

# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

Please read the following statements carefully.

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

If your child is pregnant or becomes pregnant while taking POMALYST, it is important to know that the unborn baby can have severe birth defects or even die.

Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism) can happen if you take POMALYST.

For more information, please see the POMALYST Medication Guide.

### INSTRUCTIONS

*Before your child starts treatment with POMALYST, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the POMALYST REMS® materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at 1-888-423-5436.

\*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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## OMALYST® (pomalidomide) Patient-Physician Agreement Form

### Female Child Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

#### Section 1. Patient Agreement

**I understand and confirm that:**

- POMALYST can cause severe birth defects or death to the 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 POMALYST
- It is possible for my child to get pregnant if:
  - She has her period (is menstruating) or has shown any sign of puberty, or
  - Her period has stopped because of treatment
  - 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 POMALYST

- My child's POMALYST prescription is **only** for her and is not to be shared with others
- We have read and understood the POMALYST Patient Guide to the POMALYST REMS® Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST 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 Celgene to assist with the POMALYST REMS® program
- My child will NOT donate blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

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**POMALYST® (pomalidomide) Patient-Physician Agreement Form**

**Female Child Who Can Get Pregnant**

**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 rings, 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:
  - Starting at least 4 weeks before taking POMALYST

- While taking POMALYST
- During breaks (dose interruptions)
- For at least 4 weeks after stopping POMALYST

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- She must have pregnancy tests—performed by her healthcare provider—according to the schedule listed below:
  - 10 to 14 days before receiving her first prescription for POMALYST, and again 24 hours before receiving her first prescription for POMALYST
  - Every week during the first 4 weeks of her treatment with POMALYST
  - Every 4 weeks during the rest of her treatment if she has a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if she has an irregular menstrual cycle
- 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 healthcare provider if her medication is not dispensed within 7 days of taking her pregnancy test
- She must stop taking POMALYST and I will call her healthcare provider right away if:
  - She becomes pregnant while taking POMALYST, or
  - She misses her period or has unusual menstrual bleeding or
  - She stops using birth control, or
  - 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 Celgene Customer Care Center at **1-888-423-5436**

- She must stop taking POMALYST immediately and you should call her healthcare provider right away if she had 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 Celgene Customer Care Center at **1-888-423-5436**
- We will complete the mandatory confidential monthly survey while she is taking POMALYST
- We will keep her POMALYST prescription out of the reach of other children
- We will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused POMALYST capsules can also be returned to my child's POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to my child

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

### Section 2. 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 Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
  - Analyze data for internal business purposes on the use of POMALYST
  - Evaluate the effectiveness of the POMALYST REMS® program
  - Use in any other manner as required or permitted by law
  - Provide me and my child with information about POMALYST or my child's condition
- This authorization will remain in effect for 12 months after my child stops POMALYST. 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 POMALYST REMS® program
- 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 POMALYST REMS® program. I understand that by refusing to have my child participate in the POMALYST REMS® program, she will not be able to receive POMALYST. 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 POMALYST**



Pomalyst REMS®



POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS® is a trademark of Celgene Corporation.

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

### 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 POMALYST REMS® program, she will not be able to receive POMALYST. 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 manufacturer of POMALYST 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 POMALYST (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 POMALYST REMS® program.

Patient		Prescriber
<i>Name</i>		<i>Name</i>
<i>Identification Number</i>		<i>Identification Number</i>
<i>Address</i>		<i>Address</i>
<i>Telephone Number</i>		<i>Telephone Number</i>
<i>Date of Birth</i>	<i>Sex</i>	<i>Fax Number</i>
<i>Risk Category</i>		
Menstruating:		
Surgical Menopause:		
Natural Menopause (24 months):		
<i>Diagnosis</i>		
<i>Patient or Authorized Representative's Signature:</i>		<i>Prescriber's Signature:</i>
<i>Signature Date:</i>		<i>Signature Date:</i>

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.  
 Give a copy of the form to the parent/guardian.

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