

((REVLIMID REMS logo))

Program for REVLIMID[®] (lenalidomide) Education and Prescribing Safety

Dear Prescriber:

Enclosed are your REVLIMID REMS[®] education materials.

Celgene Corporation is pleased to provide you with the enclosed materials for use in the REVLIMID REMS[®] program (formerly known as the RevAssist[®] program).

Important Information about the REVLIMID REMS[®] program

- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called “REVLIMID REMS[®]”
- Lenalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with lenalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of lenalidomide in human semen. Male patients taking REVLIMID should not donate sperm. Males receiving REVLIMID 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 REVLIMID REMS[®] can prescribe and dispense REVLIMID to patients who are enrolled and meet all the conditions of the REVLIMID REMS[®] program

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

Prescriber Materials

- REVLIMID REMS[®] software and Installation Guide
- Prescriber Guide to REVLIMID REMS[®] Program
- REVLIMID Full Prescribing Information

Patient Materials (Patient Resource Pack)

- Patient Guide to REVLIMID REMS[®] 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 REVLIMID[®] (lenalidomide)

- REVLIMID is similar to the medicine thalidomide (THALOMID[®]). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or embryo-fetal death. REVLIMID 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 REVLIMID
- REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients
- REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine

REVLIMID in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM).

REVLIMID is indicated for patients with transfusion-dependent anemia due to Low- or Intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

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

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