PS-Pomalidomide REMS

At-A-Glance

Important information about pomalidomide and PS-Pomalidomide Risk Evaluation and Mitigation Strategy (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
- To avoid embryo-fetal exposure, pomalidomide is available only through a special program called PS-Pomalidomide REMS (Risk Evaluation and Mitigation Strategy)
- Only prescribers and pharmacies certified with PS-Pomalidomide REMS can prescribe and dispense pomalidomide to patients who are enrolled and meet all the conditions of PS-Pomalidomide REMS
- Information about pomalidomide and PS-Pomalidomide REMS can be obtained by visiting **www.PS-PomalidomideREMS.com**, or calling the REMS Call Center toll-free at **1-888-423-5436**

There are other risks associated with pomalidomide treatment. Please see relevant Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS at www.PS-PomalidomideREMS.com.

The PS-Pomalidomide REMS includes both POMALYST® (pomalidomide) and generic pomalidomide products. The pomalidomide manufacturers have a contractual agreement for administration of the PS-Pomalidomide REMS. All manufacturers retain responsibility for the actions described in the REMS.

PS-Pomalidomide REMS

Prescribing pomalidomide under PS-Pomalidomide 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 1 test within 24 hours prior to writing an initial prescription for pomalidomide.
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive methods. For appropriate contraceptive use, refer to the Prescriber Guide for PS-Pomalidomide REMS. Patients should be instructed to not extensively handle or open pomalidomide capsules.
3. Obtain, review, and complete the PS-Pomalidomide REMS Patient-Physician Agreement Form online by visiting **www.BMSREMSPatientSafety.com/prescriber** or by calling the REMS Call 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 PS-Pomalidomide REMS Patient-Physician Agreement Form online through **www.BMSREMSPatientSafety.com/prescriber**, to the REMS Call Center via fax (1-888-432-9325), or email (REMSCustomerCare@bms.com).
5. Instruct female patients to complete a brief initial mandatory confidential survey by visiting **www.BMSREMSPatientSafety.com**, accessing the REMS Companion App, 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.BMSREMSPatientSafety.com/prescriber** or calling the REMS Call 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 methods. For appropriate contraceptive use, refer to the Prescriber Guide for PS-Pomalidomide REMS. Patients should be instructed to not extensively handle or open pomalidomide 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.BMSREMSPatientSafety.com/prescriber** or calling the REMS Call 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.

Prescribing pomalidomide under PS-Pomalidomide REMS

(Note: Prescriber has already enrolled in PS-Pomalidomide REMS)

1. New Patient: Complete the Patient-Physician Agreement Form (PPAF)

Send the completed PPAF via

- **www.BMSREMSPatientSafety.com/prescriber**
- Fax (1-888-432-9325), or email (REMSCustomerCare@bms.com)

PS-Pomalidomide REMS

2. Complete Prescriber Survey

Complete the Prescriber Survey via

- **www.BMSREMSPatientSafety.com/prescriber**
- Call the REMS Call Center at **1-888-423-5436**

PS-Pomalidomide REMS

3. Obtain Authorization Number

An authorization number will be issued upon completion of the survey

4. Write Prescription

Include the authorization number, patient risk category, daily dose, and total number of days supplied

5. Send the Prescription to a Certified Pharmacy

Prescribe no more than a 28-day supply, with no automatic refills or telephone prescriptions

Initial Prescription

Provide mandatory counseling:

- No drug sharing
- No blood or sperm donation
- Appropriate contraceptive use. Please refer to the table on the back page for appropriate contraception
- Patients should be instructed to not extensively handle or open pomalidomide capsules

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 (blood or urine test by laboratory or prescriber's office depending on test sensitivity)
  - 10 to 14 days prior
  - 24 hours prior to writing prescription

Initial Patient Survey

- Instruct female patients to complete the survey via
  - **www.BMSREMSPatientSafety.com**
  - The REMS Companion App, or
  - Call the REMS Call Center at **1-888-423-5436**
- Males do not need to complete the initial survey

Subsequent Prescriptions

- **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
- A prescriber survey is needed for every prescription. An authorization number from PS-Pomalidomide REMS is needed for every prescription
- **Patient surveys**
  - 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

Questions

- Call the REMS Call Center at **1-888-423-5436**

Please see important information about pomalidomide and PS-Pomalidomide REMS on back.

Effective Methods of Birth Control Used at the Same Time

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) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	+	Male latex or synthetic condom Diaphragm Cervical cap

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

PS-Pomalidomide Risk Evaluation and Mitigation Strategy (REMS) Program

- 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
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