Please read the following statements carefully.

Your doctor 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 your child is pregnant or becomes pregnant while 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](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.
Section 1. Patient Agreement

I understand and confirm that:

☐ THALOMID 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 now and will not get pregnant while being treated with THALOMID

☐ 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 now and will not breastfeed while being treated with THALOMID

☐ My child’s THALOMID prescription is only for her 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

☐ My child will NOT donate blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

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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 doctor. Her doctor 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.

<table>
<thead>
<tr>
<th>Highly effective birth control methods</th>
<th>Additional effective birth control methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrauterine device (IUD)</td>
<td>Male latex or synthetic condom</td>
</tr>
<tr>
<td>Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)</td>
<td>+ Diaphragm</td>
</tr>
<tr>
<td>Tubal ligation (having your tubes tied)</td>
<td>Cervical cap</td>
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<tr>
<td>Partner’s vasectomy (tying of the tubes to prevent the passing of sperm)</td>
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</tr>
</tbody>
</table>

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

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Page 3 of 6 © 2013 Celgene Corporation 1/13
REMS- THA12139

(continued on next page)
Female Child Who Can Get Pregnant

☐ 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 THALOMID, and again 24 hours before receiving her first prescription for THALOMID
  – Every week during the first 4 weeks of her treatment with THALOMID
  – 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 THALOMID and I will call her doctor right away if she:
  – Becomes pregnant while taking THALOMID, or
  – Misses her period or has unusual menstrual bleeding, or
  – Stops using birth control, or
  – Thinks—for any reason—that she is pregnant or may be pregnant
☐ If she becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information about emergency contraception if my child’s doctor is not available
☐ We will complete the mandatory confidential monthly survey while she is taking THALOMID
☐ We will keep her 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 me 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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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

☐ 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, she will not be able to receive THALOMID. However, I understand that I can speak with my child’s doctor 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® is a registered trademark of Celgene Corporation. THALOMID REMS™ is a trademark of Celgene Corporation.
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, she 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 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 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.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Prescriber</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Name</td>
</tr>
<tr>
<td>Identification Number</td>
<td>Identification Number</td>
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<tr>
<td>Address</td>
<td>Address</td>
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<tr>
<td>Telephone Number</td>
<td>Telephone Number</td>
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<tr>
<td>Date of Birth</td>
<td>Fax Number</td>
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<td>Date of Birth</td>
<td>Date of Birth</td>
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<tr>
<td>Sex</td>
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<tr>
<td>Diagnosis</td>
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<tr>
<td>Patient or Authorized Representative’s Signature:</td>
<td>Prescriber’s Signature:</td>
</tr>
<tr>
<td>Signature Date:</td>
<td>Signature Date:</td>
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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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