Pharmacy Guide to

Lenalidomide REMS

Risk Evaluation and Mitigation Strategy (REMS)

Important information about lenalidomide and Lenalidomide REMS

- Lenalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with lenalidomide provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, lenalidomide is only available under a restricted distribution program called “Lenalidomide REMS” (Risk Evaluation and Mitigation Strategy)
- Only prescribers and pharmacies certified with Lenalidomide REMS can prescribe and dispense the product to patients who are enrolled and meet the conditions of Lenalidomide REMS
- Dispensing pharmacists must be educated on Lenalidomide REMS and on dispensing procedures for lenalidomide
- Information about lenalidomide and Lenalidomide REMS can be obtained by visiting **www.LenalidomideREMS.com** or calling Lenalidomide REMS toll-free at **1-888-423-5436**

REMS administered by: Celgene

The Lenalidomide REMS includes both REVLIMID® (lenalidomide) and generic lenalidomide products. The Lenalidomide Manufacturers have a contractual agreement under which Celgene Corporation administers the REMS on behalf of the Lenalidomide Manufacturers. All manufacturers retain responsibility for the actions described in the REMS.

Lenalidomide REMS

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Guidelines for ordering, counseling, and dispensing lenalidomide

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

Step 1. Review incoming lenalidomide 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 patients

A. Make sure a **certified Lenalidomide 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 lenalidomide and any suspected pregnancy occurring during the treatment with lenalidomide, make sure to document these experiences using acceptable documentation as noted on the checklist.

Acceptable documentation examples:

1. Adverse Drug Event form and fax confirmation
2. Pharmacy log

D. Report all suspected pregnancies to Lenalidomide REMS within 24 hours. See the Suspected Pregnancy Reporting Procedure on page 7 for more information.

Guidelines for ordering, counseling, and dispensing lenalidomide (continued)

Step 3. Obtain confirmation number from Lenalidomide REMS

A. Prior to each prescription, contact Lenalidomide REMS at **1-888-423-5436**.

- 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 lenalidomide.

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 Lenalidomide REMS 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 lenalidomide (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

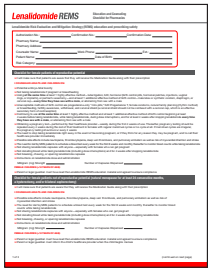
A. Pharmacy shall keep an inventory log for lenalidomide, by strength, reflecting its on-hand inventory at all times.

B. Do not transfer lenalidomide to another pharmacy without prior authorization from Lenalidomide REMS.

C. Accept unused lenalidomide (previously dispensed) from a patient or patient caregiver and return the capsules to Lenalidomide REMS for proper disposal.

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

Rules for dispensing and shipping

Making sure before you release lenalidomide

DO NOT DISPENSE OR SHIP LENALIDOMIDE TO A PATIENT UNLESS ALL OF 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 lenalidomide prescription

For further information about lenalidomide, please refer to the relevant full Prescribing Information at www.LenalidomideREMS.com.

Suspected pregnancy reporting procedure for healthcare professionals

Please report any suspected pregnancy occurring during the treatment with lenalidomide to Lenalidomide REMS using any of the following methods.

REPORTING TO LENALIDOMIDE REMS

- Online: **www.celgene.com/contact-us/**
- 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** (Lenalidomide REMS)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 86 Morris Avenue, Summit, NJ 07901

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of lenalidomide and any suspected pregnancy occurring during the treatment with lenalidomide 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-FDA-1088**
- Fax: **1-800-FDA-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information about lenalidomide and Lenalidomide REMS, please visit **www.LenalidomideREMS.com**, or call Lenalidomide REMS at **1-888-423-5436**.

Lenalidomide REMS
86 Morris Ave
Summit, NJ 07901

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

Please see relevant full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS at www.LenalidomideREMS.com.

Lenalidomide REMS

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