THALOMID® (thalidomide) Patient-Physician Agreement Form

Male Child

Please read the following statements carefully.

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

If a female your child has sex with is pregnant or becomes pregnant by your child while he is taking THALOMID, it is important to know that the unborn baby can have severe birth defects or even die.

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

INSTRUCTIONS

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

1. Complete sections 1 and 2 of this form and sign and date on page 6.

2. Read the THALOMID 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**, 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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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:

- ❒ THALOMID 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 THALOMID 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 THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID
- ❒ Not having sex is the only birth control method that is 100% effective
- ❒ My child's THALOMID prescription is **only** for him and is not to be shared with others
- ❒ We have read and understood the THALOMID Patient Guide to THALOMID REMS® Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID 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 THALOMID 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 the 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 THALOMID
- During breaks (dose interruptions)
- For 4 weeks after stopping THALOMID

❒ 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 pregnant

If 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 THALOMID

❒ We will keep his THALOMID prescription out of the reach of other children

❒ We will return any unused THALOMID 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 THALOMID capsules can also be returned to my child's THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to my child

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❒ He must **not** share his THALOMID capsules with anyone even if they have symptoms like his
❒ He must **not** donate blood or sperm while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID

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 THALOMID
- Evaluate the effectiveness of the THALOMID REMS® program
- Use in any other manner as required or permitted by law
- Provide me and my child with information about THALOMID or my child's condition

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- ❒ This authorization will remain in effect for 12 months after my child stops THALOMID. 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 THALOMID 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 THALOMID REMS® program. I understand that by refusing to have my child participate in the THALOMID REMS® program, he will not be able to receive THALOMID. 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 THALOMID**

THALOMID 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 THALOMID REMS® program, he will not be able to receive THALOMID. 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 THALOMID 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 THALOMID (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 THALOMID REMS® program.

Patient	Prescriber
Name	*Name*
Identification Number	*Identification Number*
Address	*Address*
Telephone Number	*Telephone Number*
Date of Birth	*Fax Number*
Sex	
Diagnosis	
Patient or Authorized Representative's Signature: *Signature Date:*	*Prescriber's Signature:* *Signature Date:*

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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