

THALOMID Risk Evaluation and Mitigation Strategy (REMS) program education and prescribing safety

Authorization No.: _____ Confirmation No.: _____ Confirmation Date: _____
Pharmacy Name: _____
Pharmacy Address: _____
Counselor Name: _____ Work Phone: _____ Ext.: _____
Patient Name: _____ Date of Birth: _____
Risk Category: _____

Checklist for female patients of reproductive potential

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Potential embryo-fetal toxicity
- ☐ Not taking THALOMID® (thalidomide) if pregnant or breastfeeding
- ☐ Using **at the same time** at least 1 highly effective method—tubal ligation, intrauterine device (IUD), hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male
- ☐ 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)
- ☐ Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking THALOMID, while taking THALOMID, during dose interruptions, and for at least 4 weeks after stopping THALOMID **every time they have sex with a male**, or abstaining from sex with a male
- ☐ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- ☐ The need to stop taking THALOMID right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately
- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- ☐ Not breaking, chewing, or opening THALOMID capsules
- ☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength _____

Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

☐ Parent or legal guardian must have read the THALOMID REMS education material and agreed to ensure compliance

Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

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I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- ☐ Not breaking, chewing, or opening THALOMID capsules
- ☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength _____

Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the THALOMID REMS education material and agreed to ensure compliance
- ☐ Parent or legal guardian must inform the child's healthcare provider when the child begins menses

Checklist for male patients

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant, even if the patient has had a successful vasectomy)
- ☐ Female partners of males taking THALOMID® (thalidomide) must call their healthcare provider right away if they get pregnant
- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood or sperm while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- ☐ Not breaking, chewing, or opening THALOMID capsules
- ☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength _____

Number of Capsules Dispensed _____

MALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the THALOMID REMS® education material and agreed to ensure compliance

All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.

Counselor Signature: _____ **Date:** _____

For more information about THALOMID and the THALOMID REMS program, please visit www.ThalomidREMS.com, or call the REMS Call Center at **1-888-423-5436**.

THALOMID is only available under a restricted distribution program, THALOMID REMS.

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



THALOMID REMS®

THALOMID®
(thalidomide) Capsules