

POMALIDOMIDE RISK EVALUATION AND MITIGATION STRATEGEMENTSERATION
(REMS)

Pharmacy Guide

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Important Information About the Pomalidomide REMS

- 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.
- 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.
- Dispensing pharmacists must be educated on the Pomalidomide REMS and on dispensing procedures for pomalidomide.
- Information about pomalidomide and the Pomalidomide REMS can be obtained by visiting www.PomalidomideREMSProgram.com, or by calling the REMS Coordinating Center toll-free at 1-866-245-7925.

Guidelines for Ordering, Counseling, and Dispensing Pomalidomide

Dispensing pharmacies must be certified in the Pomalidomide REMS and must be educated in the following dispensing procedures.

Step 1. Review Incoming Pomalidomide Prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them
- 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 Pomalidomide REMS** counselor counsels the patient.
 - Pomalidomide REMS counselors must:
 1. Be licensed healthcare professionals
 2. Complete the Pomalidomide REMS training as provided by the certified pharmacy Authorized Representative
 3. Educate patient by telephone or in person before treatment can be dispensed
 4. Understand and counsel patients on the potential for birth defects or death to an unborn baby
 5. Counsel patients on possible side effects
 - Other pharmacy staff involved in dispensing treatment must:
 1. Be educated on the guidelines for dispensing
- B. Complete the corresponding section (based on the patient risk category) of the **Education and Counseling Checklist for Pharmacies** 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 pomalidomide and any suspected pregnancy occurring during the treatment with pomalidomide, make sure to document these experiences and notify the Pomalidomide REMS.
- D. Report adverse drug experiences that are suspected to be associated with the use of pomalidomide to the Pomalidomide REMS within 24 hours.

Guidelines for Ordering, Counseling, and Dispensing Pomalidomide

Step 3. Obtain a Confirmation Number from the Pomalidomide REMS

- A. Prior to each prescription, ensure the patient and prescriber are enrolled in the Pomalidomide REMS by obtaining a confirmation number from the REMS Coordinating Center (**1-866-245-7925**) or visiting the Pomalidomide REMS website (**www.PomalidomideREMSProgram.com**).
- B. The pharmacy will confirm that both the patient and the prescriber have both completed the mandatory confidential survey prior to each prescription and a valid authorization number was received. Once there is confirmation that all REMS requirements have been met, the pharmacy will obtain a confirmation number from the Pomalidomide REMS.
 - Authorization numbers are valid for 7 days from the date of 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.
 - Confirmation numbers can be obtained:
 1. Search Certified Prescriber (name and National Provider Identifier (NPI))
 2. Search Enrolled Patient (name and date of birth)
 3. Enter Authorization Number
 4. Enter Number of Capsules and Milligram Strength
 5. Generate Confirmation Number
 6. Document Confirmation Number
- C. Faxed prescriptions are permissible depending on state laws.
- D. If you do not obtain a confirmation number after confirming that all REMS requirements have been met, do not dispense pomalidomide.

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, i.e., dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **you must generate a new confirmation number**. For female patients who can get pregnant, 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 for Pharmacies** (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 shipments and dispenses if picked up by patient.
- G. Pharmacies must submit records of pomalidomide dispensing to the Pomalidomide REMS.

Step 5. Perform drug accountability

- A. Pharmacy shall keep an inventory log for pomalidomide, by strength, reflecting its on-hand inventory at all times.
- B. Do not transfer pomalidomide to another pharmacy without permission from the Pomalidomide REMS.
- C. Accept unused pomalidomide (previously dispensed) from a patient or patient caregiver.
- D. Return unused product from the patient or the prescriber to the Pomalidomide REMS.

Pomalidomide 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 pomalidomide, a checklist for each patient must be completed based on the patient risk category. 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:

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



Rules for Dispensing and Shipping

Making sure before you release pomalidomide

DO NOT DISPENSE OR SHIP POMALIDOMIDE 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. For females who can get pregnant, 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 pomalidomide prescription.

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

Adverse Drug Experience Reporting Procedure for Healthcare Professionals

Please report adverse drug experiences that are suspected to be associated with the use of pomalidomide and any suspected pregnancy occurring during the treatment with pomalidomide to the Pomalidomide REMS using any of the following methods.

REPORTING TO POMALIDOMIDE REMS

- Online: www.PomalidomideREMSProgram.com
- Email: drugsafety@UBC.com
- Telephone: **1-866-245-7625**
- Fax: **1-844-872-5446**
- Mail to: **2083 Pinecrest Dr, Morgantown, WV 26505**

REPORTING TO THE FDA

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 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/Fax or Mail: **1-800-FDA-1088** Fax: **1-800-FDA-0178** 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.

Pomalidomide is only available under a restricted distribution program, Pomalidomide REMS.

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