

RevAssist[®] At-A-Glance

IMPORTANT INFORMATION ABOUT RevAssist[®]

- To avoid fetal exposure, REVLIMID[®] (lenalidomide) is only available under a special restricted distribution program called “RevAssist[®]”
 - Only prescribers registered with RevAssist[®] can prescribe REVLIMID[®] (lenalidomide)
 - Only RevAssist[®] contract pharmacies can dispense REVLIMID[®] (lenalidomide)
 - In order to receive REVLIMID[®] (lenalidomide), patients must enroll in RevAssist[®] and agree to comply with the requirements of the RevAssist[®] program
 - Information about REVLIMID[®] (lenalidomide) and the RevAssist[®] program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.REVLIMID.com
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Initial prescription process (for all patients unless otherwise noted)

1. For females of childbearing potential, obtain two negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained within 10–14 days and one test within 24 hours prior to writing an initial prescription of REVLIMID® (lenalidomide)
2. Obtain a baseline Complete Blood Count
3. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraception
4. Complete, print, and sign REVLIMID® Patient-Physician Agreement Form
 - **Males (adults and children)**
 - **Females of childbearing potential include females who have not undergone a natural menopause** for at least 24 consecutive months
 - **Females not of childbearing potential include females who have been postmenopausal naturally** for at least 24 consecutive months, or had a hysterectomy, or a bilateral oophorectomy
5. Fax completed and signed REVLIMID® Patient-Physician Agreement Form to 1-888-432-9325
6. Instruct patient to complete phone survey by calling 1-888-423-5436 prior to prescriber obtaining an authorization number
 - **All males:** REVLIMID® Patient-Physician Agreement Form is considered the initial phone survey
 - **All females:** Complete the appropriate phone survey
7. Complete a prescriber phone survey for all patients by calling 1-888-423-5436 and obtain a new authorization number for each prescription
 - You will need to enter the following information:
 - Prescriber's DEA number or Social Security number
 - Patient's Social Security number
 - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days
 - Daily dose
 - Total number of days supplied (cannot exceed 28 days)
8. Provide the authorization number on the prescription; authorization number and prescription are valid for 7 days for females of childbearing potential and 14 days for all other patients
9. Healthcare provider contacts a RevAssist® contract pharmacy to fill the prescription
10. RevAssist® contract pharmacy contacts patient for counseling and dispenses REVLIMID® with the FDA-approved MEDICATION GUIDE and educational material

Subsequent REVLIMID® prescriptions (for all patients unless otherwise noted)

1. For females of childbearing potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
2. Obtain Complete Blood Counts as necessary
3. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraception
4. Instruct patient to complete surveys **as scheduled**, prior to prescriber obtaining an authorization number and filling prescription
 - Monthly:
 - **Males (adults and children)**
 - **Females of childbearing potential (adults and children), female children not of childbearing potential**
 - Every 6 months:
 - **Adult females not of childbearing potential (who have been postmenopausal naturally for at least 24 consecutive months, or had a hysterectomy, or a bilateral oophorectomy)**
5. Complete a prescriber phone survey for all patients by calling 1-888-423-5436 and obtain a new authorization number for each prescription
 - You will need to enter the following information:
 - Prescriber's DEA number or Social Security number
 - Patient's Social Security number
 - Date and result of patient's last pregnancy test (if applicable); valid only for 7 days
 - Daily dose
 - Total number of days supplied (cannot exceed 28 days)
6. Provide the authorization number on the new prescription; authorization number and prescription are valid for 7 days for females of childbearing potential and 14 days for all other patients
7. Healthcare provider contacts RevAssist® contract pharmacy to fill the prescription
8. RevAssist® contract pharmacy contacts patients for counseling and dispenses REVLIMID® with the FDA-approved MEDICATION GUIDE



REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.

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

WARNINGS:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS.

LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. FEMALES SHOULD BE ADVISED TO AVOID PREGNANCY WHILE TAKING REVLIMID® (lenalidomide).

Special Prescribing Requirements

BECAUSE OF THIS POTENTIAL TOXICITY AND TO AVOID FETAL EXPOSURE TO REVLIMID® (lenalidomide), REVLIMID® (lenalidomide) IS ONLY AVAILABLE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM. THIS PROGRAM IS CALLED “REVASSIST®”. UNDER THIS PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM CAN PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, REVLIMID® (lenalidomide) MUST ONLY BE DISPENSED TO PATIENTS WHO ARE REGISTERED AND MEET ALL THE CONDITIONS OF THE REVASSIST® PROGRAM.

2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).

THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA. EIGHTY PERCENT OF PATIENTS WITH DEL 5q MYELODYSPLASTIC SYNDROMES HAD TO HAVE A DOSE DELAY/REDUCTION DURING THE MAJOR STUDY. THIRTY-FOUR PERCENT OF PATIENTS HAD TO HAVE A SECOND DOSE DELAY/REDUCTION. GRADE 3 OR 4 HEMATOLOGIC TOXICITY WAS SEEN IN 80% OF PATIENTS ENROLLED IN THE STUDY. PATIENTS ON THERAPY FOR DEL 5q MYELODYSPLASTIC SYNDROMES SHOULD HAVE THEIR COMPLETE BLOOD COUNTS MONITORED WEEKLY FOR THE FIRST 8 WEEKS OF THERAPY AND AT LEAST MONTHLY THEREAFTER. PATIENTS MAY REQUIRE DOSE INTERRUPTION AND/OR REDUCTION. PATIENTS MAY REQUIRE USE OF BLOOD PRODUCT SUPPORT AND/OR GROWTH FACTORS. (SEE DOSAGE AND ADMINISTRATION)

3. DEEP VEIN THROMBOSIS AND PULMONARY EMBOLISM.

THIS DRUG HAS DEMONSTRATED A SIGNIFICANTLY INCREASED RISK OF DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) IN PATIENTS WITH MULTIPLE MYELOMA WHO WERE TREATED WITH REVLIMID® (lenalidomide) COMBINATION THERAPY. PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. IT IS NOT KNOWN WHETHER PROPHYLACTIC ANTICOAGULATION OR ANTIPLATELET THERAPY PRESCRIBED IN CONJUNCTION WITH REVLIMID® (lenalidomide) MAY LESSEN THE POTENTIAL FOR VEIN THROMBOEMBOLIC EVENTS. THE DECISION TO TAKE PROPHYLACTIC MEASURES SHOULD BE DONE CAREFULLY AFTER AN ASSESSMENT OF AN INDIVIDUAL PATIENT'S UNDERLYING RISK FACTORS.

You can get the information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at www.REVLIMID.com or by calling the manufacturer's toll free number 1-888-423-5436.

IMPORTANT SAFETY INFORMATION

Hypersensitivity: REVLIMID® (lenalidomide) is contraindicated in any patients who have demonstrated hypersensitivity to the drug or its components.

Renal impairment: REVLIMID® (lenalidomide) is substantially excreted by the kidney, so the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it would be prudent to monitor renal function.

Nursing mothers: It is not known whether REVLIMID® (lenalidomide) is excreted in human milk. Because of the potential for adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

Other most common adverse events: Multiple Myeloma (REVLIMID®/dexamethasone): constipation (39%), fatigue (38%), insomnia (32%), muscle cramp (30%), diarrhea (29%), neutropenia (28%), anemia (24%), asthenia (23%), pyrexia (23%), nausea (22%), headache (21%), peripheral edema (21%), dizziness (21%), dyspnea (20%), tremor (20%), decreased weight (18%), thrombocytopenia (17%), rash (16%), back pain (15%), hyperglycemia (15%), and muscle weakness (15%). **del 5q MDS (REVLIMID®):** diarrhea (49%), pruritus (42%), rash (36%), fatigue (31%), constipation (24%), nausea (24%), nasopharyngitis (23%), arthralgia (22%), pyrexia (21%), back pain (21%), peripheral edema (20%), cough (20%), dizziness (20%), headache (20%), muscle cramp (18%), dyspnea (17%), and pharyngitis (16%).

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

For more information about REVLIMID® and RevAssist®, please call the Celgene Customer Care Center at 1-888-423-5436 or visit www.REVLIMID.com

