

Pharmacy Enrollment Form

Instructions:

Pomalidomide is available only through the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS), a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the Pomalidomide REMS can prescribe, dispense, and receive pomalidomide.

Dispensing of pomalidomide is limited to certified pharmacies. These pharmacies must enroll in the Pomalidomide REMS in order to dispense pomalidomide. If you have any questions about the Pomalidomide REMS, please call 1-866-245-7925.

You must designate an authorized representative to complete and submit this form on behalf of this pharmacy.

Instructions for Authorized Representative:

1. Review the **Prescribing Information**, **Pharmacy Training**, and **Pharmacy Guide**.
2. Complete and submit this **Pharmacy Enrollment Form** and fax it to the Pomalidomide REMS at 1-844-872-5446 or complete it online at www.PomalidomideREMSProgram.com.
3. Successfully pass the **Pharmacy Certification Quiz**.

Complete all fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the Pomalidomide REMS will notify the pharmacy upon successful certification.

AUTHORIZED REPRESENTATIVE RESPONSIBILITIES

I am the Authorized Representative designated by my pharmacy to carry out the certification process and oversee implementation of and compliance with the Pomalidomide REMS. By signing this form, I agree to comply with the requirements of the Pomalidomide REMS and as the Authorized Representative, understand that my pharmacy must also comply with the Pomalidomide REMS requirements:

1. Review the Prescribing Information, **Pharmacy Training** and the **Pharmacy Guide**.
2. Enroll in the REMS by completing the **Pharmacy Enrollment Form** and submitting it to the Pomalidomide REMS.
3. Train all relevant staff involved in counseling and dispensing pomalidomide using the **Pharmacy Guide**, **Pharmacy Training** and the **Education and Counseling Checklist for Pharmacies** and maintain a record of training.
4. Successfully pass the **Pharmacy Certification Quiz**.
5. Establish processes and procedures to verify there are 7 days or less remaining on the patient's existing prescription, no more than 28 days' supply is dispensed, and the prescriber provided the authorization number and patient risk category on the prescription.
6. Inform the Pomalidomide REMS if the Authorized Representative changes and complete a new **Pharmacy Enrollment Form** with the new Authorized Representative.

Before dispensing, I will ensure that all pharmacy staff must:

1. Counsel all patients on the benefits and risks of pomalidomide using the **Education and Counseling Checklist for Pharmacies**.
 - a. For females (adult and children) who can get pregnant: Counsel the patient on the embryo-fetal toxicity with exposure to pomalidomide and her safe-use conditions.
 - b. For adult females who cannot get pregnant: Counsel the patient on safe-use requirements.
 - c. For female children who cannot get pregnant: Counsel the patient to inform the prescriber when menses begins, and on safe use requirements.
 - d. For males (adult and children): Counsel the patient on the embryo-fetal toxicity with exposure to pomalidomide and additional safe-use requirements.
2. Verify that a prescription authorization number and patient risk category are documented on each prescription through the processes and procedures established as a requirement of the REMS program.
3. Obtain confirmation number to dispense each prescription by contacting the REMS program to verify the prescriber is certified, the patient is enrolled and is not pregnant, and the authorization number is valid.
4. Document the confirmation number and the date it was obtained on the prescription.
5. Complete the **Education and Counseling Checklist for Pharmacies**. Retain a completed copy in the patient's record.

POMALIDOMIDE REMS

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AUTHORIZED REPRESENTATIVE RESPONSIBILITIES (Continued)

6. Dispense no more than a 28 days' supply.
7. Dispense only if there are 7 days or less remaining on the existing prescription.
8. Do not accept verbal prescription orders over the phone.
9. Do not dispense refills.
10. Ship dispensed product within 24 hours of receiving the confirmation number or it must be picked up within 24 hours of obtaining the confirmation number.
11. For females (adult and children) who can get pregnant: Ship pomalidomide the same day the confirmation number is obtained or it must be picked up within 24 hours of obtaining the confirmation number.

At all times, I will ensure that all pharmacy staff must:

1. Report pregnancies immediately to the Pomalidomide REMS.
2. Do not distribute, transfer, loan, or sell pomalidomide, except with the permission of the Pomalidomide REMS.
3. Maintain records of each prescription dispensed with the corresponding confirmation number, date it was obtained, and completed [Education and Counseling Checklist for Pharmacies](#).
4. Comply with audits carried out by the Pomalidomide REMS to ensure that all processes and procedures are in place and are being followed.
5. Accept unused product from the patient or the prescriber.
6. Return unused product from the patient or the prescriber to the Pomalidomide REMS.
7. Maintain records documenting staff's completion of Pomalidomide REMS training.
8. Maintain and make available appropriate documentation reflecting that all processes and procedures are in place and are being followed for the Pomalidomide REMS.

I understand and acknowledge that I must maintain compliance with the requirements of the Pomalidomide REMS; otherwise, my pharmacy will no longer have the ability to dispense pomalidomide.

PHARMACY INFORMATION All fields must be completed

Pharmacy Name:

Pharmacy Address 1:

City:

State:

ZIP Code:

Pharmacy Address 2:

Pharmacy National Provider Information # (NPI):

PHARMACY AUTHORIZED REPRESENTATIVE INFORMATION

First Name:

Last Name:

Telephone Number:

Alternate Telephone Number:

Office Fax Number:

Email:

Preferred Method of Contact:

Authorized Representative Signature:

Date:

