

# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Male Child

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 a female your child has sex with is pregnant or becomes pregnant by your child while he is 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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For Example Purposes Only: Call 1-888-423-5436  
for patient enrollment information.

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## Male Child

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 has sex with a female who is pregnant or who is able to get pregnant during his treatment
- My child's semen may contain POMALYST 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 while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST
- Not having sex is the only birth control method that is 100% effective
- My child's POMALYST prescription is **only** for him 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

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### 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 passing of sperm)
- 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:
  - While taking POMALYST
  - During breaks (dose interruptions)
  - For 4 weeks after stopping POMALYST
- I will call his healthcare provider right away if:
  - He has unprotected sex with a female who is pregnant or who is able to get pregnant
  - He thinks—**for any reason**—that his sexual partner is pregnant or may be pregnant
  - His partner becomes pregnant or she thinks she may be pregnantIf my child's 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 my child is taking POMALYST
- We will keep his 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 us 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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- He must **not** share his POMALYST capsules with anyone even if they have symptoms like his
- He must **not** donate blood or sperm while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST

### 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

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- 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, he 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®



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### 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, he 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 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 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>Fax Number</i>
<i>Sex</i>	
<i>Diagnosis</i>	
<i>Patient or Authorized Representative's Signature:</i>	<i>Prescriber's Signature:</i>
<i>Signature Date:</i>	<i>Signature Date:</i>

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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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