

THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

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). 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, 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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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 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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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 methods.

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

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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 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 healthcare provider right away if:
 - She becomes pregnant while taking THALOMID, 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 **1-888-423-5436**

- She must stop taking THALOMID 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 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 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 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[®]

THALOMID[®]
(thalidomide) Capsules

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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, 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 the use of two methods of effective 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 THALOMID 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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