

POMALIDOMIDE REMS

Patient-Physician Agreement Form Female Child Who Can Get Pregnant

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 your child is pregnant or becomes pregnant while 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 she 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. Use contraception and not get pregnant as described in the **Patient Guide**
4. Get a pregnancy test as directed by the prescriber
5. Complete this **Patient-Physician Agreement Form** with your child's doctor
6. Keep a copy of this form for your records
7. Complete the patient survey
8. 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:	Risk Category: <input type="checkbox"/> Menstruating <input type="checkbox"/> Surgical Menopause <input type="checkbox"/> Natural Menopause (24 months)			

PRESCRIBER INFORMATION

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

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 my child's unborn baby if my child is pregnant or becomes pregnant during treatment
- My child is not pregnant and will not get pregnant while being treated with pomalidomide
- It is possible for my child to get pregnant if:
 - o She has her period (is menstruating) or has shown any sign of puberty, or
 - o Her period has stopped because of treatment
 - o And she has sex with a male
- Not having sex is the **only** birth control method that is 100% effective
- My child is not breastfeeding and will not breastfeed while being treated with pomalidomide
- My child's pomalidomide prescription is **only** for her 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
- My child will NOT donate blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide

I will tell my child that:

- She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male unless otherwise recommended by her healthcare provider. Her healthcare provider may recommend that she use **at the same time** 2 different birth control methods **every time** she has sex with a male if she cannot use a hormonal or intrauterine device (IUD) method.

Unless she chooses not to have sexual intercourse with a male at any time (abstinence), she must always use acceptable birth control

Highly Effective Birth Control Methods	Additional Effective Birth Control Methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal ring, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	 Male latex or synthetic condom Diaphragm Cervical cap

Not having any sex is the only birth control that is 100% effective. Unacceptable methods of birth control are progesterone-only "mini-pills," IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, and cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception).

- She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male:
 - o Starting at least 4 weeks before taking pomalidomide
 - o While taking pomalidomide
 - o During breaks (dose interruptions)
 - o For at least 4 weeks after stopping pomalidomide

PATIENT INFORMATION

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

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I will tell my child that:

- She must have pregnancy tests- performed by her healthcare provider- according to the schedule listed below:
 - o Before treatment initiation (first prescription):
 - 10-14 days prior to initiation of pomalidomide therapy
 - Within 24 hours of the initial prescription
 - o During treatment:
 - Weekly during the first 4 weeks of use
 - Thereafter,
 - Every 4 weeks for female patients who can get pregnant with regular menstrual cycles
 - Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles
- She must have these pregnancy tests even if she does not get her period because of her treatment
- She must take another pregnancy test performed by her doctor if her medication is not dispensed within 7 days of taking her pregnancy test
- She must stop taking pomalidomide and call her healthcare provider right away if:
 - o She becomes pregnant while taking pomalidomide, or
 - o She misses her period or has unusual menstrual bleeding, or
 - o She stops using birth control, or
 - o She thinks **-for any reason-** that she is pregnant or may be pregnant

If my child's healthcare provider is not available, I will call the Pomalidomide REMS at **1-866-245-7925**

She must stop taking pomalidomide immediately and you should call her healthcare provider right away if she has sex with a male without using birth control or if she thinks her birth control has failed. Her healthcare provider will discuss her options, which may include emergency birth control. If she becomes pregnant or thinks she may be pregnant, and her 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 she is taking pomalidomide (online or by telephone interview)
- We will keep my child's pomalidomide prescription out of the reach of other children
- She must **not** share her pomalidomide capsules with anyone
- She will not break, chew, or open her pomalidomide capsules
- We will return any unused pomalidomide capsules for disposal. Unused pomalidomide capsules can be returned to the Pomalidomide REMS, her prescriber, or the pharmacy that dispensed her pomalidomide
- She must **not** donate blood while taking pomalidomide (including 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:
 - 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 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, she 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, she 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 her 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 her parent/guardian if they have any questions regarding the child's treatment with, including the use of two methods of birth control (at least one highly effective method and one effective method) at the same time, 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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