

Pomalidomide is approved through a restricted distribution program, approved by the Food and Drug Administration, called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS).

POMALIDOMIDE RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Prescriber Guide

This guide contains important information for prescribers about:

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

Pomalidomide REMS Resources for Prescribers Include:

- [Prescriber Guide](#)
- Prescribing Information*

**Please note, the Pomalidomide REMS Education and Prescribing Safety Kit includes Prescribing Information from each generic pomalidomide manufacturer participating in the Pomalidomide REMS.*

Table of Contents

2	Risks of Pomalidomide
2	The Pomalidomide REMS
4	Prescribing Pomalidomide Under the Pomalidomide REMS
5	Pomalidomide REMS Patient Enrollment
8	Initial Mandatory Confidential Survey
8	Additional Information for the Prescriber
8	Subsequent Prescription Requirements
9	After the Last Dose of Pomalidomide
9	Reporting Adverse Events

Risks of Pomalidomide

Pomalidomide has a **Boxed Warning** for embryo-fetal toxicity and thromboembolic events, including deep venous thrombosis (DVT) and pulmonary embolism (PE), myocardial infarction and stroke.

Because it is an analogue of thalidomide, a known teratogen, pomalidomide is contraindicated in pregnant females or females capable of becoming pregnant. Females who can get pregnant may be treated with pomalidomide if they take adequate precautions to avoid pregnancy.

Deep Venous Thrombosis (DVT), Pulmonary Embolism (PE), myocardial infarction and stroke occur in patients with multiple myeloma treated with pomalidomide.

This is not a comprehensive description of risks associated with the use of pomalidomide.

Please see Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, for further information.

The Pomalidomide REMS

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

In order to receive pomalidomide, all patients must be enrolled in the Pomalidomide REMS and agree to comply with the requirements of the Pomalidomide REMS. Information about pomalidomide and the Pomalidomide REMS can be obtained by visiting www.PomalidomideREMSProgram.com, or calling the REMS Coordinating Center at **1-866-245-7925**.

Key Points of the Pomalidomide REMS

Prescribers

- The prescriber reviews the Prescribing Information for pomalidomide.
- The prescriber enrolls and becomes certified in the Pomalidomide REMS by completing the **Prescriber Enrollment Form** and submitting it to the Pomalidomide REMS.
- The prescriber counsels patients on the benefits and risks of pomalidomide therapy, including Boxed Warnings and the need to complete mandatory patient surveys with the Pomalidomide REMS using the information in the Medication Guide, the **Patient Guide** and the **Patient-Physician Agreement Form**.
- The prescriber provides contraception and emergency contraception counseling with each new prescription prior to and during pomalidomide treatment.
 - For males (adults and children): Counsel the patient on the barrier contraception requirements and emergency contraception using the **Patient Guide** and the **Emergency Contraception Brochure**, and provide a copy of the materials to the patient.
 - For females (adults and children) who can get pregnant: Counsel the patient on contraception requirements and emergency contraception using the **Patient Guide** and the **Emergency Contraception Brochure**, and provide a copy of the materials to the patient.
- The prescriber provides scheduled pregnancy testing for females who can get pregnant and verify negative pregnancy test results prior to writing a new prescription or subsequent prescription.
 - For females (adults and children) who can get pregnant: Assess the patient's pregnancy status by ordering and confirming a negative test result at the following timeframes:
 - **Before treatment initiation (first prescription):**
 - 10-14 days prior to initiation of pomalidomide therapy
 - Within 24 hours of the initial prescription
 - **During treatment:**
 - Every 4 weeks for female patients who can get pregnant with regular menstrual cycles
 - Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles
- The prescriber enrolls each patient by completing the appropriate **Patient-Physician Agreement Form** and sends to the REMS Coordinating Center.

- The prescriber/patient completes applicable mandatory confidential surveys.
- The prescriber obtains authorization by contacting the REMS program and completing the prescriber survey to verify the patient's reproductive status, negative pregnancy test status, and completion of counseling. The prescriber must document the prescription authorization number and the patient's risk category on the prescription.
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions.
- The prescriber sends the pomalidomide prescription to a certified pharmacy.

Pharmacies

- The pharmacy enrolls into the Pomalidomide REMS to become certified by completing the **Pharmacy Enrollment Form** and submitting it to the Pomalidomide REMS.
- The pharmacy reviews or completes the following: **Pharmacy Guide**, **Pharmacy Training**, and **Pharmacy Certification Quiz**.
- The certified pharmacy counsels the patient on the benefits and risks of pomalidomide, and safe-use requirements using the **Education and Counseling Checklist for Pharmacies**.
- The certified pharmacy verifies that a prescription authorization number and patient risk category is documented on each prescription.
- The certified pharmacy must obtain a confirmation number to dispense each prescription by contacting the REMS program to verify the prescriber is certified, the patient enrolled is not pregnant, and the prescriber's authorization number is valid.
- The certified pharmacy documents the confirmation number and the date it was obtained on the prescription.
- The certified pharmacy completes the **Education and Counseling Checklist for Pharmacies**.
- The certified pharmacy dispenses no more than a 28 days' supply of pomalidomide to the patient along with a Medication Guide, only if there are 7 days or less remaining on the existing prescription.

Prescribing Pomalidomide Under the Pomalidomide REMS

FEMALES

Patient Counseling

Instruct your patients on why and how they and their partners should prevent pregnancy. Also inform them not to share the drug, not to donate blood, and about using 2 effective methods of contraception (at least one highly effective method and one effective method) at the same time. Patient should be instructed not to extensively handle or open pomalidomide capsules.

Pregnancy Tests Only in Females

Who Can Get Pregnant

Conduct initial pregnancy test within 10-14 days of treatment initiation. Confirm the patient is not pregnant with a second pregnancy test within 24 hours prior to writing an initial prescription and verify a negative test result weekly during the first 4 weeks of use. During treatment, pregnancy testing should be repeated every 4 weeks if the patient has regular menses or is amenorrheic, or every 2 weeks if the patient has irregular menses.

Enrollment

Both you and your patients must understand and agree to comply with the Pomalidomide REMS, including the pregnancy prevention steps. The applicable **Patient-Physician Agreement Form** must be signed by both patient and physician and submitted to the REMS Coordinating Center via fax (1-844-872-5446) or electronically at www.PomalidomideREMSProgram.com.

Complete Mandatory Confidential Survey

Your female patients need to complete a brief survey by phone or online. You will also need to complete a mandatory survey by phone or online. You must complete this survey every time a pomalidomide prescription is written. After your patient completes her survey, you will also be asked to complete a survey. Once you complete the survey you will then receive an authorization number to write the prescription. You must complete this survey to obtain a new authorization number every time a pomalidomide prescription is written. Female patients who can get pregnant and all female children must complete surveys monthly in order to obtain subsequent prescriptions. Adult female patients who cannot get pregnant must complete surveys every 6 months.

MALES

Patient Counseling

Instruct your patients on why and how they and their partners should prevent pregnancy. Also, inform them not to share the drug, not to donate blood, or sperm, and about appropriate contraceptive use. Patients should be instructed not to extensively handle or open pomalidomide capsules.

Enrollment

Both you and your patients must understand and agree to comply with the Pomalidomide REMS, including the pregnancy prevention steps.

The applicable **Patient-Physician Agreement Form** must be signed by both patient and physician and submitted to the REMS Coordinating Center via fax (1-844-872-5446) or electronically www.PomalidomideREMSProgram.com.

Complete Mandatory Confidential Survey

Your male patients will need to complete a brief survey by phone or online. You will also need to complete a mandatory survey by phone or online, after which you will receive an authorization number. You must complete this survey to obtain a new authorization number every time a pomalidomide prescription is written. The *initial survey* is *not required* for male patients, but they must complete surveys monthly for subsequent prescriptions.

Pomalidomide REMS Patient Enrollment

- Obtain, review, and complete the applicable **Patient-Physician Agreement Form** online by visiting www.PomalidomideREMSProgram.com or submit the form via fax **1-844-872-5446**.
- Prescribers who do not have access to a computer will be provided with Pomalidomide REMS materials. For additional assistance, please contact the REMS Coordinating Center at **1-866-245-7925**.

Help Ensure Timely Processing of Each Prescription: Fill Out Form as Directed

- The form must be completed and signed by both prescriber and patient.

Instructions for Female Patients

- Provide information on whether the patient has been in surgical 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 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 **Patient-Physician Agreement Form**.
- 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 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 REMS Coordinating Center, along with the Patient-Physician Agreement Form.**
- This letter must contain the following: A statement that the incompetent patient lacks the capacity to complete the **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 Pomalidomide REMS and is authorized to consent to treatment with pomalidomide on behalf of the patient.

Send in Completed Forms

- Send the completed **Patient-Physician Agreement Form** to the REMS Coordinating Center via fax (**1-844-872-5446**) or electronically at www.PomalidomideREMSProgram.com.
- You will receive confirmation electronically that the patient is enrolled.
- Once the **Patient-Physician Agreement Form** is received, both female patients and prescribers can take their surveys as required. Male patients do not take initial surveys.

NOTE: *If therapy with pomalidomide is discontinued for 12 consecutive months, the patient must enroll again in the Pomalidomide REMS. Follow the above procedures to re-enroll the patient.*

Prescription Requirements

All Patients

- Provide comprehensive counseling on the benefits and risks of therapy with pomalidomide, including risks described in the Boxed Warnings and the need to complete mandatory patient surveys with the Pomalidomide REMS using the [Patient Guide](#) and **Patient-Physician Agreement Form**.
- Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with pomalidomide.
- Provide counseling not to share pomalidomide, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of pomalidomide, as well as counseling on appropriate contraceptive use, including emergency contraception.
- Provide patients with educational materials provided in the Pomalidomide REMS.
- Patients should be instructed to not extensively handle or open pomalidomide capsules.
- Instruct patients to return unused pomalidomide for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.

Female Patients

Determine if female patient is able to get pregnant

Two Categories

1

Females Who Can Get Pregnant

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 who cannot get pregnant category

2

Females Who Cannot Get Pregnant

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 or show signs of puberty

Females Who Can Get Pregnant

Pregnancy Test Requirements

- Obtain a negative pregnancy test 10 to 14 days prior to writing an initial prescription for pomalidomide and again within 24 hours prior to writing an initial prescription for pomalidomide 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 be repeated weekly for at least the first 4 weeks, and then every 4 weeks if patient has regular menses, or every 2 weeks if irregular menses.

Prescription Requirements

- If a patient misses her period or if there is any abnormality in menstrual bleeding, pomalidomide should be discontinued immediately. Obtain a pregnancy test and counsel the patient.
- **If pregnancy does occur during treatment, pomalidomide must be immediately discontinued.** Any suspected embryo-fetal exposure to pomalidomide must be reported immediately to the FDA via the MedWatch number at **1-800-FDA-1088** and also to the REMS Coordinating Center at **1-866-245-7925**. 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 pomalidomide.

Patient Counseling on Contraception Requirements

Contraception Requirements

- Female patients who can get pregnant must either completely abstain from heterosexual sexual contact or must use 2 effective methods of contraception (at least one highly effective method and one effective method) at the same time.
- The 2 effective 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.
- The 2 effective contraceptive methods must be started at least 4 weeks before pomalidomide therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy.

Effective Methods of Birth Control to Use at the Same Time

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, two other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after stopping therapy.

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

Females Who Cannot Get Pregnant

- 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 pre-pubertal female child is not pregnant, nor is of reproductive potential as **menstruation has not yet begun**, the child does not show signs of puberty and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before pomalidomide therapy, during therapy, during dose interruptions, 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 who can get pregnant, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking pomalidomide 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 pomalidomide.

Initial Mandatory Confidential Survey

Females

Instruct the female patient to complete a brief initial mandatory confidential survey by visiting www.PomalidomideREMSProgram.com, or by calling the REMS Coordinating Center at **1-866-245-7925**.

Males

Males do not need to take the initial survey.

Prescribers

- Prescriber will complete a brief mandatory confidential survey by visiting www.PomalidomideREMSProgram.com, or calling the REMS Coordinating Center at **1-866-245-7925**, 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. Authorization numbers are valid for 7 days from the date of the last pregnancy test for females who can get pregnant 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

- Prescribers must send the prescription to a Pomalidomide REMS certified pharmacy. To locate a certified pharmacy, please visit www.PomalidomideREMSProgram.com.
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills or telephone prescriptions.

Subsequent Prescription Requirements

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

No automatic refills or telephone prescriptions are permitted.

Female Patients

- Provide counseling as outlined in the "Female Patients" section on page 4.
- Follow pregnancy test requirements as outlined in the "Pregnancy Test Requirements" section on page 6.
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
 - Before prescription is obtained
 - Monthly
 - Adult who can get pregnant
 - All female children
 - Every 6 months
 - Adult females who cannot get pregnant

Male Patients

- Provide patient counseling as outlined in the "Male patients" section on page 4.
- Male patients must complete a brief mandatory confidential survey once a month.
 - Males do not complete an initial survey.

After the Last Dose of Pomalidomide

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

All Patients

- Must not share pomalidomide
- Must return any unused pomalidomide capsules for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide
- Must not donate blood for 4 weeks after stopping pomalidomide

Females Who Can Get Pregnant

- Must not get pregnant for at least 4 weeks after stopping pomalidomide by using 2 effective methods of contraception (at least one highly effective method and one effective method) each time engaging in sexual activity with a male

Male Patients

- Must use a latex or synthetic condom each time when engaging in sexual activity for 4 weeks after stopping pomalidomide, even if they have undergone a successful vasectomy
- Must not donate sperm for 4 weeks after stopping pomalidomide

Reporting Adverse Events

Adverse drug experiences that are suspected to be associated with the use of pomalidomide and any suspected pregnancy occurring during the treatment with pomalidomide may be reported to the Pomalidomide REMS www.PomalidomideREMSProgram.com or via the REMS Coordinating Center at **1-866-245-7925**.

You may also report to the FDA via <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, phone: 1-800-FDA-1088, Fax: 1-800-FDA-0178 or mail MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

For more information about pomalidomide and the Pomalidomide REMS, please visit www.PomalidomideREMSProgram.com, or call the REMS Coordinating Center at **1-866-245-7925**.