THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed THALOMID for you. 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, 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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THALOMID® (thalidomide) Patient Physician Agreement Form

Adult Female Who Can Get Pregnant

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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

❒ 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 doctor. My doctor 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

❒ 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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

❒ 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 doctor right away if I:

- Become pregnant while taking THALOMID, or
- Miss my period or have unusual menstrual bleeding, or
- Stop using birth control, or
- Think—**for any reason**—that I am pregnant or may be pregnant

❒ If I become pregnant or think I 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 doctor is not available

❒ 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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.THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

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
- Provide me with information about THALOMID or my condition

❒ 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 doctor about other treatment options for my condition

❒ Upon signing this form, **I authorize my healthcare provider to begin my treatment with THALOMID**

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

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 appropriate birth control methods) 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.

<table>
<tr><th>Patient</th><th>Prescriber</th></tr>
<tr><td colspan="2">Name</td><td>Name</td></tr>
<tr><td colspan="2">Identification Number</td><td>Identification Number</td></tr>
<tr><td colspan="2">Address</td><td>Address</td></tr>
<tr><td colspan="2">Telephone Number</td><td>Telephone Number</td></tr>
<tr><td>Date of Birth</td><td>Sex</td><td>Fax Number</td></tr>
<tr><td colspan="2">Risk Category
Menstruating:
Surgical Menopause:
Natural Menopause (24 months):</td><td rowspan="2"></td></tr>
<tr><td colspan="2">Diagnosis</td></tr>
<tr><td colspan="2">Patient or Authorized Representative's Signature:

Signature Date:</td><td>Prescriber's Signature :

Signature Date:</td></tr>
</table>

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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed THALOMID for you. 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, you must read and agree to all of the instructions in the THALOMID REMS™ program.

Any unborn baby of a female taking THALOMID 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 5.

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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

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 unborn babies of females taking THALOMID

❒ I am not pregnant

❒ I am not able to get pregnant because:

- I have had both of my ovaries and/or my uterus removed, or
- I have been in menopause for at least 2 years

❒ 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

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

I will:

❒ I will complete the mandatory confidential survey every 6 months 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

I will not:

❒ I will **not** share my THALOMID capsules with anyone even if they have symptoms like mine

❒ I will **not** donate blood while taking THALOMID **(including dose interruptions)** and for 4 weeks after stopping THALOMID

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

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
- Provide me with information about THALOMID or my condition

❒ 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 doctor about other treatment options for my condition

❒ Upon signing this form, **I authorize my healthcare provider to begin my treatment with THALOMID**

Celgene THALOMID REMS™ THALOMID® (thalidomide) Capsules

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

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 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.

<table>
<tr><th>Patient</th><th>Prescriber</th></tr>
<tr><td>Name</td><td>Name</td></tr>
<tr><td>Identification Number</td><td>Identification Number</td></tr>
<tr><td>Address</td><td>Address</td></tr>
<tr><td>Telephone Number</td><td>Telephone Number</td></tr>
<tr><td>Date of Birth | Sex</td><td>Fax Number</td></tr>
<tr><td>Risk Category
Menstruating:
Surgical Menopause:
Natural Menopause (24 months):
Diagnosis</td><td></td></tr>
<tr><td>Patient or Authorized Representative's Signature:

Signature Date:</td><td>Prescriber's Signature :

Signature Date:</td></tr>
</table>

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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Male

Please read the following statements carefully.

Your doctor has prescribed THALOMID for you. 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, you must read and agree to all of the instructions in the THALOMID REMS™ program.

If a female you have sex with is pregnant or becomes pregnant by you while you are 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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Male

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 have sex with a female who is pregnant or who is able to get pregnant during my treatment

❒ My semen may contain THALOMID even after I stop treatment. I must use a latex or synthetic condom **every time** I have 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 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

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Male

❒ I will use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant, even if I have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

❒ I will use a latex or synthetic condom **every time** I have 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 my doctor right away if I:

- Have unprotected sex with a female who is pregnant or who is able to get pregnant
- Think—**for any reason**—that my sexual partner is pregnant or may be pregnant

❒ If my partner 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 doctor is not available

❒ 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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THALOMID® (thalidomide) Patient Physician Agreement Form

Adult Male

❒ I will **not** share my THALOMID capsules with anyone even if they have symptoms like mine

❒ I will **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 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
- Provide me with information about THALOMID or my condition

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Male

❒ 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 doctor about other treatment options for my condition

❒ Upon signing this form, **I authorize my healthcare provider to begin my treatment with THALOMID**

Celgene THALOMID REMS™ THALOMID® (thalidomide) Capsules

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Adult Male

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 he has any questions regarding his treatment with THALOMID (including appropriate birth control methods) 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
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 patient.

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

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**, 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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

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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THALOMID® (thalidomide) Patient-Physician Agreement Form

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

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

❒ 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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THALOMID® (thalidomide) Patient-Physician Agreement Form

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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

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**

Celgene THALOMID REMS™ THALOMID® (thalidomide) Capsules

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

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>
<tr><th>Patient</th><th>Prescriber</th></tr>
<tr><td>Name</td><td>Name</td></tr>
<tr><td>Identification Number</td><td>Identification Number</td></tr>
<tr><td>Address</td><td>Address</td></tr>
<tr><td>Telephone Number</td><td>Telephone Number</td></tr>
<tr><td>Date of Birth | Sex</td><td>Fax Number</td></tr>
<tr><td>Risk Category
Menstruating:
Surgical Menopause:
Natural Menopause (24 months):</td><td rowspan="2"></td></tr>
<tr><td>Diagnosis</td></tr>
<tr><td>Patient or Authorized Representative's Signature:

Signature Date:</td><td>Prescriber's Signature :

Signature Date:</td></tr>
</table>

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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

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.

Any unborn baby of a girl taking THALOMID 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 5.

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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

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 unborn babies of females taking THALOMID
- ❒ My child is not pregnant
- ❒ My child is not able to get pregnant because she has not yet started her period (is not menstruating)
- ❒ 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

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

I will tell my child that:

- ❒ We will complete the mandatory confidential monthly survey while my child is taking THALOMID
- ❒ We will keep my child's 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
- ❒ She must **not** share THALOMID capsules with anyone even if they have symptoms like hers
- ❒ She must **not** donate blood while taking THALOMID **(including dose interruptions)** and for 4 weeks after stopping THALOMID

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

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**

Celgene THALOMID REMS™ THALOMID (thalidomide) Capsules

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

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 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>
<tr><th>Patient</th><th>Prescriber</th></tr>
<tr><td>Name</td><td>Name</td></tr>
<tr><td>Identification Number</td><td>Identification Number</td></tr>
<tr><td>Address</td><td>Address</td></tr>
<tr><td>Telephone Number</td><td>Telephone Number</td></tr>
<tr><td>Date of Birth | Sex</td><td>Fax Number</td></tr>
<tr><td>Risk Category
Menstruating:
Surgical Menopause:
Natural Menopause (24 months):</td><td rowspan="2"></td></tr>
<tr><td>Diagnosis</td></tr>
<tr><td>Patient or Authorized Representative's Signature:

Signature Date:</td><td>Prescriber's Signature :

Signature Date:</td></tr>
</table>

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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Male Child

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 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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THALOMID® (thalidomide) Patient Physician Agreement Form

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:

- ❒ 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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Male Child

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 doctor right away if he:
  - Has unprotected sex with a female who is pregnant or who is able to get pregnant
  - Thinks—**for any reason**—that his sexual partner is pregnant or may be pregnant
- ❒ If my child's partner 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 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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Male Child

❒ 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
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- 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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THALOMID® (thalidomide) Patient-Physician Agreement Form

Male Child

- ❒ 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 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**

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THALOMID® (thalidomide) Patient-Physician Agreement Form

Male Child

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).

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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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