

**DO NOT GET**



**PREGNANT**

**WARNING** to patients taking  
**THALOMID®** (thalidomide) Capsules

### **Attention Women:**

Do NOT take THALOMID® (thalidomide) if you are pregnant, if you are breast-feeding, or if you are able to become pregnant and are not using the required two forms of birth control.

### **Attention Men:**

You must use a latex condom EVERY TIME you have sexual contact with a woman who can become pregnant.

**If you have any questions,  
call 1-888-423-5436**

### **All Patients:**

Unused drug should be returned to Celgene for disposal. Call 1-888-423-5436.



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System for Thalidomide Education  
and Prescribing Safety (S.T.E.P.S.®)

# Important Information for Men and Women Taking

 **THALOMID®**  
(thalidomide) Capsules

#### WARNINGS:

##### 1. SEVERE, LIFE-THREATENING HUMAN BIRTH DEFECTS.

IF THALIDOMIDE IS TAKEN DURING PREGNANCY, IT CAN CAUSE SEVERE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. THALIDOMIDE SHOULD NEVER BE USED BY WOMEN WHO ARE PREGNANT OR WHO COULD BECOME PREGNANT WHILE TAKING THE DRUG. EVEN A SINGLE DOSE [1 CAPSULE (REGARDLESS OF STRENGTH)] TAKEN BY A PREGNANT WOMAN DURING HER PREGNANCY CAN CAUSE SEVERE BIRTH DEFECTS.

BECAUSE OF THIS TOXICITY AND IN AN EFFORT TO MAKE THE CHANCE OF FETAL EXPOSURE TO THALOMID® (thalidomide) AS NEGLIGIBLE AS POSSIBLE, THALOMID® (thalidomide) IS APPROVED FOR MARKETING ONLY UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM APPROVED BY THE FOOD AND DRUG ADMINISTRATION. THIS PROGRAM IS CALLED THE "SYSTEM FOR THALIDOMIDE EDUCATION AND PRESCRIBING SAFETY (S.T.E.P.S.®)" UNDER THIS RESTRICTED DISTRIBUTION PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM ARE ALLOWED TO PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, PATIENTS MUST BE ADVISED OF, AGREE TO, AND COMPLY WITH THE REQUIREMENTS OF THE S.T.E.P.S.® PROGRAM IN ORDER TO RECEIVE PRODUCT.

##### 2. VENOUS THROMBOEMBOLIC EVENTS.

THE USE OF THALOMID® (thalidomide) IN MULTIPLE MYELOMA RESULTS IN AN INCREASED RISK OF VENOUS THROMBOEMBOLIC EVENTS, SUCH AS DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLUS. THIS RISK INCREASES SIGNIFICANTLY WHEN THALIDOMIDE IS USED IN COMBINATION WITH STANDARD CHEMOTHERAPEUTIC AGENTS INCLUDING DEXAMETHASONE. IN ONE CONTROLLED TRIAL, THE RATE OF VENOUS THROMBOEMBOLIC EVENTS WAS 22.5% IN PATIENTS RECEIVING THALIDOMIDE IN COMBINATION WITH DEXAMETHASONE COMPARED TO 4.9% IN PATIENTS RECEIVING DEXAMETHASONE ALONE ( $P=0.002$ ). PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. PRELIMINARY DATA SUGGEST THAT PATIENTS WHO ARE APPROPRIATE CANDIDATES MAY BENEFIT FROM CONCURRENT PROPHYLACTIC ANTICOAGULATION OR ASPIRIN TREATMENT.

**WARNING: FOR YOUR HEALTH AND SAFETY, PLEASE READ THIS BOOKLET CAREFULLY. ALSO, BE SURE YOU UNDERSTAND WHAT YOUR DOCTOR HAS TOLD YOU ABOUT THALOMID® (thalidomide) BEFORE STARTING TREATMENT.**

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## Before taking THALOMID® (thalidomide), you must:

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- Understand that THALOMID® (thalidomide) can cause severe birth defects.
- Know how to prevent pregnancy, if you are a woman.
- Understand that you must use latex condoms EVERY TIME you have sexual contact with a woman who can become pregnant, if you are a man.
- Understand that you must NEVER share this drug with friends, relatives, or anyone else.
- Know about other health problems called “side effects.”
- Understand that you must NEVER donate blood or sperm while you are taking THALOMID® (thalidomide).

## How to Use This Booklet

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For easy reading, this booklet has four sections. If you are a woman, read all of Sections 1, 2, and 4. If you are a man, read all of Sections 1, 3, and 4.

This booklet contains important information about THALOMID® (thalidomide), but may not answer all of your questions about the drug. If you need more information, ask your doctor before starting treatment.



When you see this symbol, it means the information nearby is an important reminder **NOT TO GET PREGNANT**. THALOMID® (thalidomide) can cause severe birth defects.

## Section 1: Information for All Patients

### General guidelines for taking THALOMID® (thalidomide)

- THALOMID® (thalidomide) MUST NEVER be used by pregnant women or women who are able to become pregnant and are not using the required two methods of birth control. Just ONE CAPSULE taken by a pregnant woman can cause severe birth defects.
- Men taking THALOMID® (thalidomide) must use latex condoms every time they have sexual contact with women who can become pregnant since THALOMID® (thalidomide) is found in semen or sperm. The risk to the fetus from the semen of male patients taking THALOMID® (thalidomide) is unknown.
- This medicine is ONLY for you. DO NOT SHARE IT WITH ANYONE, even someone who has symptoms like yours. It must be kept out of the reach of children and should never be given to women who are able to become pregnant.
- Contact your doctor immediately if you have any strange or unusual reactions to THALOMID® (thalidomide).
- Keep THALOMID® (thalidomide) in a cool, dry place.
- THALOMID® (thalidomide) does not induce abortion of the fetus and should never be used for contraception.

### WARNING

#### Birth defects

#### READ THIS SECTION CAREFULLY!

If a woman taking THALOMID® (thalidomide) gets pregnant, her baby will almost certainly have severe birth defects—or may even die. Women taking THALOMID® (thalidomide) MUST NOT become pregnant, and men taking THALOMID® (thalidomide) must not have sexual contact with a woman who can become pregnant without using a latex condom.

If you have sexual contact without birth control for any reason, stop taking THALOMID® (thalidomide) immediately and talk to your doctor. If your doctor is not available, call 1-888-423-5436.



*THALOMID® (thalidomide) can cause severe birth defects, including missing or severely deformed legs and arms. These babies often have hands attached directly to their shoulders and feet attached directly to their hips. Photo reprinted by permission.*

## WARNING

### Blood Clots

#### READ THIS SECTION CAREFULLY!

Events associated with blood clots have been reported in patients taking THALOMID® (thalidomide), especially when used with other cancer drugs. Your healthcare provider may recommend treatment which could help prevent blood clots. Talk to your healthcare provider if you have shortness of breath, chest pains, or arm or leg swelling.

## WARNINGS

### Other medical problems

#### Warnings for all patients:

THALOMID® (thalidomide) can cause other health problems called “side effects,” including:

- **Drowsiness:**

THALOMID® (thalidomide) often causes drowsiness. If you are drowsy, you should not operate machinery or drive a car while taking THALOMID® (thalidomide).

- **Nerve damage:**

Nerve damage is a common and potentially severe side effect that may be irreversible. Arms, hands, legs, and feet may tingle, hurt, or feel numb. If so, stop taking THALOMID® (thalidomide) and call your doctor right away.

## Precaution

Do not drink alcohol or take any other medicines that may make you sleepy without consulting your doctor.

Do not open or unnecessarily handle THALOMID® (thalidomide) capsules. If a broken capsule (or the powder in the capsule) comes in contact with your skin, wash the area with soap and water.

- **Allergic reaction:**

If you have a red, itchy rash, stop taking THALOMID® (thalidomide) and call your doctor right away. You may also have a fever or fast heartbeat.

- **Dizziness:**

If you feel dizzy, sit upright for a few minutes prior to standing up from a lying down or sitting position.

**ANY OF THESE SIDE EFFECTS SHOULD BE REPORTED TO YOUR DOCTOR IMMEDIATELY!**

Ask your doctor about other side effects associated with THALOMID® (thalidomide).

## Section 2: Facts for Women

**WARNING: SEVERE, LIFE-THREATENING HUMAN BIRTH DEFECTS.**

IF THALIDOMIDE IS TAKEN DURING PREGNANCY, IT CAN CAUSE SEVERE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. THALIDOMIDE SHOULD NEVER BE USED BY WOMEN WHO ARE PREGNANT OR WHO COULD BECOME PREGNANT WHILE TAKING THE DRUG. EVEN A SINGLE DOSE (1 CAPSULE (REGARDLESS OF STRENGTH)) TAKEN BY A PREGNANT WOMAN DURING HER PREGNANCY CAN CAUSE SEVERE BIRTH DEFECTS. BECAUSE THALIDOMIDE IS PRESENT IN THE SEMEN OF MALE PATIENTS, MALES RECEIVING THALIDOMIDE MUST ALWAYS USE A LATEX CONDOM DURING SEXUAL CONTACT WITH WOMEN OF CHILDBEARING POTENTIAL EVEN IF HE HAS UNDERGONE A SUCCESSFUL VASECTOMY.



## Before treatment:

- You must sign a Patient-Physician Agreement Form that says you understand the risk of birth defects, and that you agree not to become pregnant while taking THALOMID® (thalidomide).

- Remember that this medicine is ONLY for you. YOU MUST NOT SHARE IT with ANYONE, even someone who has symptoms like yours. It must be kept out of the reach of children and should never be given to women who are able to have children.
- If there is ANY chance that you can get pregnant you must begin **TWO** methods of birth control 4 weeks BEFORE you start taking THALOMID® (thalidomide).
- Your doctor must give you a pregnancy test within the 24 hours before you begin taking THALOMID® (thalidomide). **If you are pregnant, YOU CANNOT TAKE THALOMID® (thalidomide).**
- You will have pregnancy tests before and during treatment, even if you agree not to have sexual contact.
- You will be given information about the following acceptable birth control methods:

### Highly effective methods

- Intrauterine device (IUD)
- Hormonal (birth control pills, hormonal patches, injections, or implants)
- Tubal ligation (tubes tied)
- Partner's vasectomy

### Additional effective methods

- Latex condom
- Diaphragm
- Cervical cap

**Remember: You must use at least one highly effective method and one additional effective method AT THE SAME TIME. However, your doctor may recommend that you use two barrier methods for medical reasons.**

**Talk to your doctor to make sure that other medicines or supplements you are taking do not interfere with your hormonal birth control method. Some medicines and herbal supplements, such as St. John's Wort, can prevent hormonal birth control methods from working properly. You may be required to stop taking these medicines or supplements 1 month before starting THALOMID® (thalidomide) if using a hormonal birth control method.**

**REMEMBER THAT THE ONLY METHOD OF BIRTH CONTROL THAT IS 100% EFFECTIVE IS NOT HAVING SEXUAL CONTACT AT ALL.**

### During treatment:

- You must take part in a mandatory, confidential survey that will help make sure that everyone taking THALOMID® (thalidomide) receives, understands, and follows information designed to prevent birth defects.
- If you are able to have children, you must continue to use **TWO** methods of birth control, as discussed with your doctor.
- You must talk to your doctor before changing any birth control methods you have already agreed to use.

### If you are able to have children:

- You must have a pregnancy test done by your doctor every week during the first 4 weeks of treatment. You will then have a pregnancy test every 4 weeks if you do not have a period or if your monthly menstrual cycles are regular, or every 2 weeks if your cycles are irregular. You may also need to have a pregnancy test if you miss your period or have unusual menstrual bleeding.
- You will receive no more than a 4-week (28-day) supply of THALOMID® (thalidomide) at a time. You will not receive any THALOMID® (thalidomide) capsules unless testing proves that you are not pregnant. A new prescription is required for further dispensing.
- If you have sexual contact without birth control or if, for any reason, you think you may be pregnant, you must IMMEDIATELY stop taking THALOMID® (thalidomide) and tell your doctor. If your doctor is not available, call 1-888-423-5436.
- If you get pregnant, you must IMMEDIATELY stop taking THALOMID® (thalidomide). Contact your doctor immediately to discuss your pregnancy. If you do not have an obstetrician, your doctor will refer you to one for care and counseling.
- You must not breast-feed a baby while you are being treated with THALOMID® (thalidomide).
- You must NEVER donate to a blood bank while you are being treated with THALOMID® (thalidomide).
- You should be examined by your doctor for nerve damage every month for 3 months after beginning treatment and periodically thereafter. Tests for nerve damage are simple and are not painful.

## After treatment:

- You must continue to use the same **TWO** methods of birth control for 4 weeks after you receive your last dose of THALOMID® (thalidomide).

## Section 3: Facts for Men

### **WARNING: SEVERE, LIFE-THREATENING HUMAN BIRTH DEFECTS.**

IF THALIDOMIDE IS TAKEN DURING PREGNANCY, IT CAN CAUSE SEVERE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. THALIDOMIDE SHOULD NEVER BE USED BY WOMEN WHO ARE PREGNANT OR WHO COULD BECOME PREGNANT WHILE TAKING THE DRUG. EVEN A SINGLE DOSE (1 CAPSULE (REGARDLESS OF STRENGTH)) TAKEN BY A PREGNANT WOMAN DURING HER PREGNANCY CAN CAUSE SEVERE BIRTH DEFECTS. BECAUSE THALIDOMIDE IS PRESENT IN THE SEMEN OF MALE PATIENTS, MALES RECEIVING THALIDOMIDE MUST ALWAYS USE A LATEX CONDOM DURING SEXUAL CONTACT WITH WOMEN OF CHILDBEARING POTENTIAL EVEN IF HE HAS UNDERGONE A SUCCESSFUL VASECTOMY.



## Before treatment:

- You must sign a Patient-Physician Agreement Form that says you understand the risk of birth defects and that you agree to NEVER have sexual contact with a woman unless you use a latex condom (read Section 1).
- Remember that this medicine is ONLY for you. You CANNOT share it with ANYONE, even someone who has symptoms like yours. It must be kept out of the reach of children and should never be given to women who are able to have children.

## During treatment:

- You must take part in a mandatory, confidential survey that will help make sure that everyone taking THALOMID® (thalidomide) receives, understands, and follows information in the survey designed to help prevent birth defects. Men must participate in the survey because having sexual contact without a latex condom with a woman who can become pregnant or sharing THALOMID® (thalidomide) capsules could result in exposing an unborn baby to the drug.

- While you are taking THALOMID® (thalidomide), you must use a latex condom **every time** you have sexual contact with a woman who can become pregnant and for 4 weeks after you stop taking the drug.
- You must tell your doctor if you have sexual contact with a woman who can become pregnant without using a latex condom, or if you think for any reason that your partner may be pregnant. If your doctor is not available, call 1-888-423-5436.

**REMEMBER THAT THE ONLY BIRTH CONTROL METHOD THAT IS 100% EFFECTIVE IS NO SEXUAL CONTACT AT ALL.**

- You must NOT donate to a sperm or blood bank while you are taking THALOMID® (thalidomide) or for 4 weeks after you stop taking the drug.
- You should be examined by your doctor for nerve damage every month for 3 months after beginning treatment and periodically thereafter. Tests for nerve damage are simple and are not painful.

## After treatment:

- For 4 weeks after receiving your last dose of THALOMID® (thalidomide), you must use a latex condom EVERY TIME you have sexual contact with a woman who can become pregnant.



## Section 4: A Letter from the Thalidomide Victims Association of Canada (TVAC)

Dear Doctor/Patient:

**Have you ever met someone who was born disabled after exposure to thalidomide?**

We have. In fact, we are *thalidomiders* — the name we have adopted to describe the surviving children of mothers who were prescribed thalidomide during their pregnancy as a sedative or for nausea and other symptoms of “morning sickness.”

You've undoubtedly seen the **dramatic photographs of babies with severe birth defects** caused when thalidomide is taken EVEN ONCE by a pregnant woman. You know the risks!

The **Thalidomide Victims Association of Canada (TVAC)** was formed to meet the needs of the approximately 125 thalidomiders alive in Canada today, and to aid the surviving 10 thalidomiders living in the United States. Of the 10,000 to 12,000 children born with thalidomide deformities around the world in the early sixties, 5,000 survive today. No one will ever know how many children were miscarried or were stillborn because of thalidomide.

TVAC exists as a survivors group to determine and find solutions to the ongoing problems we face. TVAC has also undertaken a mandate of monitoring the responsible use of thalidomide and ensuring the tragedy of the past *never happens again*.

Because of our own personal traumas, and those of our families, we have always stated that we can never accept a world with thalidomide in it.

However, as we know first-hand how people may suffer, we also concede that no one should suffer needlessly. If thalidomide can extend a life, or offer a better quality of life to people with debilitating or chronic illnesses, then we are forced to accept the fact that thalidomide use may be their choice.

As well, we are forced to prefer the regulated use of thalidomide over the alternative:

*One thalidomide baby born out of ignorance is far worse than one born out of a legitimate attempt to regulate and control the distribution process of this drug.*

Since you may soon be involved in prescribing or taking thalidomide, we need for you to be **fully aware of the power you have ...**

- the responsibility to see that you **fully understand the risks thalidomide poses ...**
- the **commitment** to do whatever it takes to make sure that NOT EVEN ONE woman loses a child due to thalidomide.

We were as surprised as anyone when the people at Celgene Corporation, makers of THALOMID® (thalidomide), sought the opinions and input of those of us at TVAC

concerning the use of thalidomide in the United States. We felt it was a respectful step in the right direction that our feelings, opinions, and knowledge were being considered.

We are also consoled to know that Celgene Corporation has instituted a comprehensive program to help physicians and pharmacists inform patients about side effects and risks and ensure that they are aware of precautions they must take before, during and after therapy.

The **System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.®)** is a multifaceted program developed to help ensure that fetal exposure to THALOMID® (thalidomide) does not occur. All of the materials you need to comply with this system are enclosed.

Meanwhile, we make you one promise:

*The Thalidomide Victims Association of Canada will continue to watch the progression of events where thalidomide use is concerned.*

We have to!

For further information regarding the history of thalidomide or the status of survivors today, please feel free to contact us.

Sincerely,



Randolph Warren  
Chief Executive Officer  
Thalidomide Victims  
Association of Canada



Giselle Cole  
Past President  
Thalidomide Victims  
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