

[Housing Unit Front Cover Flap]  
((THALOMID REMS® logo))

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

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### About THALOMID® (thalidomide)

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

### **Risks of THALOMID**

**THALOMID has a Boxed Warning for embryo-fetal toxicity and venous thromboembolism (deep venous thrombosis [DVT] and pulmonary embolism [PE]).**

**A known teratogen,** THALOMID is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID if they take adequate precautions to avoid pregnancy.

**The use of THALOMID in MM results in an increased risk of venous thromboembolism, such as deep venous thrombosis and pulmonary embolism.** This risk increases significantly when THALOMID is used in combination with standard chemotherapeutic agents including dexamethasone. Patients and physicians should be observant for the signs and symptoms of thromboembolism. Instruct patients to seek medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Consider thromboprophylaxis based on an assessment of individual patients' underlying risk factors.

**This is not a comprehensive description of risks associated with the use of THALOMID.**

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

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### Prescriber quick reference guide

1. The prescriber provides comprehensive counseling.
2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
3. The prescriber completes THALOMID® (thalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
4. Female patients complete initial mandatory confidential survey by:
  - Visiting **www.CelgeneRiskManagement.com**
  - Accessing the Celgene REMS mobile app
  - Calling the Celgene Customer Care Center at **1-888-423-5436**Male patients do not need to complete the initial survey.  
All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to THALOMID REMS® Program.
5. The prescriber completes mandatory confidential survey and receives authorization number by:
  - Visiting **www.CelgeneRiskManagement.com**
  - Accessing the Celgene REMS mobile app
  - Calling the Celgene Customer Care Center at **1-888-423-5436**
6. The prescriber writes THALOMID prescription and includes authorization number and patient risk category
7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the THALOMID REMS® procedures.

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

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