

## Program for THALOMID<sup>®</sup> (thalidomide)

### Education and Prescribing Safety

Dear Prescriber:

#### **Enclosed are your THALOMID REMS<sup>®</sup> program education materials**

Celgene Corporation is pleased to provide you with the enclosed materials for use in the THALOMID REMS<sup>®</sup> program (formerly known as the S.T.E.P.S.<sup>®</sup> program).

Important information about the THALOMID REMS<sup>®</sup> program

- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called “THALOMID REMS<sup>®</sup>”
- 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<sup>®</sup> program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS<sup>®</sup> program

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

#### **Prescriber Materials**

- THALOMID REMS<sup>®</sup> software and Installation Guide
- Prescriber Guide to THALOMID REMS<sup>®</sup> Program
- THALOMID Full Prescribing Information

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

- Patient Guide to THALOMID REMS<sup>®</sup> Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,

Jerome B. Zeldis, MD, PhD

Chief Medical Officer

Enclosures

**Risks of THALOMID® (thalidomide)**

- If THALOMID is used during pregnancy, it can cause birth defects or embryo-fetal death. THALOMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking THALOMID
- THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma. The effectiveness of THALOMID is based on response rates (see CLINICAL STUDIES section). There are no controlled trials demonstrating a clinical benefit, such as an improvement in survival.

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.

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

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((THALOMID REMS® logo))

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