTERINE GROWTH RETARDATION	<input type="checkbox"/>	<input type="checkbox"/>	
NEONATAL COMPLICATIONS	<input type="checkbox"/>	<input type="checkbox"/>	IF YES, PLEASE SPECIFY:
BIRTH DEFECT NOTED?	<input type="checkbox"/>	<input type="checkbox"/>	IF YES, PLEASE SPECIFY:
Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female	Birth Weight: __lbs _ oz. or __ kg		Length: _____ inches or ___ cm.
Apgar Score:	Unknown:	1 min:	5 min: 10 min:

SIGNATURE OF PERSON COMPLETING THIS FORM

DATE

MCN:

**Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner-
Pregnancy Outcome**

Telephone: (908) 673-9667

Fax: (908) 673-9115

Email: Drugsafety@celgene.com

Date _____

Name of Patient or Name of Male Patient of Partner _____

Please provide the outcome of your or your partner's pregnancy.

Normal baby

Abnormal baby, please specify defect _____

Therapeutic abortion

Please specify any abnormality of the fetus if known: _____

Spontaneous abortion or miscarriage

Please specify any abnormality of the fetus if known: _____

**Event-Specific Questionnaire for Primary Care Physician or Pediatrician –
Infant Follow-up**

Telephone: (908) 673-9667

Fax: (908) 673-9115

Email: Drugsafety@celgene.com

Date: _____

Name of Patient or Name of Male Patient of Partner (Mother) _____

Name of Infant (if known) _____

Please provide information for the period from [Date] to [Date].

Anomalies Diagnosed Since Initial Report:

None

Developmental Assessment:

Normal

Abnormal, specify _____

Infant Illnesses, Hospitalizations, Drug Therapies:

Infant Illnesses	Hospitalized?	Drug Therapies
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	

SIGNATURE OF PERSON COMPLETING THIS FORM

DATE

APPENDIX 2: DEFINITIONS

Fetus: covers the whole prenatal development from the conception until birth.

Pregnancy outcome: the end products of pregnancy which include three main categories: fetal death, termination of pregnancy and live birth.

- Fetal death (intrauterine death, in utero death): death prior to complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation the fetus does not show any evidence of life (WHO ICD 10).
 - Early fetal death (before 20 completed weeks of gestation) comprises ectopic pregnancy and miscarriage
 - Late fetal death (after 20 completed weeks of gestation) – known as stillbirth

Miscarriage: spontaneous abortion, molar pregnancy

Termination of pregnancy (induced abortion, elective abortion): artificial interruption of pregnancy

Live birth: the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy, which, after such separation, breathes or shows any evidence of life (WHO ICD 10)

Gestational age or length: duration of gestation is measured from the first day of the last normal menstrual period. Gestation age is expressed in completed days or completed weeks (e.g., events occurring 280 to 286 days after the onset of the last menstrual period are considered to have occurred at 40 weeks of gestation).

Last menstrual period (LMP): according to international consensus, the gestational age is measured from the first day of the LMP.

Birth weight: the initial weight of the infant at birth

Pre-term baby (previously premature birth): less than 37 completed weeks (less than 259 days) of gestation

Term birth: from 37 to less than 42 completed weeks (259 to 293 days)

Post-term birth: 42 completed weeks or more (294 days or more)

Low birth weight: less than 2,500 gram (up to and including 2,499 g) of body weight of the newborn at birth

Intrauterine growth retardation (small for gestational age): the observed weight of a live born infant or size of a fetus is lower than expected on the basis of gestational age.

Confidential and Proprietary

30

Celgene REMS Programs Pharmacy Training: POMALYST REMS™

Section 1: What Is a REMS?



In this section



- What is a REMS?
- Celgene REMS programs
- Pharmacy staff knowledge check



What is a REMS?

- REMS stands for **Risk Evaluation and Mitigation Strategies**
- REMS programs are mandated by the **US Food and Drug Administration (FDA)**
- According to the FDA, a REMS program is:
 - A strategy to manage a known or potential serious risk associated with a drug or biological product
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

Celgene REMS programs



- Celgene has REMS programs for THALOMID[®] (thalidomide), REVLIMID[®] (lenalidomide), and POMALYST[®] (pomalidomide):
 - THALOMID REMS[™] program (formerly known as the S.T.E.P.S.[®] program) for THALOMID
 - REVLIMID REMS[™] program (formerly known as the RevAssist[®] program) for REVLIMID
 - POMALYST REMS[™] for POMALYST
- If these treatments are used during pregnancy, they can cause serious birth defects or embryo-fetal death
- The goals of these REMS programs are:
 - To prevent the risk of embryo-fetal exposure to these treatments
 - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

Celgene REMS programs (continued)



For more information on Celgene REMS programs:

- Call Celgene Customer Care at 1-888-423-5436
- Visit the specific product website

Did you know?

Celgene Customer Care has Compliance Specialists to educate and train pharmacy staff on Celgene REMS program guidelines and compliance.

Pharmacy staff knowledge check



- REMS stands for Risk Evaluation and Mitigation Strategies.
 - A. True
 - B. False

Correct Answer: A. True

- REMS stands for **Risk Evaluation and Mitigation Strategies**
- A REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product

Pharmacy staff knowledge check (continued)



- Who mandates REMS programs?
 - A. Celgene
 - B. The FDA
 - C. The EPA

Correct Answer: B. The FDA

- REMS programs are mandated by the FDA
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

Pharmacy staff knowledge check (continued)



- Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment.
 - A. True
 - B. False

Correct Answer: A. True

- The goals of the Celgene REMS programs are:
 - To prevent the risk of embryo-fetal exposure to these treatments
 - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

Celgene REMS Programs Pharmacy Training: POMALYST REMS™

Section 2: Program Requirements for Patients and Prescribers

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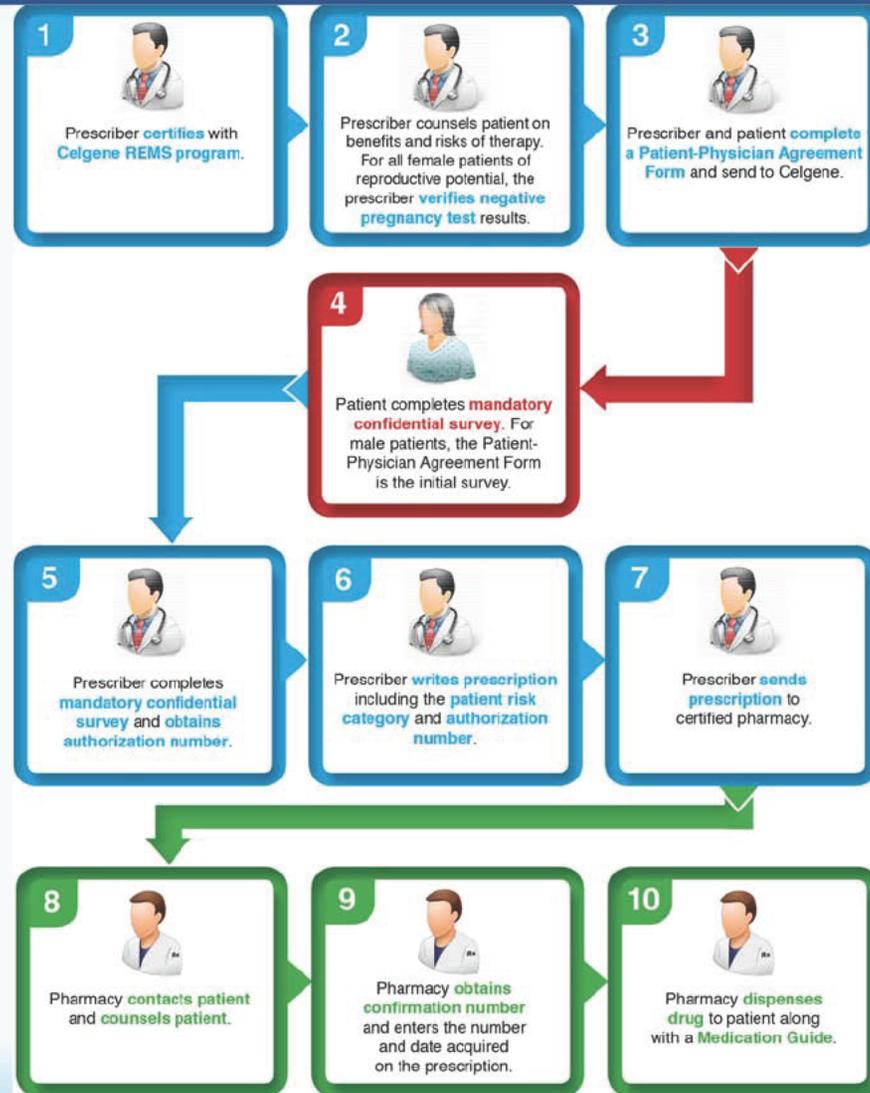


In this section



- Program overview
- Certification and enrollment requirements for prescribers and patients
- Patient risk categories
- Contraception requirements
- Pregnancy test requirements
- Mandatory confidential surveys
- Pharmacy staff knowledge check

Celgene REMS program overview



Certification and enrollment requirements for prescribers and patients



- Prescribers must be certified with the Celgene REMS program in order to prescribe a product with a REMS program for a patient
 - Prescribers must complete the REMS program enrollment and agree to comply with the program requirements
- Prescribers are required to enroll patients in a specific Celgene REMS program before starting a patient on a therapy with a REMS
 - Patients must enroll in the REMS program and agree to comply with the program requirements

Patient risk categories



- There are 6 different patient risk categories for patients enrolled in Celgene REMS programs:
 - Adult female of reproductive potential
 - Female child of reproductive potential
 - Adult female not of reproductive potential
 - Female child not of reproductive potential
 - Adult male
 - Male child

Definition of females of reproductive potential



Females of reproductive potential include all females who:

- Are menstruating
- Are amenorrheic from previous medical treatments
- Are under 50 years of age
- Are perimenopausal
- Do not qualify for the females not of reproductive potential category

The risk categories for **females of reproductive potential** are:

- Adult female of reproductive potential
- Female child of reproductive potential

Definition of females not of reproductive potential



Females not of reproductive potential include females who:

- Have been in natural menopause for at least 24 consecutive months
- Have had a hysterectomy and/or bilateral oophorectomy
- Have not started menstruating

The risk categories for **females not of reproductive potential** are:

- Adult female not of reproductive potential
- Female child not of reproductive potential

Definition of males



Males include adults and children (under 18 years of age)

The risk categories for **males** are:

- Adult Male
- Male Child

Contraception requirements: Females of reproductive potential



- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time **at least 1 highly effective method** and **at least 1 additional method** of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Highly effective methods

Tubal ligation

Intrauterine device (IUD)

Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)

Partner's vasectomy

Additional effective methods

Male latex or synthetic condom

Diaphragm

Cervical cap

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

Contraception requirements: Females of reproductive potential (continued)



- **Unacceptable contraception methods:**
 - Progesterone-only “mini-pills”
 - IUD Progesterone T
 - Female condoms
 - Natural family planning (rhythm method) or breastfeeding
 - Fertility awareness
 - Withdrawal
 - Cervical shield
 - A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

Contraception requirements: Males



- Male patients must use a latex or synthetic condom:
 - Every time they have sexual intercourse with a female of reproductive potential
 - Even if they have undergone a successful vasectomy
 - During therapy (including dose interruptions)
 - For 4 weeks after discontinuation of therapy

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

Pregnancy test requirements



- For females of reproductive potential, prescriber must obtain a negative pregnancy test:
 - 10 to 14 days before an initial prescription
 - Within 24 hours before an initial prescription
 - The pregnancy test must be sensitive to at least 50 mIU/mL
- Subsequent pregnancy testing should occur:
 - Weekly during the first 4 weeks of use, then
 - Every 4 weeks if patient has regular menses or no menses, or
 - Every 2 weeks if irregular menses

Pregnancy test requirements (continued)



If pregnancy does occur:

- Treatment must be **immediately** discontinued
- Any suspected embryo-fetal exposure must be reported **immediately** to Celgene Global Drug Safety and reported to the FDA
 - Celgene Global Drug Safety: 1-800-640-7854
 - FDA MedWatch number: 1-800-332-1088
- The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling

Mandatory confidential surveys



- All patients must complete brief mandatory confidential surveys in order to obtain treatment
 - Surveys can be completed via CelgeneRiskManagement.com or by calling Celgene Customer Care at 1-888-423-5436

Patient Mandatory Confidential Survey Schedule for Adults and Children

Risk category	Initial Prescription	Subsequent Prescriptions
Females of reproductive potential	Complete appropriate survey	Monthly survey
Females not of reproductive potential	Complete appropriate survey	Child: Monthly survey Adult: Survey every 6 months
Males	Do not need to take initial survey	Monthly survey

Pharmacy staff knowledge check



- How many patient risk categories are there in the Celgene REMS programs?
 - A. 3
 - B. 5
 - C. 6

Correct Answer: C. 6

Celgene REMS program patient risk categories	
Adult	Child (under 18)
Adult female of reproductive potential	Female child of reproductive potential
Adult female not of reproductive potential	Female child not of reproductive potential
Adult male	Male child

Pharmacy staff knowledge check (continued)



- For all Celgene REMS products, female patients of reproductive potential must take a pregnancy test:
 - A. 10-14 days before first prescription
 - B. Within 24 hours before first prescription
 - C. 10-14 days and within 24 hours before first prescription

Correct Answer:

C. 10-14 days and within 24 hours before first prescription

- Prescribers must obtain 2 negative pregnancy tests before the first prescription for females of reproductive potential:
 - 10 to 14 days before an initial prescription
 - Within 24 hours before an initial prescription

Pharmacy staff knowledge check (continued)



- Which is a **highly effective** method of contraception?
 - A. Male latex or synthetic condom
 - B. IUD
 - C. Female condom

Correct Answer: B. IUD

Highly effective methods	Additional effective methods
Tubal ligation	Male latex or synthetic condom
Intrauterine device (IUD)	Diaphragm
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Cervical cap
Partner's vasectomy	

Celgene REMS Programs Pharmacy Training: POMALYST REMS™

Section 3: Program Requirements for Pharmacies

Celgene Confidential: For Celgene Business Use Only



In this section



- Training and certification requirements
- Pharmacy compliance
- Pharmacy staff knowledge check

Training and certification requirements



- Celgene REMS program certified counselors must:
 - Be licensed healthcare professionals
 - Complete the Celgene-sponsored training on all required modules **annually** and pass certification exam **with 100% accuracy**
 - Educate patient by telephone or in person before treatment can be dispensed
 - Understand and counsel patients on the potential for birth defects or death to an unborn baby
 - Counsel patients on possible side effects
- Other pharmacy staff involved in dispensing treatment must:
 - Be educated on the guidelines for dispensing

Pharmacy compliance



- Pharmacy manager responsibilities
 - Educate all staff regarding dispensing guidelines
 - Includes floater pharmacists, pharmacy technicians, or anyone else handling the product
 - Make sure counselors are registered and certified in ComplianceWire[®] and advise Celgene of inactive counselors
 - Complete and return all documentation that pertains to non-compliance

Did you know? Pharmacy managers can call Celgene Customer Care at **1-888-423-5436** with questions. Ask for Risk Compliance.

Pharmacy compliance (continued)



- Pharmacy deviations
 - The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
 - Celgene will work with the pharmacy to implement appropriate corrective actions and a timeframe for those actions
 - If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy

Pharmacy compliance (continued)



- A High Risk Deviation is:
 - Any action taken by the pharmacy that is inconsistent or non-compliant with the Celgene REMS program that increases the risk of embryo-fetal exposure
 - Any action that occurs on a consistent basis that shows a pharmacy's negligent or willful disregard to the Celgene REMS program requirements
- If there are 3 High Risk Deviations within 1 year, the pharmacy will be deactivated and will no longer be permitted to dispense product

Pharmacy staff knowledge check



- Celgene REMS program certified counselors must complete the Celgene-sponsored training:
 - A. Annually
 - B. Every 6 months
 - C. Every 2 years

Correct Answer: A. Annually

- Counselors must complete the Celgene-sponsored training annually

Pharmacy staff knowledge check (continued)



- All counselors must pass the certification test with an accuracy of:
 - A. 100%
 - B. 90%
 - C. 95%

Correct Answer: A. 100%

- Counselors must pass the certification exam with 100% accuracy

Pharmacy staff knowledge check (continued)



- Celgene may deactivate pharmacies for deviations.
 - A. True
 - B. False

Correct Answer: A. True

- The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
- If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy

Celgene REMS Programs Pharmacy Training: POMALYST REMS™

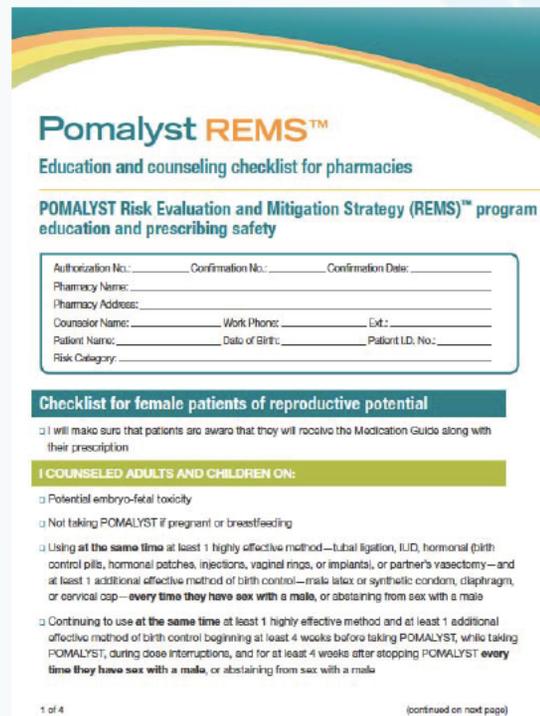
Section 4: Guidelines for Counseling

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In this section

- Counseling for female patients of reproductive potential
- Counseling for female patients not of reproductive potential
- Counseling for male patients
- Additional counseling for all patients taking POMALYST® (pomalidomide)
- Pharmacy staff knowledge check



Pomalyst REMS™
Education and counseling checklist for pharmacies

POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety

Authorization No.: _____ Confirmation No.: _____ Confirmation Date: _____
 Pharmacy Name: _____
 Pharmacy Address: _____
 Counselor Name: _____ Work Phone: _____ Ext.: _____
 Patient Name: _____ Date of Birth: _____ Patient ID No.: _____
 Risk Category: _____

Checklist for female patients of reproductive potential

I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity
- Not taking POMALYST if pregnant or breastfeeding
- Using at the **same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male
- Continuing to use at the **same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking POMALYST, while taking POMALYST, during dose interruptions, and for at least 4 weeks after stopping POMALYST **every time they have sex with a male**, or abstaining from sex with a male

1 of 4 (continued on next page)

The sequence of this section is based on the Education and Counseling Checklist for Pharmacies.

Remember to fill out this checklist for every patient for every prescription.

Counseling for female patients of reproductive potential



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

COUNSEL ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity
- Not taking treatment if pregnant or breastfeeding
- Using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time they have sex with a male**, or abstaining from sex with a male
 - **Highly effective** methods of contraception: Tubal ligation, intrauterine device (IUD), hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy
 - **Additional effective** methods of contraception: Male latex or synthetic condom, diaphragm, or cervical cap

Counseling for female patients of reproductive potential (continued)



COUNSEL ADULTS AND CHILDREN ON:

- Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
 - Beginning at least 4 weeks before treatment
 - During treatment
 - During dose interruptions
 - For at least 4 weeks after stopping treatment
 - **Every time they have sex with a male**, or abstaining from sex with a male

Counseling for female patients of reproductive potential (continued)



COUNSEL ADULTS AND CHILDREN ON:

- Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use
 - Pregnancy testing should be repeated:
 - Every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all
 - If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- The need to stop treatment right away **in the event of becoming pregnant, or if they think for any reason they may be pregnant**, and to call their healthcare provider immediately

Counseling for female patients of reproductive potential (continued)



COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
 - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance

Counseling for female patients not of reproductive potential



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
 - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

Counseling for female patients not of reproductive potential (continued)



FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance
- Parent or legal guardian must inform the child's doctor when the child begins menses

Counseling for male patients



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

COUNSEL ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity and contraception
 - Wearing a latex or synthetic condom every time when engaging in sexual intercourse with a female who can get pregnant
- Female partners of males receiving treatment must call their healthcare provider right away if they get pregnant

Counseling for male patients (continued)



COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood or sperm during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
 - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

FOR MALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance

Additional counseling for all patients taking POMALYST® (pomalidomide)



COUNSEL ADULTS AND CHILDREN ON:

- Possible side effects include deep vein thrombosis and pulmonary embolism

Counsel patient to **contact healthcare provider** if experiencing any side effects.

Pharmacy staff knowledge check



- Which of these is **not** something patients need to be counseled on?
 - A. Not sharing capsules
 - B. Not breaking, chewing, or opening capsules
 - C. Wearing gloves while taking capsules

Correct Answer: C. Wearing gloves while taking capsules.

- Patients must be counseled on:
 - Not sharing capsules with anyone—especially with females who can get pregnant
 - Not breaking, chewing, or opening capsules

Pharmacy staff knowledge check (continued)



- Female patients of reproductive potential must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control for 4 weeks after stopping treatment.
 - A. True
 - B. False

Correct Answer: A. True

- Female patients of reproductive potential must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
 - Beginning at least 4 weeks before treatment
 - During treatment
 - During dose interruptions
 - For at least 4 weeks after stopping treatment
 - **Every time they have sex with a male**, or abstaining from sex with a male

Pharmacy staff knowledge check (continued)



- All patients must receive a Medication Guide along with their prescription.
 - A. True
 - B. False

Correct Answer: A. True

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

Celgene REMS Programs Pharmacy Training: POMALYST REMS™

Section 5: Guidelines for Dispensing



Celgene Confidential: For Celgene Business Use Only



In this section

- Pharmacy and prescription requirements
- Dispensing guidelines
- Steps for dispensing
- Pharmacy staff knowledge check

Pharmacy and prescription requirements



- Dispensing pharmacies must be certified in the applicable Celgene REMS program and educated on the program and on dispensing procedures for the treatment
- Pharmacy must ensure that every prescription includes:
 - Patient and prescriber demographics and contact information
 - Patient risk category
 - Dosing information and instructions
 - Authorization number
 - Prescriber signature
- Authorization numbers are valid for **7 days** from the date of last pregnancy test for female patients of reproductive potential and **30 days** from the date it is issued for all other patients
- No automatic refills or telephone prescriptions are permitted
- Faxed prescriptions are permissible depending on state laws

Dispensing guidelines



- Dispense **no more than a 4-week (28-day) supply** with the Medication Guide. A new prescription is required for further dispensing
- **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription**
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product **must be shipped the same day** confirmation number is obtained **or picked-up within 24 hours** of obtaining confirmation
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame
 - Pharmacy must obtain a new confirmation number by calling Celgene Customer Care at 1-888-423-5436 when ready to ship or have the product picked-up

Dispensing guidelines (continued)



- When shipping, pharmacy must require a signature confirming receipt
- Pharmacy shall keep an inventory log for the drug, by strength, reflecting its on-hand inventory at all times
- Do not transfer the drug to another pharmacy without prior authorization from Celgene
- Accept unused capsules (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal

Steps for dispensing



Review incoming prescriptions

- Only accept prescriptions with all of the following information:
 - Patient and prescriber demographics and contact information
 - Patient risk category
 - Dosing information and instructions
 - Authorization number
 - Prescriber signature
- Make sure the prescription is signed and dated
- Confirm the prescription is written for a 4-week (28-day) supply or less
- For subsequent prescriptions, verify there are 7 days or less of therapy remaining on the existing prescription

Steps for dispensing (continued)



Counsel patient

- Patients must receive counseling from a Celgene REMS program certified pharmacy counselor
- Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist
 - Make sure form is signed and dated by the counselor and appropriate boxes are checked off
 - Keep a copy of the checklist and the associated prescription
- Please report adverse drug experiences that are suspected to be associated with the use of the drug and any suspected pregnancy occurring during the treatment

Steps for dispensing (continued)



Obtain confirmation number from Celgene

- Prior to each prescription, contact Celgene Customer Care at 1-888-423-5436, available 24 hours a day, 7 days a week
 1. Enter the pharmacy NABP number or DEA number
 2. Enter the authorization number written on the prescription
 3. Enter the number of capsules and milligram strength being dispensed
 4. Write the **confirmation number** and **date** on the prescription. Note: the confirmation number is **only valid for 24 hours**
- If you do not obtain a confirmation number, you are not permitted to dispense the product to the patient

If you have questions about the validity of the authorization or confirmation numbers, call Celgene Customer Care.

Steps for dispensing (continued)



Dispense prescription

- Include a Medication Guide with each prescription
- Document the dispense date on either the shipping receipt or pharmacy dispensing log
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product **must be shipped the same day** confirmation number is obtained **or handed to the patient within 24 hours**

Pharmacy staff knowledge check



- A confirmation number is valid for:
 - A. 24 hours
 - B. 7 days
 - C. 30 days

Correct Answer: A. 24 hours

- The confirmation number is **only valid for 24 hours**
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame

Pharmacy staff knowledge check (continued)



- Each prescription must have both an authorization number and a patient risk category written on it.
 - A. True
 - B. False

Correct Answer: A. True

- Only accept prescriptions with all of the following information:
 - Patient and prescriber demographics and contact information
 - Patient risk category
 - Dosing information and instructions
 - Authorization number
 - Prescriber signature

Pharmacy staff knowledge check (continued)



- The pharmacy must dispense no more than a 4-week (28-day) supply.
 - A. True
 - B. False

Correct Answer: A. True

- Dispense **no more than a 4-week (28-day) supply** with the Medication Guide
- A new prescription is required for further dispensing

You May Want Emergency Contraception If

- His condom broke or slipped off, and he ejaculated inside your vagina.
- You forgot to take your birth control pills.
- Your diaphragm, cap, or shield slipped out of place, and he ejaculated inside your vagina.
- You miscalculated your "safe" days.
- He didn't pull out in time.
- You weren't using any birth control.
- He forced you to have unprotected vaginal sex.

Contact your health care provider immediately if you have had unprotected intercourse and you think you might become pregnant. **Ask about emergency contraception.**



www.plannedparenthood.org
www.teenwire.com
Other publications —
www.ppfastore.org

EC — Emergency Contraception
2675 9/08-180 2.13.5
ISBN 1-930996-91-8
Printed in the U.S.A.

**How Well Emergency Contraception Works**

- **Progestin-only EC reduces the risk of pregnancy by 89 percent if started within 72 hours of unprotected intercourse.** For example, eight out of 100 women will become pregnant after having unprotected sex once during the second or third week of their cycles. But only one woman out of 100 will become pregnant after taking progestin-only EC.
- **Combination EC reduces the risk of pregnancy by 75 percent if started within 72 hours of unprotected intercourse.** Only two women out of 100 will become pregnant after taking combination EC.

Emergency contraception is meant as backup birth control only. EC is not as effective as the correct and consistent use of reversible contraception — the IUD, the shot, the pill, the patch, or the ring.

EC does not continue to prevent pregnancy during the rest of the cycle. Other methods of birth control must be used.

Emergency contraception offers no protection against sexually transmitted infections. You may want to consider testing for sexually transmitted infections if there is a possibility that unprotected sex put you at risk.

How to Get Emergency Contraception

Plan B is now available over the counter for women 18 and older. Plan B and other forms of emergency contraception are also available by prescription for all women. Contact your local Planned Parenthood at 1-800-230-PLAN to get EC or to get a prescription for EC if you are younger than 18. You may also get EC at your local pharmacy if you are older than 18.

If you are younger than 18, you may want to ask your clinician for a prescription for EC before you need it. This will allow you to use EC in emergency situations without having to wait to get an appointment.

Costs Vary Widely

Costs depend on which of the following services are needed. Here are some estimates:

EC	Range of Costs
Plan B	\$10 – \$60
one pack of combination pills	\$20 – \$50
visit with health care provider	\$35 – \$150
pregnancy test	\$10 – \$20
Range of Total Cost	\$10 – \$255

Fees may be less at family planning clinics and health centers. Some use a sliding scale based on income. Costs vary from community to community, based on regional and local expenses. Contact your nearest Planned Parenthood health center at 1-800-230-PLAN for information about costs in your area.

Emergency IUD Insertion**IUDs can also be used as backup birth control.**

A clinician can insert a Copper T 380A IUD (ParaGard®) for emergency contraception within five days of unprotected intercourse. It can be left in place for up to 12 years for very effective contraception. Or the IUD can be removed after your next menstrual period, when it is certain that you are not pregnant. Emergency IUD insertion reduces the risk of pregnancy by 99.9 percent.

For more information about the advantages and disadvantages of the IUD as a regular method of birth control, read the Planned Parenthood pamphlet, *Understanding IUDs*.

Update — Jon Knowles, September 2008
Original version — Jon Knowles, 1996

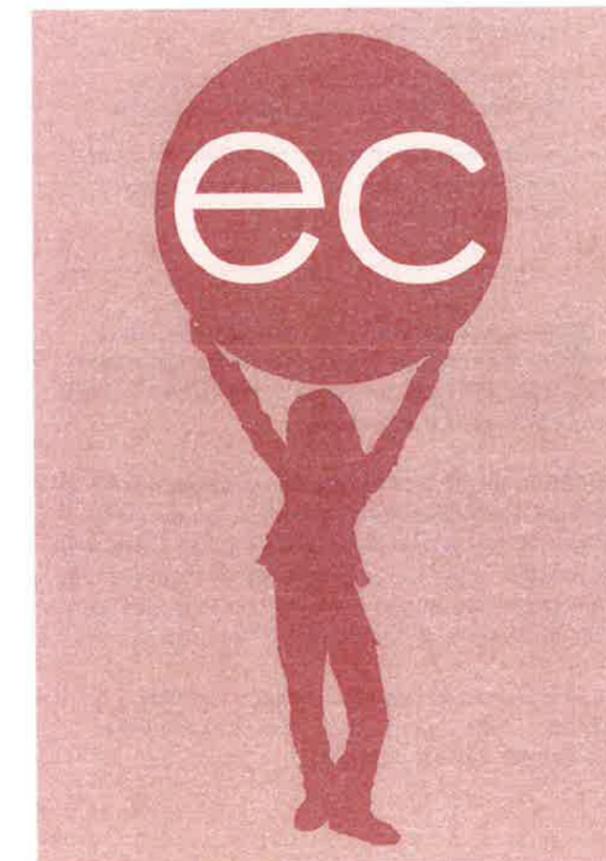
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ISBN 1-930996-91-8

Emergency Contraception

 **Planned Parenthood**
America's most trusted name in women's health.®





- **EC can prevent pregnancy after unprotected vaginal intercourse.** It is also called "the morning-after pill," emergency birth control, or backup birth control.
- **EC must be started within 120 hours — five days — after unprotected intercourse.**
- **The sooner it is started, the better.** EC reduces the risk of pregnancy by 75–89 percent when the first dose is taken within 72 hours.

EC contains hormones found in birth control pills and prevents pregnancy by stopping ovulation or fertilization. Theoretically, EC could also prevent implantation, but that has not been proven scientifically.

Plan B® is a brand of hormone pills approved by the FDA specifically for emergency contraception. Certain birth control pills may also be prescribed for use as emergency contraception. Some EC regimens use "combination pills" with estrogen and progestin — synthetic hormones like the ones a woman's body makes. Plan B has progestin only.

EC will not cause an abortion or affect an existing pregnancy. Still, a woman should not use emergency contraception if she is pregnant.

How to Use EC

Plan B can be taken in one dose or in two doses, 12 hours apart. Combined hormone pills must be taken in two doses, 12 hours apart. The number of pills in a dose varies with the brand of the pill. Use the same brand for both doses.

Swallow the pill(s) in the first dose as soon as possible, up to 120 hours — five days — after having unprotected sex. EC may cause nausea and vomiting. This risk is much higher for combination pills than for progestin-only pills.

To reduce the risk of nausea, you may want to take an anti-nausea medication, such as Dramamine or Bonine one hour before taking EC.

If you are taking the pills in two doses, swallow the second dose 12 hours after taking the first. If you vomited after the first dose, be sure to use an anti-nausea medication one hour before taking the second dose. Or you may want to take the second dose as a vaginal suppository by inserting the pills with your fingers as high into your vagina as you can reach. (The medication will be absorbed through the vaginal tissue.)

If you vomit the second dose, do not take any extra pills. They probably won't reduce the risk of pregnancy. But they will probably make you sick to your stomach.

Pill Brand	1st Dose (within 120 hours)	2nd Dose (12 hours later)
Plan B	1 white pill	1 white pill*
Alesse	5 pink pills	5 pink pills
Aviane	5 orange pills	5 orange pills
Cryselle	4 white pills	4 white pills
Enpresse	4 orange pills	4 orange pills
Jolessa	4 pink pills	4 pink pills
Lessina	5 pink pills	5 pink pills
Levlen	4 light-orange pills	4 light-orange pills
Levlite	5 pink pills	5 pink pills
Levora	4 white pills	4 white pills
Lo/Ovral	4 white pills	4 white pills
Low-Ogestrel	4 white pills	4 white pills
Lutera	5 white pills	5 white pills
Lybrel	6 yellow pills	6 yellow pills
Nordette	4 light-orange pills	4 light-orange pills
Ogestrel	2 white pills	2 white pills
Ovral	2 white pills	2 white pills
Portia	4 pink pills	4 pink pills
Quasense	4 white pills	4 white pills
Seasonale	4 pink pills	4 pink pills
Seasonique	4 light-blue-green pills	4 light-blue-green pills
Tri-Levlen	4 yellow pills	4 yellow pills
Triphasil	4 yellow pills	4 yellow pills
Trivora	4 pink pills	4 pink pills

*Both doses of Plan B can be taken at the same time.

After You Take the Pills

- Your next period may be earlier or later than usual.
- Your flow may be heavier, lighter, more spotty, or the same as usual.
- Tell any other health care provider you may see before you get your next period that you have taken EC.
- Schedule a follow-up visit with your clinician if you do not have your period in three weeks or if you have symptoms of pregnancy.
- Be sure to use another method of contraception if you have vaginal intercourse any time before you get your period again.
- Continue using the birth control method of your choice for as long as you want to avoid pregnancy.

Side Effects

Side effects associated with the use of EC usually taper off within a day or two.

- Half of the women who take the combination pills feel sick to their stomachs, but only for about 24 hours. Less than one out of five women vomit with combination pills.
- The risk of nausea and vomiting is much lower with progestin-only EC, like Plan B — less than one in four women feel sick to their stomachs.
- Breast tenderness, irregular bleeding, dizziness, and headaches may also occur.

There have been no reports of serious complications among the millions of women who have used EC.

Frequent use of EC may cause periods to become irregular and unpredictable.

The side effects of anti-nausea medication may include drowsiness. Please follow the precautions on the package insert.

continued over →

Prescriber Guide to Pomalyst REMS™ Risk Evaluation and Mitigation Strategy (REMS)™ Program

Due to its structural similarity to thalidomide, a known teratogen, POMALYST® (pomalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program.

This guide contains important information for prescribers about:

- The risks of POMALYST, including a boxed warning for
 - Embryo-fetal toxicity
 - Venous thromboembolism
- The POMALYST REMS™ program
 - Prescriber Certification
 - Patient Enrollment
 - Contraceptive Requirements and Counseling for Patients
 - Initial and Subsequent Prescription Requirements

POMALYST REMS™ Resources for Prescribers Include:

- Prescriber Guide to POMALYST REMS™ Program
- CD-ROM, including Patient-Physician Agreement Form and Patient Prescription Form Software and Installation Instructions
- Full Prescribing Information for POMALYST

Table of contents

About POMALYST® (pomalidomide).....	3
The POMALYST REMS™ program	4
Key points of the POMALYST REMS™ program.....	4
Patient enrollment into POMALYST REMS™ program.....	5
Initial prescription requirements	7
• All patients.....	7
• Female patients.....	7
◦ Females of reproductive potential	8
◦ Females not of reproductive potential	10
• Male patients.....	10
Initial mandatory confidential survey	11
• Additional information for the prescriber	11
Subsequent prescription requirements	12
After the last dose of POMALYST.....	13
Ordering English and non-English materials	14
Adverse drug experience reporting procedure for healthcare professionals.....	15

About POMALYST® (pomalidomide)

POMALYST 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.

Risks of POMALYST

POMALYST has a Boxed Warning for embryo-fetal toxicity and venous thromboembolism.

Due to the fact that it is an analogue of thalidomide, a known teratogen, POMALYST is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST if they take adequate precautions to avoid pregnancy.

Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE) occurred in patients with multiple myeloma treated with pomalidomide. The decision to take prophylactic measures should be done carefully after an assessment of an individual patient's underlying risk factors.

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 POMALYST REMS™ and agree to comply with the requirements of the POMALYST REMS™ program. Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center toll-free at 1-888-423-5436.

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 POMALYST REMS™
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy dispenses POMALYST to patient along with a Medication Guide

POMALYST REMS™ patient enrollment

- Obtain, review, and complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form online at www.CelgeneRiskManagement.com, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at 1-888-423-5436
- Prescribers who do not have access to a computer, or whose computer systems are not compatible with the software, will be provided with POMALYST REMS™ program materials. For additional assistance, please contact the Celgene Customer Care Center or your Celgene Hematology Oncology Consultant
- Patient, parent/legal guardian, and/or authorized representative must read the POMALYST® (pomalidomide) Patient-Physician Agreement Form in the language of their choice

Help Ensure Timely Processing of Each Prescription

Fill Out Form as Directed

- Write only in the designated areas on the POMALYST® (pomalidomide) Patient-Physician Agreement Form
- The box next to each statement must be marked (with an “X”) to indicate understanding
- The form must be completed and signed by both prescriber and patient

Instructions for Female Patients

- For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

Instructions for Minors

- If the patient is under 18 years of age, his or her legal guardian must read this material, mark the statement in each block of the form (with an “X”) and agree to ensure compliance by signing and dating the form

Instructions for Incompetent Adult Patients

- For an incompetent adult patient, an authorized representative must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form

POMALYST REMS™ patient enrollment (continued)

- An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient's behalf
- The authorized representative must read the material, mark the statements, and agree to ensure compliance by signing and dating the form
- If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the POMALYST® (pomalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the POMALYST REMS™ program and is authorized to consent to treatment with POMALYST on behalf of the patient

Send in Completed Forms

- Send the completed POMALYST® (pomalidomide) Patient-Physician Agreement Form online through www.CelgeneRiskManagement.com, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**
- You will receive confirmation electronically or via fax to your office once the patient is enrolled
- Once the POMALYST® (pomalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys
- In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

Note: If therapy with POMALYST is discontinued for 12 consecutive months, the patient must enroll again in the POMALYST REMS™ program. Follow the above procedures to re-enroll the patient.

Initial prescription requirements

ALL PATIENTS

- Provide comprehensive counseling on the benefits and risks of therapy with POMALYST® (pomalidomide)
- Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with POMALYST
- Provide counseling not to share POMALYST capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of POMALYST, as well as counseling on appropriate contraceptive use, including emergency contraception
- Provide patients with education materials provided in the POMALYST REMS™ Patient Resource Pack
- Patients should be instructed to not extensively handle or open POMALYST capsules
- Instruct patients to return unused POMALYST capsules for disposal to Celgene or to their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them

FEMALE PATIENTS

Determine if female patient is of reproductive potential

Two categories:

1. Females of Reproductive Potential

- All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category

2. Females Not of Reproductive Potential

- Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating

Initial prescription requirements (continued)

1. Females of Reproductive Potential

Pregnancy test requirements

- Obtain a **negative** pregnancy test 10 to 14 days prior to writing an initial prescription for POMALYST® (pomalidomide) and again within 24 hours prior to writing an initial prescription for POMALYST even if continuous abstinence is the chosen method of birth control
 - The pregnancy test must be sensitive to at least 50 mIU/mL
 - Pregnancy testing should occur weekly during the first 4 weeks of use
 - Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
 - If a patient misses her period or if there is any abnormality in menstrual bleeding, POMALYST should be discontinued immediately. Obtain a pregnancy test and counsel the patient
- **If pregnancy does occur during treatment, POMALYST must be immediately discontinued.** Any suspected embryo-fetal exposure to POMALYST must be reported immediately to the FDA via the MedWatch number at **1-800-332-1088** and also to the Celgene Customer Care Center at **1-888-423-5436**. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling
- The patient must not breastfeed a baby while being treated with POMALYST

Initial prescription requirements (continued)

Patient Counseling on Contraception Requirements

Contraception requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before POMALYST® (pomalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Effective Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
<ul style="list-style-type: none">• Intrauterine device (IUD)• Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)• Tubal ligation (having your tubes tied)• Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	<ul style="list-style-type: none">• Male latex or synthetic condom• Diaphragm• Cervical cap

Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.

Unacceptable forms of contraception:

- Progesterone-only "mini-pills"
 - IUD Progesterone T
 - Female condoms
 - Natural family planning (rhythm method) or breastfeeding
 - Fertility awareness
 - Withdrawal
 - Cervical shield*
- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

Initial prescription requirements (continued)

2. Females Not of Reproductive Potential

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy
- The parent or guardian must confirm that a prepubertal female child is not now pregnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before POMALYST® (pomalidomide) therapy, during therapy, and for at least 4 weeks after stopping therapy

MALE PATIENTS

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking POMALYST therapy is unknown
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of POMALYST

Initial mandatory confidential survey

Females

- Instruct the female patient to complete a brief initial mandatory confidential survey at www.CelgeneRiskManagement.com, or by calling **1-888-423-5436**. See page 12 for subsequent prescription requirements

Males

- Males do not need to take the initial survey

Prescribers

- Prescriber will complete a brief mandatory confidential survey by visiting www.CelgeneRiskManagement.com, or by calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted

ADDITIONAL INFORMATION FOR THE PRESCRIBER

- Healthcare provider must send the prescription to a POMALYST REMS™ certified pharmacy. To locate a certified pharmacy, please visit www.Celgene.com/PharmacyNetwork
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

Subsequent prescription requirements

The prescriber must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for POMALYST® (pomalidomide) is written.

No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

FEMALE PATIENTS

- Provide counseling as outlined in the “FEMALE PATIENTS” section on pages 7-10
- Follow pregnancy test requirements as outlined in the “Pregnancy test requirements” section on page 8
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
 - Before prescription is obtained
 - Monthly
 - Adult females of reproductive potential
 - All female children
 - Every 6 months
 - Adult females not of reproductive potential

MALE PATIENTS

- Provide patient counseling as outlined in the “MALE PATIENTS” section on page 10
- Male patients must complete a brief mandatory confidential survey once a month
 - Males do not complete an initial survey

After the last dose of POMALYST® (pomalidomide)

After patients have stopped taking POMALYST, they must do the following:

ALL PATIENTS

- Must not share POMALYST capsules—especially with females of reproductive potential
- Must return any unused POMALYST capsules for disposal to Celgene or their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them
- Must not donate blood for 4 weeks after stopping POMALYST

FEMALE PATIENTS

- Must not get pregnant for at least 4 weeks after stopping POMALYST by using the appropriate contraceptives each time engaging in sexual activity with a male

MALE PATIENTS

- Must use a latex or synthetic condom for 4 weeks after stopping POMALYST
- Must not donate sperm for 4 weeks after stopping POMALYST

Ordering English and non-English materials

CALL CELGENE CUSTOMER CARE CENTER AT 1-888-423-5436

- Materials are available in 16 languages and include:
 - POMALYST® (pomalidomide) Patient-Physician Agreement Forms
 - Patient Guide to POMALYST REMS™ Program
 - Mandatory confidential survey forms

Available languages:

Arabic	French	Japanese	Portuguese
Cambodian	German	Korean	Russian
Chinese	Greek	Laotian	Spanish
English	Italian	Polish	Vietnamese

- POMALYST® (pomalidomide) Patient-Physician Agreement Forms, Patient Guide to POMALYST REMS™ Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

Prescriber's:

Name
Identification Number
Full Address
Fax Number

Patient's:

Name
Full Address
Phone Number
Date of Birth
Identification Number
Diagnosis (most recent version of ICD code)

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of POMALYST® (pomalidomide).

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

For more information about POMALYST® (pomalidomide) and the POMALYST REMS™ program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

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



Pomalyst REMS™

Pomalyst
(pomalidomide) capsules

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1/13

REMS-POM12145

Reference ID: 3258521

Pomalyst REMS™

Prescriber Enrollment Form

All prescribers must be certified to prescribe POMALYST® (pomalidomide). To become certified the prescriber must:

1. Complete the Prescriber Enrollment Form, which is required for POMALYST REMS™ certification.
2. Agree to steps below that must be followed with every patient.

To submit this form electronically, please go to **www.CelgeneRiskManagement.com**.

To submit this form via fax, please complete all required fields below and fax all pages to 1-888-432-9325.

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.

Please review the steps below that must be followed with every patient.

When prescribing POMALYST, I agree to:

- Provide patient counseling on the benefits and risks of POMALYST therapy, including Boxed Warnings
- Submit a completed POMALYST® (pomalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during POMALYST treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed POMALYST immediately to Celgene Drug Safety (or Celgene Customer Care Center)
- Complete a mandatory and confidential prescriber survey online or by telephone for all patients and obtain a new authorization number for each prescription written and include this authorization number on the prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a POMALYST REMS™ certified pharmacy to fill the prescription
- Return to Celgene all POMALYST capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Remind patients to return all POMALYST capsules to Celgene Corporation or their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them
- Re-enroll patients in the POMALYST REMS™ program if POMALYST is required and previous therapy with POMALYST has been discontinued for 12 consecutive months.

POMALYST is only available under a restricted distribution program, POMALYST REMS™.



Please fill out the spaces below completely.

Prescriber Name _____

Degree: MD/DO/PA/NP/Fellow/Medical Resident

Specialty _____

Prescriber Identification Number _____

Please indicate which office(s) will receive POMALYST REMS™ materials and updates:

Primary Office Name _____

Attention _____

Address _____

City _____ State _____ ZIP Code _____

Phone _____ Ext. _____ Fax _____

Email Address _____

Secondary Office Name _____

Attention _____

Address _____

City _____ State _____ ZIP Code _____

Phone _____ Ext. _____ Fax _____

Email Address _____

I understand that if I fail to comply with all requirements of the POMALYST REMS™ program, my prescriptions for POMALYST® (pomalidomide) will not be honored at certified pharmacies.

Prescriber Signature _____ Date _____

Return this form to the Celgene Customer Care Center via fax or mail.

Mail to: Celgene Customer Care Center, 86 Morris Avenue, Summit, NJ 07901

Phone: 1-888-423-5436

Fax: 1-888-432-9325

www.CelgeneRiskManagement.com



Pomalyst REMS™



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1/13

REMS-POM12154

Reference ID: 3258521

Pomalyst REMS™

At-A-Glance

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
- Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center toll-free at 1-888-423-5436

For more information about POMALYST and the POMALYST REMS™ program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436.

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



Pomalyst REMS™



Initial prescription (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for POMALYST® (pomalidomide).
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open POMALYST capsules.
3. Obtain, review, and complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form online at www.CelgeneRiskManagement.com, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**.
 - **Males (adults and children)**
 - **Females of reproductive potential include all females who are menstruating**, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
 - **Females not of reproductive potential include females who have been in natural menopause for at least 24 consecutive months**, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating
4. Send the completed and signed POMALYST® (pomalidomide) Patient-Physician Agreement Form online through www.CelgeneRiskManagement.com, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**.
5. Instruct female patients to complete a brief initial mandatory confidential survey at www.CelgeneRiskManagement.com, or by calling **1-888-423-5436**, prior to prescriber obtaining an authorization number.
 - Males do not need to complete the initial survey
6. Complete a prescriber brief mandatory confidential survey by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written.
 - You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)

7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
8. Send the prescription to a certified pharmacy.

Subsequent prescriptions (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open POMALYST capsules.
3. Instruct patient to complete a brief mandatory confidential survey **as scheduled**, prior to prescriber obtaining an authorization number and filling the prescription.
 - Monthly:
 - **Males (adults and children)**
 - **Females of reproductive potential (adults and children)**
 - **Female children not of reproductive potential**
 - Every 6 months:
 - **Adult females not of reproductive potential**
4. Complete a prescriber brief mandatory confidential survey by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center at **1-888-423-5436**, for every patient before each prescription is written.
 - You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
5. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
6. Send the prescription to a certified pharmacy.

Pharmacy Guide to

Pomalyst REMS™

Risk Evaluation and Mitigation Strategy (REMS)™ Program

Important information about POMALYST® (pomalidomide) and the POMALYST 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 with the POMALYST REMS™ program can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program
- Dispensing pharmacists must be educated on the POMALYST REMS™ program and on dispensing procedures for POMALYST
- Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**



Table of contents

Guidelines for ordering, counseling, and dispensing POMALYST® (pomalidomide)	3
POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ education and counseling checklist for pharmacies	6
Rules for dispensing and shipping	6
Adverse drug experience reporting procedure for healthcare professionals	7

Guidelines for ordering, counseling, and dispensing POMALYST® (pomalidomide)

Dispensing pharmacies must be certified in the POMALYST REMS™ program with Celgene and must be educated in the following dispensing procedures.

Step 1. Review incoming POMALYST prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them.
 - Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted
 - Faxed prescriptions are permissible depending on state laws
- B. Make sure the prescription is signed and dated.
- C. Confirm the prescription is written for a 4-week (28-day) supply or less.
- D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription.

Step 2. Counsel patient

- A. Make sure a **certified POMALYST REMS™** counselor counsels the patient.
- B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.
- C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST, make sure to document these experiences using acceptable documentation as noted on the checklist.
 - **Acceptable documentation examples:**
 1. Celgene ADE form and fax confirmation
 2. Pharmacy log
- D. Report adverse drug experiences that are suspected to be associated with the use of POMALYST to Celgene Drug Safety within 24 hours. See the Adverse Drug Experience Reporting Procedure on page 7 for more information.

Guidelines for ordering, counseling, and dispensing POMALYST® (pomalidomide) (continued)

Step 3. Obtain confirmation number from Celgene Customer Care

- A. Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week.
- Enter the pharmacy NABP number or DEA number
 - Enter the authorization number written on the prescription
 - Enter the number of capsules and milligram strength being dispensed
- B. Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.
- C. If you do not obtain a confirmation number, do not dispense POMALYST.

Step 4. Dispensing

- A. No Refills. A new prescription is required for each dispense. **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.**
- B. Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.
- C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.
- **Acceptable documentation examples:**
 1. Signed Education and Counseling checklist (if counseling pharmacist and dispensing pharmacist are the same)
 2. Pharmacy log

Guidelines for ordering, counseling, and dispensing POMALYST® (pomalidomide) (continued)

- D. Document the dispense date and maintain a record on acceptable documentation.

- **Acceptable documentation examples:**

1. Shipping receipt
2. Pharmacy dispensing log

- E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.

- F. A signature is required for all shipping and dispense if picked up by patient.

Step 5. Perform drug accountability

- A. Pharmacy shall keep an inventory log for POMALYST, by strength, reflecting its on-hand inventory at all times.
- B. Do not transfer POMALYST to another pharmacy without prior authorization from Celgene.
- C. Accept unused POMALYST (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal.

POMALYST Risk Evaluation and Mitigation Strategy (REMS)[™] education and counseling checklist for pharmacies

Ensure your patients know the risks

Before you are able to fill a prescription for POMALYST[®] (pomalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off (✓) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.



Be prepared to provide the following information for each checklist:

Authorization Number	Confirmation Number	Confirmation Date
Pharmacy Name	Pharmacy Address (including City, State, ZIP Code)	
Counselor Name	Work Phone Number	Extension
Patient Name	Patient Date of Birth	Patient Identification Number

Rules for dispensing and shipping

Making sure before you release POMALYST

DO NOT DISPENSE OR SHIP POMALYST TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing POMALYST prescription

For further information about POMALYST, please refer to the full Prescribing Information, enclosed.

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of POMALYST[®] (pomalidomide).

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 at: <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

For more information about POMALYST® (pomalidomide) and the POMALYST REMS™ program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

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



Pomalyst REMS™

Pomalyst
(pomalidomide) capsules

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1/13

REMS-POM12156

Pomalyst REMS™

Education and counseling checklist for pharmacies

POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety

Authorization No.: _____ Confirmation No.: _____ Confirmation Date: _____

Pharmacy Name: _____

Pharmacy Address: _____

Counselor Name: _____ Work Phone: _____ Ext.: _____

Patient Name: _____ Date of Birth: _____ Patient I.D. No.: _____

Risk Category: _____

Checklist for female patients of reproductive potential

- I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity
- Not taking POMALYST if pregnant or breastfeeding
- Using **at the same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner’s vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male
- Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking POMALYST, while taking POMALYST, during dose interruptions, and for at least 4 weeks after stopping POMALYST **every time they have sex with a male**, or abstaining from sex with a male

- ❑ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- ❑ The need to stop taking POMALYST® (pomalidomide) right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately
- ❑ Possible side effects include deep vein thrombosis and pulmonary embolism
- ❑ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant
- ❑ Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST
- ❑ Not breaking, chewing, or opening POMALYST capsules
- ❑ Instructions on POMALYST dose and administration
Milligram (mg) Strength _____ Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

- ❑ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

- ❑ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ❑ Possible side effects include deep vein thrombosis and pulmonary embolism
- ❑ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant
- ❑ Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST
- ❑ Not breaking, chewing, or opening POMALYST capsules
- ❑ Instructions on POMALYST dose and administration
Milligram (mg) Strength _____ Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

- ❑ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance
- ❑ Parent or legal guardian must inform the child’s doctor when the child begins menses

Checklist for male patients

- ❑ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ❑ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant)
- ❑ Female partners of males taking POMALYST® (pomalidomide) must call their healthcare provider right away if they get pregnant
- ❑ Possible side effects include deep vein thrombosis and pulmonary embolism
- ❑ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant
- ❑ Not donating blood or sperm while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST
- ❑ Not breaking, chewing, or opening POMALYST capsules
- ❑ Instructions on POMALYST dose and administration
Milligram (mg) Strength _____ Number of Capsules Dispensed _____

MALE CHILDREN (<18 YEARS OF AGE):

- ❑ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

Rules for dispensing and shipping

DO NOT DISPENSE OR SHIP POMALYST® (pomalidomide) TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- Prescription has an authorization number and patient risk category written on it
- You have counseled the patient
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing POMALYST prescription

All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.

Counselor Signature: _____ **Date:** _____

For more information about POMALYST and the POMALYST REMS™ program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

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



Pomalyst REMS™

Pomalyst
(pomalidomide) capsules

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1/13

REMS-POM12155



Patient Guide to

Pomalyst REMS™

Risk Evaluation and Mitigation Strategy (REMS)™ Program

This guide provides you important information about:

- The risks of POMALYST® (pomalidomide)
 - Birth defects (deformed babies) or death of an unborn baby
 - Blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)
- The POMALYST REMS™ program
 - What females who can get pregnant need to know
 - Birth control options
 - What females who can not get pregnant need to know
 - What males need to know

Table of contents

Risks of POMALYST® (pomalidomide).....	4
What is the POMALYST REMS™ program?	4
What do all patients need to know about the POMALYST REMS™ program?.....	5
What do females who can get pregnant need to know about the POMALYST REMS™ program?.....	6
What do females who can not get pregnant need to know about the POMALYST REMS™ program?.....	12
What do males need to know about the POMALYST REMS™ program?.....	14
Mandatory confidential patient surveys.....	16
Warning to patients taking POMALYST.....	18

Risks of POMALYST® (pomalidomide)

POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or death to unborn babies. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST.

POMALYST causes higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

What is the POMALYST REMS™ program?

To avoid serious risks to unborn babies, POMALYST is only available under a restricted distribution program called the “POMALYST Risk Evaluation and Mitigation Strategy (REMS)™.” Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST. In order to receive POMALYST, patients must be enrolled in the POMALYST REMS™ program and agree to follow the requirements.

For more information about POMALYST and the POMALYST REMS™ program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center toll-free at **1-888-423-5436**.

What do all patients need to know about the POMALYST REMS™ program?

General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects
- POMALYST® (pomalidomide) must be kept out of the reach of children
- Do not open or unnecessarily handle POMALYST capsules
- Keep POMALYST in a cool, dry place
- Do **not** donate blood while you are taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST
- Unused POMALYST capsules should be returned for disposal to Celgene by calling **1-888-423-5436**, or to your POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to you

What do females who can get pregnant need to know about the POMALYST REMS™ program?

A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says you understand that POMALYST should not be used during pregnancy, and that you agree not to become pregnant while taking POMALYST
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking POMALYST
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for POMALYST, and again within 24 hours before you receive your first prescription for POMALYST. If you are pregnant, you cannot take POMALYST
- You will have pregnancy tests before starting POMALYST and while taking POMALYST, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for POMALYST, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies

- Before dispensing POMALYST® (pomalidomide), your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

- Your healthcare provider will talk with you about your birth control options

1. Choose at least 1 highly effective method and at least 1 additional effective method of birth control. Talk to your healthcare provider about the following acceptable birth control methods. See below.

Reliable Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom
Tubal ligation (having your tubes tied)	+ Diaphragm
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Cervical cap

2. Use the 2 methods of birth control at the same time

- Remember:** You must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons

What do females who can get pregnant need to know about the POMALYST REMS™ program? (continued)

- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- **Remember, not having sex is the only method of birth control that is 100% effective**

3. Unacceptable methods of birth control

- Progesterone-only “mini-pills”
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield*

4. Take pregnancy tests

- You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for POMALYST® (pomalidomide) and again within 24 hours before receiving your first prescription for POMALYST. Both pregnancy tests must have a negative result

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

B. While taking POMALYST® (pomalidomide)

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use
- You will have a pregnancy test performed by your healthcare provider:
 - Every week during the first 4 weeks of treatment, then
 - Every 4 weeks if your menstrual cycles are regular, or
 - Every 2 weeks if your cycles are irregular
 - If you miss your period or have unusual menstrual bleeding, or
 - If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control, stop taking POMALYST immediately and call your healthcare provider right away

What do females who can get pregnant need to know about the POMALYST REMS™ program? (continued)

- If you get pregnant, or think you may be pregnant, you must **immediately** stop taking POMALYST® (pomalidomide). Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must not breastfeed a baby while you are taking POMALYST
- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking POMALYST® (pomalidomide)

- You must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
 - For at least 4 weeks after stopping POMALYST, or
 - Do not have any sex with a male for 4 weeks after stopping POMALYST

See also “General guidelines” on page 5 for requirements for all patients.

What do females who can not get pregnant need to know about the POMALYST REMS™ program?

A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
 - You have been in natural menopause for at least 2 years, or
 - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting POMALYST
- Before your healthcare provider can write your prescription for POMALYST, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies

- Before dispensing POMALYST® (pomalidomide), your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

B. While taking POMALYST

- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

See “General guidelines” on page 5 for requirements for all patients.

What do males need to know about the POMALYST REMS™ program?

- You must use a latex or synthetic condom **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form. You must agree that while taking POMALYST you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant
- Before dispensing POMALYST, your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

B. While taking POMALYST

- You must use a latex or synthetic condom **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only method of birth control that is 100% effective**

- You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must **not** donate sperm while taking POMALYST® (pomalidomide) (including during breaks [dose interruptions])
- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking POMALYST

- For 4 weeks after receiving your last dose of POMALYST, you must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping POMALYST

See also “General guidelines” on page 5 for requirements for all patients.

Mandatory confidential patient surveys

As a patient who is enrolled in the POMALYST REMS™ program for POMALYST® (pomalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

Adult females who can get pregnant

- Initial survey before first prescription
- Monthly

Adult females who can not get pregnant

- Initial survey before first prescription
- Every six months

Female children

- Initial survey before first prescription
- Monthly

Males

- No initial survey
- Monthly

Mandatory confidential survey process

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a POMALYST REMS™ certified pharmacy. The POMALYST REMS™ certified pharmacy will contact you to discuss your POMALYST® (pomalidomide) therapy. You will not receive your medication until you speak with the POMALYST REMS™ certified pharmacy

For more information, contact the Celgene Customer Care Center at **1-888-423-5436**

Warning to patients taking POMALYST® (pomalidomide)

Attention females:

Do **not** take POMALYST if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

Attention males:

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST.

Attention all patients:

You must **not** donate blood while taking POMALYST® (pomalidomide), during breaks (dose interruptions), and for 4 weeks after stopping POMALYST.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects.

POMALYST must be kept out of the reach of children. Return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**, or to your POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to you.

For more information about POMALYST® (pomalidomide) and the POMALYST REMS™ program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.



Pomalyst REMS™

Pomalyst
(pomalidomide) capsules

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Reference ID: 3258521

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REMS-POM12146



REMS Patient Survey Reminder

Patient Name _____ Date Survey Available _____

Doctor Office Contact and Phone # _____

Product _____ Pharmacy Name _____

Telephone Survey

OR

Website Survey



From a touchtone phone dial
1-888-423-5436

Press

2

Para español, oprime el numero dos

Press

1

to identify that you are a patient

Press

1

to take a survey



Enter your 9-digit patient identification number (the number you provided during the enrollment process – for example your Social Security Number).

From the menu provided, select the drug that you have been prescribed.

Press

1

OR

Press

2

OR

Press

3

Your survey will then begin. Please answer all of the questions. Confirmation that the survey has been completed will be provided at the end of your survey.

Access the internet and type in the website address
www.CelgeneRiskManagement.com

You are not required to have a User Name or Password to complete a survey. To take your survey, left click your mouse on the button

Patient Surveys

You will be asked for the following information. Please enter the information exactly as it was provided during your enrollment process

Please enter your details in the form below to continue with the patient survey.

* Patient Last Name:

* Patient First Name:

* Patient Identification Number:

Social Security Number e.g. 123456789

Please be sure to complete the survey in its entirety and upon completion send to Celgene.

After entering the information above, click

Start Survey

Survey questions will be displayed 1 per page. Please be sure to complete the survey in its entirety. A summary page displaying your survey answers will be displayed at the end of your survey. Upon completion, send the survey to Celgene by clicking

Send to Celgene

Pomalyst REMS™

Dear Prescriber:

Enclosed are your POMALYST REMS™ program education materials

Celgene Corporation is pleased to provide you with the enclosed materials for use in the POMALYST REMS™ program.

Important Information about the POMALYST REMS™ program

- To avoid embryo-fetal exposure, POMALYST® (pomalidomide) is only available under a special restricted distribution program called “POMALYST REMS™”
- Pomalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with pomalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of pomalidomide in human semen. Male patients taking POMALYST should not donate sperm. Males receiving POMALYST must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with POMALYST REMS™ can prescribe and dispense POMALYST to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program

As a prescriber certified in the POMALYST REMS™ program, please review and familiarize yourself with the contents of the enclosed POMALYST REMS™ Kit:

Prescriber Materials

- POMALYST REMS™ software and Installation Guide
- Prescriber Guide to POMALYST REMS™ Program
- POMALYST Full Prescribing Information

Patient Materials (Patient Resource Pack)

- Patient Guide to POMALYST REMS™ Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,



Jerome B. Zeldis, MD, PhD
Chief Medical Officer

Enclosures

Risks of POMALYST® (pomalidomide)

- POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or embryo-fetal death. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST
- POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

POMALYST 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.

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



Pomalyst REMS™



POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation.

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1/13

REMS-POM12143

Reference ID: 3258521

Pomalyst REMS[™]

POMALYST Risk Evaluation and Mitigation Strategy (REMS)[™] program
education and prescribing safety kit

Risks of POMALYST[®] (pomalidomide)

- POMALYST is similar to the medicine thalidomide (THALOMID[®]). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or embryo-fetal death. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST
- POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

POMALYST 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.

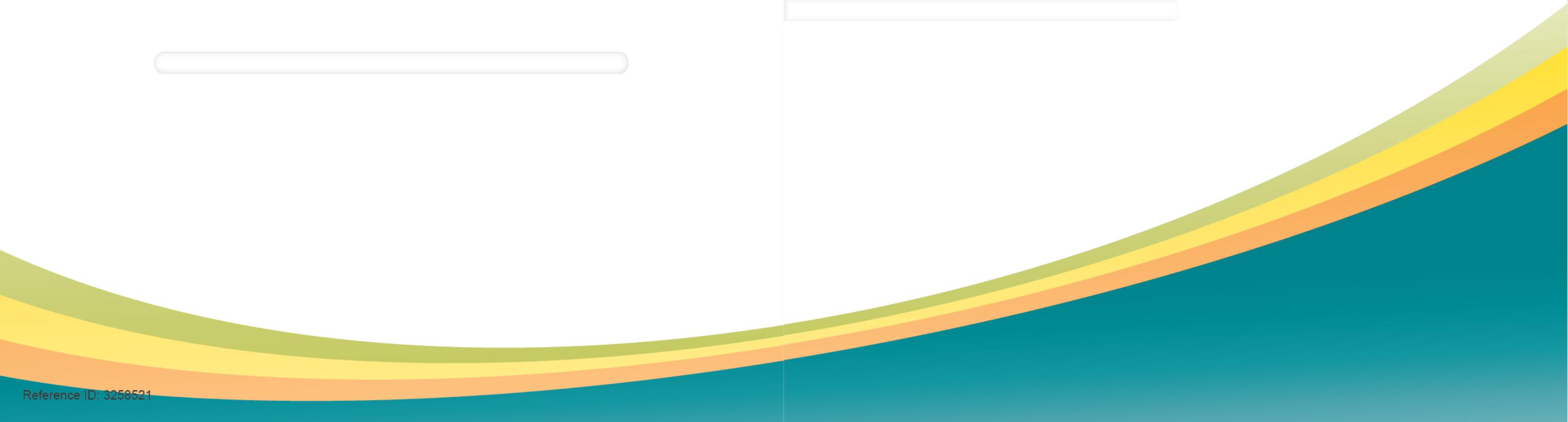


Risks of POMALYST® (pomalidomide)

- POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or embryo-fetal death. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST
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POMALYST 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™

Prescriber quick reference guide

1. The prescriber provides comprehensive counseling.
2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
3. The prescriber completes POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
4. Female patients complete initial mandatory confidential survey by:
 - Visiting **www.CelgeneRiskManagement.com**, or
 - Calling Celgene Customer Care Center at **1-888-423-5436**Male patients do not need to complete the initial survey.
All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to POMALYST REMS™ Program.
5. The prescriber completes mandatory confidential survey and receives authorization number by:
 - Visiting **www.CelgeneRiskManagement.com**, or
 - Calling Celgene Customer Care Center at **1-888-423-5436**
6. The prescriber writes POMALYST prescription and includes authorization number and patient risk category.
7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the POMALYST REMS™ procedures.

POMALYST is only available under a restricted distribution program, POMALYST REMS™.

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



Pomalyst REMS™



Pomalyst REMS™

Patient Resource Pack

POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program

The Patient Resource Pack contains:

- Patient Guide to POMALYST REMS™ Program
- Emergency Contraception Brochure
- Medication Guide

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Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.



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/s/

ANN T FARRELL

02/08/2013

Farrell, M.D. for Pazdur, M.D.