

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

Adult Female Who Can Get Pregnant

Please read the following statements carefully.

Your healthcare provider has prescribed THALOMID for you. THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS). Before taking THALOMID, you must read and agree to all of the instructions in the THALOMID REMS[®] program.

If you are pregnant or become pregnant while taking THALOMID, it is important for you to know that your 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 starting your 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.

Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the THALOMID[®] (thalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the THALOMID[®] (thalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the THALOMID REMS[®] program and is authorized to consent to treatment with THALOMID on behalf of the patient.

For more information, visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

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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 my unborn baby if I am pregnant or become pregnant during treatment
- I am not pregnant now and will not get pregnant while being treated with THALOMID
- It is possible for me to get pregnant if:
 - I am having my period (am menstruating), or
 - My period has stopped because of my treatment
 - And I have sex with a male
- Not having sex is the only birth control method that is 100% effective
- I am not breastfeeding now and will not breastfeed while being treated with THALOMID
- My THALOMID prescription is **only** for me and is not to be shared with others
- I 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 healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by Celgene to assist with the THALOMID REMS[®] program
- I will NOT donate blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

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- I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male unless otherwise recommended by my healthcare provider. My healthcare provider may recommend that I use **at the same time** 2 different birth control methods **every time** I have sex with a male if I cannot use a hormonal or intrauterine device (IUD) method

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).

- I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have 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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- I will have pregnancy tests—performed by my healthcare provider—according to the schedule listed below:
- 10 to 14 days before receiving my first prescription for THALOMID, and again 24 hours before receiving my first prescription for THALOMID
 - Every week during the first 4 weeks of my treatment with THALOMID
 - Every 4 weeks during the rest of my treatment if I have a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if I have an irregular menstrual cycle
- I will have these pregnancy tests even if I do not get my period because of my treatment
- I will need to take another pregnancy test performed by my healthcare provider if my medication is not dispensed within 7 days of taking my pregnancy test
- I will stop taking THALOMID and call my healthcare provider right away if:
- I become pregnant while taking THALOMID, or
 - I miss my period or have unusual menstrual bleeding, or
 - I stop using birth control, or
 - I think—**for any reason**—that I am pregnant or may be pregnant
- If my healthcare provider is not available I will call the Celgene Customer Care Center at **1-888-423-5436**
- I will stop taking THALOMID immediately and call my healthcare provider right away if I have sex with a male without using birth control or if I think my birth control has failed. My healthcare provider will discuss my options, which may include emergency birth control. If I become pregnant or think I may be pregnant, and my healthcare provider is not available, I will call the Celgene Customer Care Center at **1-888-423-5436**
- I will complete the mandatory confidential monthly survey while taking THALOMID
- I will keep my THALOMID prescription out of the reach of children
- I 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 I did not take. Unused THALOMID capsules can also be returned to my THALOMID prescriber or to the pharmacy that dispensed the THALOMID to me

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Section 2. Authorization

I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my 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
- This authorization will remain in effect for 12 months after I stop THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the THALOMID REMS[®] program
- Once my 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 to participate in the THALOMID REMS[®] program. I understand that by refusing to participate in the THALOMID REMS[®] program, I will not be able to receive THALOMID. However, I understand that I can speak with my healthcare provider about other treatment options for my condition
- Upon signing this form, **I authorize my healthcare provider to begin my 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 I do not follow all of the instructions regarding the THALOMID REMS[®] program, I will not be able to receive THALOMID. I also understand that the information I provide on this form and as part of the surveys I 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 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 if she has any questions regarding her 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 and prescriber's mutual satisfaction. Both patient 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>Signature Date:</i>		<i>Prescriber's Signature:</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 patient.

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