Revlimid® (lenalidomide) capsules
2.5 · 5 · 10 · 15 · 20 · 25 mg

REVLIMID Dosing Guide

REVLIMID® (lenalidomide) is indicated:

- **In combination with dexamethasone (dex) for the treatment of adult patients with multiple myeloma (MM).**
- **As maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT).**
- **For the treatment of adult 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.**
- **For the treatment of adult patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.**
- **In combination with a rituximab product for the treatment of adult patients with previously treated follicular lymphoma (FL).**
- **In combination with a rituximab product for the treatment of adult patients with previously treated marginal zone lymphoma (MZL).**

REVLIMID is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

REVLIMID is only available through a restricted distribution program, REVLIMID REMS®.

Selected Safety Information

- **REVLIMID has Boxed WARNINGS for Embryo-Fetal Toxicity, a Restricted Distribution Program—the REVLIMID REMS®, Hematologic Toxicity, and Venous and Arterial Thromboembolism.**

See page 3 and full Prescribing Information for complete Boxed WARNINGS.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Important information about REVLIMID® (lenalidomide) and the Risk Evaluation and Mitigation Strategy (REMS) program

- REVLIMID can cause fetal harm when administered to a pregnant woman and 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
- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called REVLIMID Risk Evaluation and Mitigation Strategy (REMS)
- Only prescribers and pharmacies certified with REVLIMID REMS® can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the REVLIMID REMS® program
- Female patients of reproductive potential must use at least one highly effective method of contraception and at least one additional effective method, concurrently, every time they have sex with a male
- If pregnancy does occur, REVLIMID must be immediately discontinued. Any suspected embryo-fetal exposure to REVLIMID must be reported immediately to the FDA via the MedWatch number at 1-800-FDA-1088 and also to the Celgene Customer Care Center at 1-888-423-5436. The patient should be referred to an OB/GYN experienced in reproductive toxicity for further evaluation and counseling
- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential
- Instruct patients to return unused REVLIMID capsules for disposal to Celgene, their REVLIMID prescriber, or their REVLIMID dispensing pharmacy

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Selected Safety Information: Boxed WARNINGS

WARNING: EMBRYO-FETAL TOXICITY, HEMATOLOGIC TOXICITY, and VENOUS and ARTERIAL THROMBOEMBOLISM

Embryo-Fetal Toxicity

Do not use REVLIMID® (lenalidomide) during pregnancy. Lenalidomide, a thalidomide analogue, caused limb abnormalities in a developmental monkey study. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide is used during pregnancy, it may cause birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting REVLIMID treatment. Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after REVLIMID treatment. To avoid embryo-fetal exposure to lenalidomide, REVLIMID is only available through a restricted distribution program, the REVLIMID REMS® program.

Information about the REVLIMID REMS program is available at www.celgeneriskmanagement.com or by calling the manufacturer's toll-free number 1-888-423-5436.

Hematologic Toxicity (Neutropenia and Thrombocytopenia)

REVLIMID can cause significant neutropenia and thrombocytopenia. Eighty percent of patients with del 5q MDS 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 MDS 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.

Venous and Arterial Thromboembolism

REVLIMID has demonstrated a significantly increased risk of deep vein thrombosis (DVT) and pulmonary embolism (PE), as well as risk of myocardial infarction and stroke in patients with MM who were treated with REVLIMID and dexamethasone therapy. Monitor for and advise patients about 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.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

REVLIMID® (lenalidomide) in combination with dexamethasone (dex) is indicated for the treatment of adult patients with MM.

Start with REVLIMID + dex for NDMM and RRMM[1]

Starting dose

25 mg on Days 1-21

OF REPEATED 28-DAY CYCLES

Capsule shown is not actual size.

For patients who are auto-HSCT eligible, hematopoietic stem cell mobilization should occur within 4 cycles of receiving REVLIMID-containing therapy.

- **NDMM clinical trials:** dexamethasone was dosed at 40 mg on Days 1, 8, 15, and 22 of repeated 28-day cycles. Patients >75 years received 20 mg of dexamethasone once daily on Days 1, 8, 15, and 22 of repeated 28-day cycles
- **RRMM clinical trials:** dexamethasone was dosed at 40 mg on Days 1-4, 9-12, and 17-20 of each 28-day cycle for the first 4 cycles, and reduced to 40 mg once daily on Days 1-4 for subsequent cycles

Continue treatment until disease progression or unacceptable toxicity

- Monitor complete blood counts every 7 days for the first 2 cycles, on Days 1 and 15 of Cycle 3, and every 28 days thereafter

Selected Safety Information (continued)

CONTRAINDICATIONS

Pregnancy: REVLIMID can cause fetal harm when administered to a pregnant female and is contraindicated in females who are pregnant. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risk to the fetus.

Severe Hypersensitivity Reactions: REVLIMID is contraindicated in patients who have demonstrated severe hypersensitivity (e.g., angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis) to lenalidomide.

auto-HSCT, autologous hematopoietic stem cell transplantation; dex, dexamethasone; MM, multiple myeloma; NDMM, newly diagnosed multiple myeloma; RRMM, relapsed refractory multiple myeloma.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Help patients stay on therapy with dose modifications[1]*

Grade 3/4 Hematologic Toxicities	
Neutropenia	**Dose Modification**
When ANC <1000/mcL	Interrupt REVLIMID® (lenalidomide) treatment, add G-CSF at physician's discretion, follow CBC weekly
Return to ANC ≥1000/mcL	If neutropenia is the only toxicity, resume REVLIMID at 25 mg daily or initial starting dose. If other toxicity, resume REVLIMID at next lower dose. Do not dose below 2.5 mg daily
For each subsequent drop to ANC <1000/mcL	Interrupt REVLIMID treatment
Return to ANC ≥1000/mcL	Resume REVLIMID at next lower dose. Do not dose below 2.5 mg daily
Thrombocytopenia	**Dose Modification**
When platelets <30,000/mcL	Interrupt REVLIMID treatment and follow CBC weekly
Return to platelets ≥30,000/mcL	Resume REVLIMID at next lower dose. Do not dose below 2.5 mg daily
For each subsequent drop to platelets <30,000/mcL	Interrupt REVLIMID treatment
Return to platelets ≥30,000/mcL	Resume REVLIMID at next lower dose. Do not dose below 2.5 mg daily

For non-hematologic Grade 3/4 AEs, hold treatment and after resolution to ≤Grade 2, restart at next lowest dose

Selected Safety Information (continued)

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity: See Boxed WARNINGS.

- Females of Reproductive Potential: **See Boxed WARNINGS.**
- Males: Lenalidomide is present in the semen of patients receiving the drug. Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking REVLIMID and for up to 4 weeks after discontinuing REVLIMID, even if they have undergone a successful vasectomy. Male patients taking REVLIMID must not donate sperm.

*Until disease progression or unacceptable toxicity.

AE, adverse event; ANC, absolute neutrophil count; CBC, complete blood count; G-CSF, granulocyte colony stimulating factor; MM, multiple myeloma.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

REVLIMID® (lenalidomide) is indicated as maintenance therapy in adult patients with MM following auto-HSCT.

Start REVLIMID Maintenance at hematologic recovery[1]

- Hematologic recovery: ANC (absolute neutrophil count) ≥1000/mcL and/or platelet counts ≥75,000/mcL

Maintenance starting dose*

10 mg on Days 1-28

OF REPEATED 28-DAY CYCLES

Capsule shown is not actual size.

- If tolerated, dose can be increased to 15 mg after 3 cycles

Continue treatment until disease progression or unacceptable toxicity

- Monitor complete blood counts every 7 days for the first 2 cycles, on Days 1 and 15 of Cycle 3, and every 28 days thereafter
- Permanently discontinue REVLIMID for angioedema, anaphylaxis, Grade 4 rash, skin exfoliation, bullae, or any other severe dermatologic reactions

Selected Safety Information (continued)

Embryo-Fetal Toxicity: See Boxed WARNINGS (continued).

- Blood Donation: Patients must not donate blood during treatment with REVLIMID and for 4 weeks following discontinuation of the drug because the blood might be given to a pregnant female patient whose fetus must not be exposed to REVLIMID.

REVLIMID REMS® Program: See page 2 and Boxed WARNINGS.

*In 2 studies of REVLIMID Maintenance, patients were randomized to receive REVLIMID or placebo within 90-100 days post-transplant (Study 1) and 90-180 days post-transplant (Study 2).

auto-HSCT, autologous hematopoietic stem cell transplantation; MM, multiple myeloma.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Help patients stay on therapy with dose modifications[1]*

Grade 3/4 Hematologic Toxicities	
Neutropenia	**Dose Modification**
When ANC <500/mcL	Interrupt REVLIMID® (lenalidomide) treatment and follow CBC weekly
Return to ANC ≥500/mcL	Resume REVLIMID at next lower dose continuously for Days 1-28 of repeated 28-day cycles
If at the 5 mg daily dose, for a subsequent drop to ANC <500/mcL	Interrupt REVLIMID treatment[a]
Return to ANC ≥500/mcL	Resume REVLIMID at 5 mg daily for Days 1-21 of repeated 28-day cycles[a]
Thrombocytopenia	**Dose Modification**
When platelets <30,000/mcL	Interrupt REVLIMID treatment and follow CBC weekly
Return to platelets ≥30,000/mcL	Resume REVLIMID at next lower dose continuously for Days 1-28 of repeated 28-day cycles
If at the 5 mg daily dose, for a subsequent drop to platelets <30,000/mcL	Interrupt REVLIMID treatment[a]
Return to platelets ≥30,000/mcL	Resume REVLIMID at 5 mg daily for Days 1-21 of repeated 28-day cycles[a]

[a]Do not dose below 5 mg daily for Days 1-21 of 28-day cycles.

For non-hematologic Grade 3/4 AEs, hold treatment and after resolution to ≤Grade 2, restart at next lowest dose

Selected Safety Information (continued)

Hematologic Toxicity: REVLIMID can cause significant neutropenia and thrombocytopenia. Monitor patients with neutropenia for signs of infection. Advise patients to observe for bleeding or bruising, especially with use of concomitant medications that may increase risk of bleeding. Patients may require a dose interruption and/or dose reduction.

*Until disease progression or unacceptable toxicity.

AE, adverse event; ANC, absolute neutrophil count; auto-HSCT, autologous hematopoietic stem cell transplantation; CBC, complete blood count; MM, multiple myeloma.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

REVLIMID® (lenalidomide) in combination with a rituximab product is indicated for the treatment of adult patients with previously treated FL.

REVLIMID in combination with a rituximab product is indicated for the treatment of adult patients with previously treated MZL.

R^2 offers 12-cycle dosing for patients with previously treated FL/MZL[1]

R^2 (REVLIMID + rituximab) is administered for 12 cycles or until unacceptable toxicity.

- Rituximab 375 mg/m^2* on Days 1, 8, 15, and 22 of Cycle 1 and on Day 1 of Cycles 2-5 every 28 days: 5 cycles

Starting dose

20 mg on Days 1-21

OF UP TO 12 REPEATED 28-DAY CYCLES

Capsule shown is not actual size.

- Monitor complete blood counts weekly for the first 3 weeks of Cycle 1 (28 days), every 2 weeks during Cycles 2-5, and then monthly thereafter

Selected Safety Information (continued)

Venous and Arterial Thromboembolism: See Boxed WARNINGS. Venous thromboembolic events (DVT and PE) and arterial thromboses (MI and CVA) are increased in patients treated with REVLIMID. Patients with known risk factors, including prior thrombosis, may be at greater risk and actions should be taken to try to minimize all modifiable factors (e.g., hyperlipidemia, hypertension, smoking). Thromboprophylaxis is recommended and the regimen should be based on the patient's underlying risks. Erythropoietin-stimulating agents (ESAs) and estrogens may further increase the risk of thrombosis and their use should be based on a benefit-risk decision.

*Dosage calculations for rituximab were based on the patient's body surface area, using actual patient weight.

FL, follicular lymphoma; MZL, marginal zone lymphoma.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Dose modifications may help patients stay on R² for all 12 cycles[1]

Grade 3/4 Hematologic Toxicities	
Neutropenia	**Dose Modification**
When ANC <1000/mcL for ≥7 days, or <1000/mcL with an associated temperature ≥38.5°C, or <500/mcL	Interrupt REVLIMID® (lenalidomide) treatment and follow CBC weekly
Return to ANC ≥1000/mcL	If patient starting dose was 20 mg daily, resume REVLIMID at 5 mg less than previous dose. Do not dose below 5 mg daily. If patient starting dose was 10 mg daily, resume at 5 mg less than previous dose. Do not dose below 2.5 mg daily
Thrombocytopenia	**Dose Modification**
When platelets <50,000/mcL	Interrupt REVLIMID treatment and follow CBC weekly
Return to platelets ≥50,000/mcL	If patient starting dose was 20 mg daily, resume REVLIMID at 5 mg less than previous dose. Do not dose below 5 mg daily. If patient starting dose was 10 mg daily, resume at 5 mg less than previous dose. Do not dose below 2.5 mg daily

For non-hematologic Grade 3/4 AEs, hold treatment and after resolution to ≤Grade 2, restart at next lowest dose

Permanently discontinue REVLIMID for angioedema, anaphylaxis, Grade 4 rash, skin exfoliation, bullae, or any other severe dermatologic reactions.

For dose adjustments due to toxicity with rituximab, refer to the product prescribing information.

R² REVLIMID/RITUXIMAB | Revlimid® (lenalidomide) capsules 2.5 · 5 · 10 · 15 · 20 · 25 mg

AE, adverse event; ANC, absolute neutrophil count; CBC, complete blood count; FL, follicular lymphoma; MZL, marginal zone lymphoma.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Please see the rituximab full Prescribing Information for Important Safety Information at www.rituxan.com.

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

REVLIMID offers once-daily oral dosing for patients with R/R MCL[1]

Starting dose

25 mg on Days 1-21

OF REPEATED 28-DAY CYCLES

Capsule shown is not actual size.

Continue treatment until disease progression or unacceptable toxicity

- Monitor complete blood counts weekly for the first cycle (28 days), every 2 weeks during Cycles 2-4, and then monthly thereafter

Selected Safety Information (continued)

Increased Mortality in Patients With CLL: In a clinical trial in the first-line treatment of patients with CLL, single-agent REVLIMID therapy increased the risk of death as compared to single-agent chlorambucil. Serious adverse cardiovascular reactions, including atrial fibrillation, myocardial infarction, and cardiac failure, occurred more frequently in the REVLIMID arm. REVLIMID is not indicated and not recommended for use in CLL outside of controlled clinical trials.

MCL, mantle cell lymphoma; R/R, relapsed or refractory.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Dose modifications may help patients with R/R MCL stay on therapy[1]

Grade 3/4 Hematologic Toxicities	
Neutropenia	**Dose Modification**
When ANC <1000/mcL for ≥7 days, or <1000/mcL with an associated temperature ≥38.5°C, or <500/mcL	Interrupt REVLIMID® (lenalidomide) and follow CBC weekly
Return to ANC ≥1000/mcL	Resume REVLIMID at 5 mg less than the previous dose[a]
Thrombocytopenia	**Dose Modification**
When platelets <50,000/mcL	Interrupt REVLIMID and follow CBC weekly
Return to platelets ≥50,000/mcL	Resume REVLIMID at 5 mg less than the previous dose[a]

[a]Do not dose below 5 mg daily for Days 1-21 of 28-day cycle.

For non-hematologic Grade 3/4 AEs, hold treatment and after resolution to ≤Grade 2, restart at next lowest dose

Permanently discontinue REVLIMID for angioedema, anaphylaxis, Grade 4 rash, skin exfoliation, bullae, or any other severe dermatologic reactions.

Selected Safety Information (continued)

Second Primary Malignancies (SPM): In clinical trials in patients with MM receiving REVLIMID and in patients with FL or MZL receiving REVLIMID + rituximab therapy, an increase of hematologic plus solid tumor SPM, notably AML, have been observed. In patients with MM, MDS was also observed. Monitor patients for the development of SPM. Take into account both the potential benefit of REVLIMID and risk of SPM when considering treatment.

AE, adverse event; ANC, absolute neutrophil count; CBC, complete blood count; MCL, mantle cell lymphoma; R/R, relapsed or refractory.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

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

REVLIMID offers once-daily dosing for patients with del 5q MDS with or without additional cytogenetic abnormalities[1]

Starting dose

10 mg once daily

OF REPEATED 28-DAY CYCLES

Capsule shown is not actual size.

Continue treatment until disease progression or unacceptable toxicity

- Monitor complete blood counts weekly for the first 8 weeks of therapy and at least monthly thereafter. **See Boxed WARNINGS**

Selected Safety Information (continued)

Increased Mortality With Pembrolizumab: In clinical trials in patients with MM, the addition of pembrolizumab to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of patients with MM with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

del 5q, deletion 5q; MDS, myelodysplastic syndromes.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Help patients with MDS stay on therapy with dose modifications[1]

Cytopenias are associated with REVLIMID® (lenalidomide) in MDS and should be monitored closely. Dose adjustments are expected in the initial cycles of therapy and may help manage cytopenias.

Grade 3/4 Hematologic Toxicities

	Neutropenia	Dose Modification
If neutropenia develops WITHIN 4 weeks of starting at 10 mg daily	Baseline ANC ≥1000/mcL	
	When ANC <750/mcL	Interrupt REVLIMID treatment
	Return to ANC ≥50,000/mcL	Resume REVLIMID at 5 mg daily
	Baseline ANC falls to <1000/mcL	
	When ANC <500/mcL	Interrupt REVLIMID treatment
	Return to ANC ≥500/mcL	Resume REVLIMID at 5 mg daily
If neutropenia develops AFTER 4 weeks of starting at 10 mg daily	When ANC <500/mcL for ≥7 days or <500/mcL associated with fever (≥38.5°C)	Interrupt REVLIMID treatment
	Return to ANC ≥500/mcL	Resume REVLIMID at 5 mg daily
If neutropenia develops at 5 mg daily	When ANC <500/mcL for ≥7 days or <500/mcL associated with fever (≥38.5°C)	Interrupt REVLIMID treatment
	Return to ANC ≥500/mcL	Resume REVLIMID at 2.5 mg daily

Selected Safety Information (continued)

Hepatotoxicity: Hepatic failure, including fatal cases, has occurred in patients treated with REVLIMID + dexamethasone. Pre-existing viral liver disease, elevated baseline liver enzymes, and concomitant medications may be risk factors. Monitor liver enzymes periodically. Stop REVLIMID upon elevation of liver enzymes. After return to baseline values, treatment at a lower dose may be considered.

ANC, absolute neutrophil count; MDS, myelodysplastic syndromes.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Help patients with MDS stay on therapy with dose modifications (continued)[1]

Grade 3/4 Hematologic Toxicities (continued)		
	Thrombocytopenia	**Dose Modification**
If thrombocytopenia develops WITHIN 4 weeks of starting at 10 mg daily	Baseline platelets ≥100,000/mcL	
	When platelets <50,000/mcL	Interrupt REVLIMID® (lenalidomide) treatment
	Return to platelets ≥50,000/mcL	Resume REVLIMID at 5 mg daily
	Baseline platelets <100,000/mcL	
	When platelets fall to 50% of the baseline value	Interrupt REVLIMID treatment
	If baseline ≥60,000/mcL and return to platelets ≥50,000/mcL	Resume REVLIMID at 5 mg daily
	If baseline <60,000/mcL and return to platelets ≥30,000/mcL	Resume REVLIMID at 5 mg daily
If thrombocytopenia develops AFTER 4 weeks of starting at 10 mg daily	When platelets <30,000/mcL, or <50,000/mcL with platelet transfusions	Interrupt REVLIMID treatment
	Return to platelets ≥30,000/mcL (without hemostatic failure)	Resume REVLIMID at 5 mg daily
If thrombocytopenia develops at 5 mg daily	When platelets <30,000/mcL, or <50,000/mcL with platelet transfusions	Interrupt REVLIMID treatment
	Return to platelets ≥30,000/mcL (without hemostatic failure)	Resume REVLIMID at 2.5 mg daily

For non-hematologic Grade 3/4 AEs, hold treatment and after resolution to ≤Grade 2, restart at next lowest dose

Permanently discontinue REVLIMID for angioedema, anaphylaxis, Grade 4 rash, skin exfoliation, bullae, or any other severe dermatologic reactions.

AE, adverse event; MDS, myelodysplastic syndromes.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

REVLIMID® (lenalidomide) can be used in all levels of renal function[1]

Since REVLIMID is primarily excreted unchanged by the kidney, adjustments to the starting dose of REVLIMID are recommended to provide appropriate drug exposure in patients with renal impairment.[2]

REVLIMID Dosing for Renal Impairment[1]

Renal Function (Cockcroft-Gault)	MM Combination Therapy MCL	FL/MZL Combination Therapy[a]	MM Maintenance Therapy MDS
CrCl 30-60 mL/min	10 mg once daily	10 mg once daily	5 mg once daily
CrCl <30 mL/min (not requiring dialysis)	15 mg every other day	5 mg once daily	2.5 mg once daily
CrCl <30 mL/min (requiring dialysis)	5 mg once daily[b]	5 mg once daily[b]	2.5 mg once daily[b]

[a]For dose adjustments due to toxicity with rituximab, refer to the product prescribing information.
[b]On dialysis days, administer the dose following dialysis.

REVLIMID combination therapy for MM: For CrCl of 30-60 mL/min, consider escalating the dose to 15 mg after 2 cycles if the patient tolerates the 10 mg dose of REVLIMID without dose-limiting toxicity.

REVLIMID Maintenance therapy following auto-HSCT for MM and for MCL and MDS: Base subsequent REVLIMID dose increase or decrease on individual patient treatment tolerance.

REVLIMID combination therapy for FL or for MZL: For patients with CrCl of 30-60 mL/min, after 2 cycles, the REVLIMID dose may be increased to 15 mg orally if the patient has tolerated therapy.

Selected Safety Information (continued)

Severe Cutaneous Reactions: Severe cutaneous reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported. These events can be fatal. Patients with a prior history of Grade 4 rash associated with thalidomide treatment should not receive REVLIMID. Consider REVLIMID interruption or discontinuation for Grade 2-3 skin rash. Permanently discontinue REVLIMID for Grade 4 rash, exfoliative or bullous rash, or for other severe cutaneous reactions such as SJS, TEN, or DRESS.

auto-HSCT, autologous hematopoietic stem cell transplantation; CrCl, creatinine clearance; FL, follicular lymphoma; MCL, mantle cell lymphoma; MDS, myelodysplastic syndromes; MM, multiple myeloma; MZL, marginal zone lymphoma.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

CrCl is widely used to estimate GFR[3]

- GFR is an appropriate measure of renal function
- SCr alone is not a sufficient measure of renal function because age, gender, race, and body size also impact GFR

Cockcroft-Gault Equations[4]

Female Male

$$\text{CrCl} = \frac{(140 - \text{age in years}) \times (\text{weight}^{a} \text{ in kg})}{72 \times \text{SCr (mg/dL)}}$$

$$\text{CrCl} = 0.85 \times \frac{(140 - \text{age in years}) \times (\text{weight}^{a} \text{ in kg})}{72 \times \text{SCr (mg/dL)}}$$

[a]A correction for lean or ideal body weight should be considered in certain conditions (e.g., elderly, obese, fluid overload) when body weight may not be indicative of SCr levels.

Important Dosing Information

- The capsules should not be opened, broken, or chewed
- REVLIMID is primarily excreted unchanged by the kidney Since elderly patients are more likely to have decreased renal function, care should be taken in dose selection. Monitor renal function
- Treatment is continued or modified based on clinical and laboratory findings
- Dose modification guidelines are recommended to manage Grade 3/4 neutropenia or thrombocytopenia. For other Grade 3/4 toxicities judged to be related to REVLIMID, hold treatment and restart at next lower dose level when toxicity has resolved to ≤Grade 2
- For Grade 3 or 4 TFR, it is recommended to withhold treatment with REVLIMID until TFR resolves to ≤Grade 1
- Patients may require dose interruption and/or reduction
- Patients may require the use of blood product support and/or growth factors
- **MM:** Monitor CBCs every 7 days (weekly) for the first 2 cycles, on Days 1 and 15 of Cycle 3, and every 28 days (4 weeks) thereafter
- **MCL:** Monitor CBCs weekly for the first cycle (28 days), every 2 weeks during Cycles 2-4, then monthly thereafter
- **MDS:** Monitor CBCs weekly for the first 8 weeks, and at least monthly thereafter
- **FL/MZL:** Monitor CBCs weekly for the first 3 weeks of Cycle 1 (28 days), every 2 weeks during Cycles 2-4, and then monthly thereafter

CBC, complete blood count; CrCl, creatinine clearance; FL, follicular lymphoma; GFR, glomerular filtration rate; MCL, mantle cell lymphoma; MDS, myelodysplastic syndromes; MM, multiple myeloma; MZL, marginal zone lymphoma; SCr, serum creatinine; TFR, tumor flare reaction.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

NOTES

Indications

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

REVLIMID is indicated as maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT).

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

REVLIMID in combination with a rituximab product is indicated for the treatment of adult patients with previously treated follicular lymphoma (FL).

REVLIMID in combination with a rituximab product is indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL).

REVLIMID is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

REVLIMID has Boxed WARNINGS for Embryo-Fetal Toxicity, a Restricted Distribution Program—the REVLIMID REMS®, Hematologic Toxicity, and Venous and Arterial Thromboembolism.

See next page and full Prescribing Information for complete Boxed WARNINGS.

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Important Safety Information

WARNING: EMBRYO-FETAL TOXICITY, HEMATOLOGIC TOXICITY, and VENOUS and ARTERIAL THROMBOEMBOLISM

Embryo-Fetal Toxicity

Do not use REVLIMID® (lenalidomide) during pregnancy. Lenalidomide, a thalidomide analogue, caused limb abnormalities in a developmental monkey study. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide is used during pregnancy, it may cause birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting REVLIMID treatment. Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after REVLIMID treatment. To avoid embryo-fetal exposure to lenalidomide, REVLIMID is only available through a restricted distribution program, the REVLIMID REMS® program.

Information about the REVLIMID REMS program is available at www.celgeneriskmanagement.com or by calling the manufacturer's toll-free number 1-888-423-5436.

Hematologic Toxicity (Neutropenia and Thrombocytopenia)

REVLIMID can cause significant neutropenia and thrombocytopenia. Eighty percent of patients with del 5q MDS 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 MDS 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.

Venous and Arterial Thromboembolism

REVLIMID has demonstrated a significantly increased risk of deep vein thrombosis (DVT) and pulmonary embolism (PE), as well as risk of myocardial infarction and stroke in patients with MM who were treated with REVLIMID and dexamethasone therapy. Monitor for and advise patients about 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.

Please see additional Important Safety Information on pages 20-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Important Safety Information (continued)

CONTRAINDICATIONS

Pregnancy: REVLIMID® (lenalidomide) can cause fetal harm when administered to a pregnant female and is contraindicated in females who are pregnant. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risk to the fetus.

Severe Hypersensitivity Reactions: REVLIMID is contraindicated in patients who have demonstrated severe hypersensitivity (e.g., angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis) to lenalidomide.

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity: See Boxed WARNINGS.

- Females of Reproductive Potential: **See Boxed WARNINGS.**
- Males: Lenalidomide is present in the semen of patients receiving the drug. Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking REVLIMID and for up to 4 weeks after discontinuing REVLIMID, even if they have undergone a successful vasectomy. Male patients taking REVLIMID must not donate sperm.
- Blood Donation: Patients must not donate blood during treatment with REVLIMID and for 4 weeks following discontinuation of the drug because the blood might be given to a pregnant female patient whose fetus must not be exposed to REVLIMID.

REVLIMID REMS® Program: See Boxed WARNINGS.
Prescribers and pharmacies must be certified with the REVLIMID REMS program by enrolling and complying with the REMS requirements; pharmacies must only dispense to patients who are authorized to receive REVLIMID. Patients must sign a Patient-Physician Agreement Form and comply with REMS requirements; female patients of reproductive potential who are not pregnant must comply with the pregnancy testing and contraception requirements and males must comply with contraception requirements.

Hematologic Toxicity: REVLIMID can cause significant neutropenia and thrombocytopenia. Monitor patients with neutropenia for signs of infection. Advise patients to observe for bleeding or bruising, especially with use of concomitant medications that may increase risk of bleeding. Patients may require a dose interruption and/or dose reduction. **MM:** Monitor complete blood counts (CBC) in patients taking REVLIMID + dexamethasone or REVLIMID as maintenance therapy, every 7 days for the first 2 cycles, on days 1 and 15 of cycle 3, and every 28 days thereafter. **MDS:** Monitor CBC in patients on therapy for del 5q MDS, weekly for the first 8 weeks of therapy and at least monthly thereafter. **See Boxed WARNINGS** for further information. **MCL:** Monitor CBC in patients taking REVLIMID for MCL weekly for the first cycle (28 days), every 2 weeks during cycles 2-4, and then monthly thereafter.

Please see additional Important Safety Information on pages 19 and 21-25, and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Important Safety Information (continued)

Hematologic Toxicity (continued): FL/MZL: Monitor CBC in patients taking REVLIMID® (lenalidomide) for FL or MZL weekly for the first 3 weeks of Cycle 1 (28 days), every 2 weeks during Cycles 2-4, and then monthly thereafter.

Venous and Arterial Thromboembolism: See Boxed WARNINGS. Venous thromboembolic events (DVT and PE) and arterial thromboses (MI and CVA) are increased in patients treated with REVLIMID. Patients with known risk factors, including prior thrombosis, may be at greater risk and actions should be taken to try to minimize all modifiable factors (e.g., hyperlipidemia, hypertension, smoking). Thromboprophylaxis is recommended and the regimen should be based on the patient's underlying risks. Erythropoietin-stimulating agents (ESAs) and estrogens may further increase the risk of thrombosis and their use should be based on a benefit-risk decision.

Increased Mortality in Patients With CLL: In a clinical trial in the first-line treatment of patients with CLL, single-agent REVLIMID therapy increased the risk of death as compared to single-agent chlorambucil. Serious adverse cardiovascular reactions, including atrial fibrillation, myocardial infarction, and cardiac failure, occurred more frequently in the REVLIMID arm. REVLIMID is not indicated and not recommended for use in CLL outside of controlled clinical trials.

Second Primary Malignancies (SPM): In clinical trials in patients with MM receiving REVLIMID and in patients with FL or MZL receiving REVLIMID + rituximab therapy, an increase of hematologic plus solid tumor SPM, notably AML, have been observed. In patients with MM, MDS was also observed. Monitor patients for the development of SPM. Take into account both the potential benefit of REVLIMID and risk of SPM when considering treatment.

Increased Mortality With Pembrolizumab: In clinical trials in patients with MM, the addition of pembrolizumab to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of patients with MM with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

Hepatotoxicity: Hepatic failure, including fatal cases, has occurred in patients treated with REVLIMID + dexamethasone. Pre-existing viral liver disease, elevated baseline liver enzymes, and concomitant medications may be risk factors. Monitor liver enzymes periodically. Stop REVLIMID upon elevation of liver enzymes. After return to baseline values, treatment at a lower dose may be considered.

Please see additional Important Safety Information on pages 19, 20, and 22-25, and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Important Safety Information (continued)

Severe Cutaneous Reactions: Severe cutaneous reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported. These events can be fatal. Patients with a prior history of Grade 4 rash associated with thalidomide treatment should not receive REVLIMID® (lenalidomide). Consider REVLIMID interruption or discontinuation for Grade 2-3 skin rash. Permanently discontinue REVLIMID for Grade 4 rash, exfoliative or bullous rash, or for other severe cutaneous reactions such as SJS, TEN, or DRESS.

Tumor Lysis Syndrome (TLS): Fatal instances of TLS have been reported during treatment with REVLIMID. The patients at risk of TLS are those with high tumor burden prior to treatment. Closely monitor patients at risk and take appropriate preventive approaches.

Tumor Flare Reaction (TFR): TFR has occurred during investigational use of REVLIMID for CLL and lymphoma. Monitoring and evaluation for TFR is recommended in patients with MCL, FL, or MZL. Tumor flare may mimic the progression of disease (PD). In patients with Grade 3 or 4 TFR, it is recommended to withhold treatment with REVLIMID until TFR resolves to ≤Grade 1. REVLIMID may be continued in patients with Grade 1 and 2 TFR without interruption or modification, at the physician's discretion.

Impaired Stem Cell Mobilization: A decrease in the number of CD34+ cells collected after treatment (>4 cycles) with REVLIMID has been reported. Consider early referral to transplant center to optimize timing of the stem cell collection.

Thyroid Disorders: Both hypothyroidism and hyperthyroidism have been reported. Measure thyroid function before starting REVLIMID treatment and during therapy.

Early Mortality in Patients With MCL: In another MCL study, there was an increase in early deaths (within 20 weeks); 12.9% in the REVLIMID arm versus 7.1% in the control arm. Risk factors for early deaths include high tumor burden, MIPI score at diagnosis, and high WBC at baseline (≥10 x 10^9/L).

Hypersensitivity: Hypersensitivity including angioedema, anaphylaxis, and anaphylactic reactions to REVLIMID has been reported. Permanently discontinue REVLIMID for angioedema and anaphylaxis.

ADVERSE REACTIONS

Multiple Myeloma

- **In Newly Diagnosed:** The most frequently reported Grade 3 or 4 reactions included neutropenia, anemia, thrombocytopenia, pneumonia, asthenia, fatigue, back pain, hypokalemia, rash, cataract, lymphopenia, dyspnea, DVT, hyperglycemia, and leukopenia. The highest frequency of infections occurred in Arm Rd Continuous (75%) compared to Arm MPT (56%). There were more Grade 3 and 4 and serious adverse reactions of infection in Arm Rd Continuous than either Arm MPT or Rd18.

Please see additional Important Safety Information on pages 19-21 and 23-25, and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Important Safety Information (continued)

- The most common adverse reactions reported in ≥20% (Arm Rd Continuous): diarrhea (45%), anemia (44%), neutropenia (35%), fatigue (33%), back pain (32%), asthenia (28%), insomnia (28%), rash (26%), decreased appetite (23%), cough (23%), dyspnea (22%), pyrexia (21%), abdominal pain (20%), muscle spasms (20%), and thrombocytopenia (20%).
- **Maintenance Therapy Post Auto-HSCT:** The most frequently reported Grade 3 or 4 reactions in ≥20% (REVLIMID® (lenalidomide) arm) included neutropenia, thrombocytopenia, and leukopenia. The serious adverse reactions of lung infection and neutropenia (more than 4.5%) occurred in the REVLIMID arm.
- The most frequently reported adverse reactions in ≥20% (REVLIMID arm) across both maintenance studies (Study 1, Study 2) were neutropenia (79%, 61%), thrombocytopenia (72%, 24%), leukopenia (23%, 32%), anemia (21%, 9%), upper respiratory tract infection (27%, 11%), bronchitis (4%, 47%), nasopharyngitis (2%, 35%), cough (10%, 27%), gastroenteritis (0%, 23%), diarrhea (54%, 39%), rash (32%, 8%), fatigue (23%, 11%), asthenia (0%, 30%), muscle spasm (0%, 33%), and pyrexia (8%, 20%).
- **After at Least One Prior Therapy:** The most common adverse reactions reported in ≥20% (REVLIMID/dex vs dex/placebo): fatigue (44% vs 42%), neutropenia (42% vs 6%), constipation (41% vs 21%), diarrhea (39% vs 27%), muscle cramp (33% vs 21%), anemia (31% vs 24%), pyrexia (27% vs 23%), peripheral edema (26% vs 21%), nausea (26% vs 21%), back pain (26% vs 19%), upper respiratory tract infection (25% vs 16%), dyspnea (24% vs 17%), dizziness (23% vs 17%), thrombocytopenia (22% vs 11%), rash (21% vs 9%), tremor (21% vs 7%), and weight decreased (20% vs 15%).

Myelodysplastic Syndromes

- Grade 3 and 4 adverse events reported in ≥5% of patients with del 5q MDS were neutropenia (53%), thrombocytopenia (50%), pneumonia (7%), rash (7%), anemia (6%), leukopenia (5%), fatigue (5%), dyspnea (5%), and back pain (5%).
- Adverse events reported in ≥15% of del 5q MDS patients (REVLIMID): thrombocytopenia (61.5%), neutropenia (58.8%), 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%), pharyngitis (16%), epistaxis (15%), asthenia (15%), upper respiratory tract infection (15%).

Please see additional Important Safety Information on pages 19-22, 24, and 25, and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Important Safety Information (continued)

Mantle Cell Lymphoma

- Grade 3 and 4 adverse events reported in ≥5% of patients treated with REVLIMID® (lenalidomide) in the MCL trial (N=134) included neutropenia (43%), thrombocytopenia (28%), anemia (11%), pneumonia (9%), leukopenia (7%), fatigue (7%), diarrhea (6%), dyspnea (6%), and febrile neutropenia (6%).
- Adverse events reported in ≥15% of patients treated with REVLIMID in the MCL trial included neutropenia (49%), thrombocytopenia (36%), fatigue (34%), anemia (31%), diarrhea (31%), nausea (30%), cough (28%), pyrexia (23%), rash (22%), dyspnea (18%), pruritus (17%), peripheral edema (16%), constipation (16%), and leukopenia (15%).

Follicular Lymphoma/Marginal Zone Lymphoma

- Fatal adverse reactions occurred in 6 patients (1.5%) receiving REVLIMID + rituximab across both trials. Fatal adverse reactions (1 each) included: cardio-respiratory arrest, arrhythmia, cardiopulmonary failure, multiple organ dysfunction syndrome, sepsis, and acute kidney injury. The most frequent serious adverse reaction that occurred in the REVLIMID + rituximab arm was febrile neutropenia (3.0%).
- Grade 3 and 4 adverse reactions reported in ≥5% of patients treated in the FL/MZL trial with REVLIMID + rituximab were: neutropenia (50%) and leukopenia (7%).
- Adverse reactions reported in ≥15% of patients with FL/MZL treated with REVLIMID + rituximab were: neutropenia (58%), diarrhea (31%), constipation (26%), cough (24%), fatigue (22%), rash (22%), pyrexia (21%), leukopenia (20%), pruritus (20%), upper respiratory tract infections (18%), abdominal pain (18%), anemia (16%), headache (15%), thrombocytopenia (15%).

DRUG INTERACTIONS

Periodically monitor digoxin plasma levels due to increased C_{max} and AUC with concomitant REVLIMID therapy. Patients taking concomitant therapies such as ESAs or estrogen-containing therapies may have an increased risk of thrombosis. It is not known whether there is an interaction between dexamethasone and warfarin. Close monitoring of PT and INR is recommended in patients with MM taking concomitant warfarin.

Please see additional Important Safety Information on pages 19-23 and 25, and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Important Safety Information (continued)

USE IN SPECIFIC POPULATIONS

- **PREGNANCY: See Boxed WARNINGS:** If pregnancy does occur during treatment, immediately discontinue the drug and refer patient to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling. There is a REVLIMID® (lenalidomide) pregnancy exposure registry that monitors pregnancy outcomes in females exposed to REVLIMID during pregnancy as well as female partners of male patients who are exposed to REVLIMID. This registry is also used to understand the root cause for the pregnancy. Report any suspected fetal exposure to REVLIMID to the FDA via the MedWatch program at 1-800-FDA-1088 and also to Celgene Corporation at 1-888-423-5436.
- **LACTATION:** There is no information regarding the presence of lenalidomide in human milk, the effects of REVLIMID on the breastfed infant, or the effects of REVLIMID on milk production. Because many drugs are excreted in human milk and because of the potential for adverse reactions in breastfed infants from REVLIMID, advise female patients not to breastfeed during treatment with REVLIMID.
- **RENAL IMPAIRMENT:** Adjust the starting dose of REVLIMID based on the creatinine clearance value and for patients on dialysis.

REFERENCES

1. REVLIMID [package insert]. Summit, NJ: Celgene Corp; 2019.
2. Chen N, Lau H, Kong L, et al. Pharmacokinetics of lenalidomide in subjects with various degrees of renal impairment and in subjects on hemodialysis. *J Clin Pharmacol*. 2007;47(12):1466-1475.
3. National Kidney Foundation. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kl Suppl*. 2013;3(1):1-150. For additional information regarding renal guidelines, please refer to the National Kidney Foundation website.
4. Cockcroft DW, Gault MH. Prediction of creatinine clearance from serum creatinine. *Nephron*. 1976;16(1):31-41.

Please see enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

Please see the rituximab full Prescribing Information for Important Safety Information at www.rituxan.com.

Revlimid®
(lenalidomide) capsules
2.5 · 5 · 10 · 15 · 20 · 25 mg

REVLIMID is only available through a restricted distribution program, REVLIMID REMS®.

Visit REVLIMIDDosingCalendar.com to create personalized treatment calendars for your patients

Please see Important Safety Information on pages 19-25 and enclosed full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

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