

RevlimidREMS[®]

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

About REVLIMID[®] (lenalidomide)

Risks of REVLIMID

REVLIMID has a Boxed Warning for embryo-fetal toxicity, hematologic toxicity, and deep venous thrombosis (DVT) and pulmonary embolism (PE) as well as risk of myocardial infarction and stroke.

Due to its structural similarity to thalidomide, a known teratogen, REVLIMID is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID if they take adequate precautions to avoid pregnancy.

REVLIMID is associated with significant neutropenia and thrombocytopenia in patients with del 5q MDS. Many patients taking REVLIMID may require dose interruption and/or reduction. Evaluate your del 5q MDS patients closely for cytopenias. Patients on REVLIMID should have their complete blood counts monitored weekly for the first 8 weeks of therapy, and at least monthly thereafter.

There is a significant risk of deep venous thrombosis and pulmonary embolism as well as risk of myocardial infarction and stroke in patients with MM taking REVLIMID plus dexamethasone in combination. Monitor for and advise patients about the signs and symptoms of thromboembolism. Advise patients to seek immediate medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Thromboprophylaxis is recommended and the choice of regimen should be based on an assessment of the patient's underlying risks.

This is not a comprehensive description of risks associated with the use of REVLIMID. Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed, for further information regarding the use of REVLIMID.


Revlimid[®]
(lenalidomide) capsules

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 REVLIMID[®] (lenalidomide) 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 REVLIMID 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 REVLIMID 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 REVLIMID REMS[®] procedures.

REVLIMID is only available under a restricted distribution program, REVLIMID REMS[®].



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(lenalidomide)*capsules*