

POMALIDOMIDE REMS

Patient-Physician Agreement Form Male Child

For real-time processing of the **Patient-Physician Agreement Form**, go to 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. *Throughout this form, the word 'child' includes any child of whom you are the parent or guardian.*

Your healthcare provider has prescribed pomalidomide for your child. Pomalidomide is available only through a restricted distribution program called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS). Before taking pomalidomide, patients 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 your child has sex with is pregnant or becomes pregnant by your child while he is taking pomalidomide, it is important to know that the unborn baby can have severe birth defects or even die. Your child must use effective contraception if he is 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 your child starts treatment with pomalidomide, you/your child must:

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

For more information, visit www.PomalidomideREMSProgram.com or call the Pomalidomide REMS at **1-866-245-7925**.

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 ¹ <input type="checkbox"/> Email			
Diagnosis:				
PRESCRIBER INFORMATION				
First Name:	Last Name:		NPI:	
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Fax Number:			
Email Address:				

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

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SECTION 1. PATIENT AGREEMENT

I understand and confirm that:

- Pomalidomide can cause severe birth defects or death to the unborn baby if my child has sex with a female who is pregnant or who is able to get pregnant during his treatment
 - My child's semen may contain pomalidomide even after he stops treatment. He must use a latex or synthetic condom **every time** he has 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 will tell my child that he must use a latex or synthetic condom **every** time he has sex with a female who is pregnant or who is able to get pregnant, even if he has 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 child's pomalidomide prescription is **only** for him and is not to be shared with others
 - We 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 child's healthcare provider has reviewed this information with us and answered any questions we have asked
 - We may be contacted by the Pomalidomide REMS to assist with the Pomalidomide REMS
 - I will call his healthcare provider right away if:
 - o He has unprotected sex with a female who is pregnant or who is able to get pregnant
 - o He thinks **for any reason**- that his sexual partner is pregnant or may be pregnant
 - o His partner becomes pregnant or thinks she may be pregnant
- If my child's healthcare provider is not available I will call the Pomalidomide REMS at **1-866-245-7925**
- We will complete the mandatory confidential monthly survey while my child is taking pomalidomide (online or by telephone interview), even though we will not have to take a survey for his first prescription
 - We will keep his pomalidomide prescription out of the reach of other children
 - He will not break, chew, or open his pomalidomide capsules
 - We will return any unused pomalidomide capsules for disposal. Unused pomalidomide capsules can be returned to the Pomalidomide REMS, his prescriber, or the pharmacy that dispensed his pomalidomide
 - He must **not** share his pomalidomide capsules with anyone
 - He must **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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SECTION 2. PATIENT AUTHORIZATION

I understand and confirm that:

- By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with the Pomalidomide REMS Applicants and other companies they work with to:
 - Coordinate the delivery of products and services available from pharmacies and patient assistance programs, and other companies
 - Analyze data for internal business purposes on the use of pomalidomide
 - Evaluate the effectiveness of the Pomalidomide REMS
 - Use in any other manner as required or permitted by law
 - Provide me and my child with information about pomalidomide or my child's condition
- This authorization will remain in effect for 12 months after my child stops pomalidomide. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the Pomalidomide REMS
- Once my child's 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 my child to participate in the Pomalidomide REMS. I understand that by refusing to have my child participate in the Pomalidomide REMS, he will not be able to receive pomalidomide. However, I understand that I can speak with my child's healthcare provider about other treatment options for my child's condition
- Upon signing this form, I **authorize my child's healthcare provider to begin my child's 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 my child does not follow all of the instructions regarding the Pomalidomide REMS, he will not be able to receive pomalidomide. I also understand that the information we provide on this form and as part of the surveys we 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 and his parent/guardian 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 and his parent/guardian if they have any questions regarding the child's treatment with pomalidomide (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's and prescriber's mutual satisfaction. The patient, parent/guardian, 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):	
Patient or Parent/Guardian Signature:		Date:	

PRESCRIBER AUTHORIZATION

Prescriber Name:		NPI:	
Prescriber Signature:		Date:	

A copy of this form should be provided to the patient.

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