

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form Adult Male

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields below and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

Please read the following statements carefully.

**Your healthcare provider has prescribed pomalidomide for you. Pomalidomide is available only through a restricted distribution program called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS). Before taking pomalidomide, you must read and agree to all of the instructions in the Pomalidomide REMS.**

**Pomalidomide can cause birth defects in an unborn baby. If a female you have sex with is pregnant or becomes pregnant by you while you are taking pomalidomide, it is important for you to know that your unborn baby can have severe birth defects or even die. You must use effective contraception if you are going to have sex.**

Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism) can happen if you take pomalidomide. For more information, please see the pomalidomide Medication Guide.

### INSTRUCTIONS:

**Before starting your treatment with pomalidomide, you must:**

1. Receive counseling from your prescriber
2. Read the [Patient Guide](#) and the [Emergency Contraception Brochure](#)
3. Complete this **Patient-Physician Agreement Form** with your doctor
4. Keep a copy of this form for your records
5. Receive counseling from the pharmacy that will send you pomalidomide

For more information, visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) or call the Pomalidomide REMS at **1-866-245-7925**.

**Authorized Representatives:** If an 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 Pomalidomide REMS, along with the Patient-Physician Agreement Form. This letter must also 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.

### PATIENT INFORMATION All fields must be completed

First Name:	Last Name:	Date of Birth (MM/DD/YYYY):		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Mobile Phone Number:			
Email Address:	Preferred Contact Method: <input type="checkbox"/> Mobile Phone <sup>1</sup> <input type="checkbox"/> Email			
Diagnosis:				

### PRESCRIBER INFORMATION

First Name:	Last Name:	NPI:		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Email Address:	Fax Number:		

<sup>1</sup>Please note, for survey reminders sent via text, text-messaging rates may apply.

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## Patient-Physician Agreement Form for an Adult Male

### SECTION 1. PATIENT AGREEMENT

**I understand and confirm that:**

- Pomalidomide can cause severe birth defects or death to my unborn baby if I have sex with a female who is pregnant or who is able to get pregnant during my treatment
- My semen may contain pomalidomide even after I stop treatment
- I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant:
  - o While taking pomalidomide
  - o During breaks (dose interruptions)
  - o For 4 weeks after stopping pomalidomide
- I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant, even if I have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- Not having sex is the **only** birth control method that is 100% effective
- My pomalidomide prescription is **only** for me and is not to be shared with others
- I have read and understood the [Patient Guide](#), [Emergency Contraception Brochure](#) and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that pomalidomide may cause
- My healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by the Pomalidomide REMS to assist with the Pomalidomide REMS
- I will call my healthcare provider right away if:
  - o I have unprotected sex with a female who is pregnant or who is able to get pregnant
  - o I think -for any reason- that my sexual partner is pregnant or may be pregnant
  - o My partner becomes pregnant or thinks she may be pregnantIf my healthcare provider is not available I will call the Pomalidomide REMS at **1- 866-245-7925**
- I will complete the mandatory confidential monthly survey while taking pomalidomide (online or by telephone interview), even though I will not have to take a survey for my first prescription
- I will keep my pomalidomide prescription out of the reach of children
- I will not break, chew, or open my pomalidomide capsules
- I will return any unused pomalidomide capsules for disposal. Unused pomalidomide capsules can be returned to the Pomalidomide REMS, my prescriber, or the pharmacy that dispensed my pomalidomide
- I will **not** share my pomalidomide capsules with anyone
- I will **not** donate blood or sperm while taking pomalidomide, during breaks (dose interruptions), and for 4 weeks after stopping pomalidomide

### PATIENT INFORMATION

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
Prescriber Name:	NPI:

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## Patient-Physician Agreement Form for an Adult Male

### I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with the Pomalidomide REMS Applicants and other companies they work with to:
  - o Coordinate the delivery of products and services available from pharmacies and patient assistance programs, and other companies
  - o Analyze data for internal business purposes on the use of pomalidomide
  - o Evaluate the effectiveness of the Pomalidomide REMS
  - o Use in any other manner as required or permitted by law
  - o Provide me with information about pomalidomide or my condition
- This authorization will remain in effect for 12 months after I stop pomalidomide. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the Pomalidomide REMS
- Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want to participate in the Pomalidomide REMS. I understand that by refusing to participate in the Pomalidomide REMS, I will not be able to receive pomalidomide. However, I understand that I can speak with my healthcare provider about other treatment options for my condition
- Upon signing this form, I **authorize my healthcare provider to begin my treatment with pomalidomide**

### SECTION 3. AUTHORIZATION TO START TREATMENT

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the Pomalidomide REMS, I will not be able to receive pomalidomide. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the Pomalidomide REMS Applicants and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if he has any questions regarding his treatment with pomalidomide (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the Pomalidomide REMS.**

### PATIENT AUTHORIZATION

All fields must be completed

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
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Patient or Parent/Guardian Signature:	Date:
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### PRESCRIBER AUTHORIZATION

Prescriber Name:	NPI:
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Prescriber Signature:	Date:
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**A copy of this form should be provided to the patient.**

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