

((THALOMID REMS® logo))

## Program for THALOMID® (thalidomide)

### Education and Prescribing Safety

Dear Prescriber:

**Enclosed are your THALOMID REMS® program education materials.**

Celgene Corporation is pleased to provide you with the enclosed materials for use in the THALOMID REMS® program.

Important information about the THALOMID REMS® program

- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called “THALOMID REMS®”
- THALOMID is contraindicated in pregnant females and females of reproductive potential who are not using acceptable contraception or continually abstaining from heterosexual sexual contact. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- Male Patients: Thalidomide is present in semen. Male patients taking THALOMID should not donate sperm. Males receiving THALOMID must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with the THALOMID REMS® program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS® program

As a prescriber certified with the THALOMID REMS® program, please review and familiarize yourself with the contents of the enclosed THALOMID REMS® Kit:

#### **Prescriber Materials**

- Prescriber Guide to THALOMID REMS® Program
- THALOMID Full Prescribing Information

#### **Patient Materials (Patient Resource Pack)**

- Patient Guide to THALOMID REMS® Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, , please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,

Jay T. Backstrom, MD, MPH  
Chief Medical Officer  
Enclosures

## About THALOMID® (thalidomide)

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

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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