

S.T.E.P.S.® Guide to Patient Surveys

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Holding Rule and Text Do Not Print

 **THALOMID**®
(thalidomide) Capsules



Celgene Corporation
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Summit, New Jersey 07901

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1-888-423-5436 • www.THALOMID.com

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.

Please see full Prescribing Information, including
Boxed WARNINGS, CONTRAINDICATIONS,
PRECAUTIONS, and ADVERSE REACTIONS, attached.

S.T.E.P.S.[®] Guide to Patient Surveys

As a patient who is registered in the *S.T.E.P.S.*[®] program for THALOMID[®] (thalidomide), you will need to complete a brief, confidential telephone survey before you can receive a prescription for the medication.

Patient Telephone Survey Frequency: **Monthly**

- Adult females who are able to become pregnant
- Female children
- Male patients

Patient Telephone Survey Frequency: **Every 6 Months**

- Adult females who are not able to become pregnant

Patient Telephone Survey Process:

- Prior to filling your prescription, call the Celgene Customer Care Center at 1-888-423-5436 to complete the survey.
- Be prepared with your Social Security number.
- Your doctor will write an authorization number on every prescription you receive for THALOMID[®] (thalidomide).
- Prescriptions are valid only for 7 days.
- After you have completed the phone survey, take the prescription to a registered *S.T.E.P.S.*[®] pharmacy. To locate one, call 1-888-423-5436.