

[Housing Unit Front Cover Flap]

((THALOMID REMS[®] logo))

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

[Housing Unit Front Cover]

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 (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.

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[Housing Unit Spine]

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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 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 (formerly known as the *S.T.E.P.S.*[®] program).

5. The prescriber completes mandatory confidential survey and receives authorization number by:
 - Visiting **www.CelgeneRiskManagement.com**
 - Accessing the Celgene REMS mobile app
 - Calling 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[®].

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

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