Risks of THALOMID® (thalidomide)

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, for further information regarding the use of THALOMID.
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THALOMID is only available under a restricted distribution program, THALOMID REMS®.

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

The prescriber sends prescription to certified pharmacy.

The prescriber writes THALOMID prescription and includes authorization number and patient information.

The prescriber completes THALOMID® (thalidomide) Patient-Physician Agreement Form with patient and sends to Celgene.

The prescriber verifies negative pregnancy test for all female patients of reproductive potential.

The prescriber provides comprehensive counseling.

All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to THALOMID REMS® Program.

Male patients do not need to complete the initial survey.

Female patients complete initial mandatory confidential survey by:

- Calling the Celgene Customer Care Center at 1-888-423-5436
- Accessing the REMS Patient Companion app
- Visiting www.CelgeneRiskManagement.com

This risk increases significantly when THALOMID is used in combination with standard chemotherapeutic agents including dexamethasone. Patients and physicians should consider prophylactic antithrombotic therapy if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Consider using prophylactic measures in combination with standard chemotherapeutic agents. Use of prophylactic antithrombotic therapy is recommended based on an assessment of individual risk factors.

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