Drug Monograph

A - Drug Name

lenalidomide

COMMON TRADE NAME(S): Revlimid®

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B - Mechanism of Action and Pharmacokinetics

Lenalidomide is an analogue of thalidomide, developed to reduce the dose-limiting side effects of thalidomide such as sedation, constipation, thromboembolism and neuropathy. The mechanism of action of this class of agents remains to be fully characterized, but it is immunomodulatory with anti-inflammatory activity and anti-angiogenic effects. It inhibits TNF-α production, stimulates T and NK cells, reduces serum levels of vascular endothelial growth factor (VEGF), promotes G1 cell cycle arrest and apoptosis of malignant cells.

Absorption	Bioavailability	Oral: Yes. Co-administration with food does not alter the extent of absorption (AUC) but reduces C_{max} by 36%.
Distribution	The pharmacokinetics of lenalidomide are linear and dose proportional. There is no accumulation with multiple dosing at the recommended dose. Exposure is 57% higher in multiple myeloma patients than in healthy volunteers.	
	Cross blood brain barrier?	No information
	PPB	23 - 29 %
Metabolism	*In vitro*, lenalidomide does not appear to be a substrate, inducer or inhibitor of cytochrome P450 enzymes. It is a weak substrate, but not an inhibitor, of p-glycoprotein. Non-enzymatic hydrolysis of lenalidomide occurs in aqueous	

	media and plasma.	
	Inactive metabolites	Yes
Elimination	Lenalidomide is primarily excreted unchanged by the kidney	
	Urine	66 % as unchanged drug.
	Half-life	3-5 hours

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C - Indications and Status

Health Canada Approvals:

- Multiple myeloma
- Myelodysplastic syndromes (MDS)

Refer to the product monograph for a full list and details of approved indications.

Note:

Lenalidomide may only be prescribed and dispensed by physicians and pharmacists registered with a controlled distribution program. Patients must also be registered and meet all conditions of the program.

Other Uses:

- Non-Hodgkin lymphoma

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D - Adverse Effects

Emetogenic Potential: Minimal – No routine prophylaxis; PRN recommended

Extravasation Potential: Not applicable

The following table contains adverse effects reported mainly in controlled studies with myeloma patients in combination with dexamethasone, where incidence is at least 2% greater than placebo.

ORGAN SITE	SIDE EFFECT* (%)	ONSET**
Cardiovascular	Arrhythmia (<10%)	E
	Arterial thromboembolism (<10%)	E
	Cardiotoxicity (<10%)	E
	Hypertension (9%)	E
	Venous thromboembolism (9%)	E
Dermatological	Rash (22%) (may be severe: SJS, TEN, DRESS)	E
	Skin discolouration (<1%)	E
Gastrointestinal	Abdominal pain (11%)	E
	Anorexia (19%) +/- weight loss	E
	Constipation (42%)	E
	Diarrhea (39%)	E
	Dry mouth (8%)	E
	Dyspepsia (17%)	E
	Nausea, vomiting (26%)	I
General	Edema (27%)	E
	Fatigue (46%)	E
Hematological	Hemolysis (rare)	E
	INR / prothrombin time increased (rare)	E
	Myelosuppression ± infection, bleeding (35%) (grade 3 or 4, includes opportunistic infections, viral reactivation)	E
Hepatobiliary	Cholecystitis (1%) (may be severe)	E
	↑ LFTs (rare, may be severe)	E D
	Pancreatitis (rare)	E
Hypersensitivity	Hypersensitivity (<10%) (including angioedema)	I
Immune	Graft-versus-host disease (GVHD) (post-stem cell transplant; rare)	D
	Other - Solid organ transplant rejection (rare; may be fatal)	E

Metabolic / Endocrine	Abnormal electrolyte(s) (15%) (↓ K, ↓ Mg, ↓ Na, ↓ PO4)	E
	Adrenal insufficiency (rare)	D
	Hyperglycemia (16%)	E
	Hyperthyroidism (<10%)	D
	Hypothyroidism (8%)	D
	Tumor lysis syndrome (rare)	I
Musculoskeletal	Musculoskeletal pain (34%) (including muscle cramps)	E
	Rhabdomyolysis (rare)	E D
Neoplastic	Secondary malignancy (7%)	D
Nervous System	Cognitive disturbance (9%)	E
	Depression (13%)	E
	Dizziness (24%)	E
	Dysgeusia (15%)	E
	Headache (27%)	E
	Insomnia (13%)	E
	Peripheral neuropathy (9%)	E
	Syncope (3%) (grade 3 or 4)	E
	Tremor (21%)	E
Ophthalmic	Blurred vision (17%)	E
	Conjunctivitis (<10%)	E
Renal	Renal failure (1%)	E
Respiratory	Cough, dyspnea (26%)	E
	Pneumonitis (1%)	E

* "*Incidence*" may refer to an absolute value or the higher value from a reported range.
"*Rare*" may refer to events with < 1% incidence, reported in post-marketing, phase 1 studies, isolated data or anecdotal reports.

** I = *immediate* (onset in hours to days) E = *early* (days to weeks)
D = *delayed* (weeks to months) L = *late* (months to years)

The most common side effects for lenalidomide include fatigue, constipation, diarrhea, myelosuppression ± infection/bleeding, musculoskeletal pain, edema, headache, cough/dyspnea, nausea/vomiting and dizziness.

In randomized controlled trials, the incidence of myelosuppression, fatigue, GI, CNS, respiratory, musculoskeletal and skin toxicity, arterial thromboembolism, venous thromboembolism, electrolyte

abnormalities, anorexia and infection were higher than in the control arm.

Thromboembolism occurs in 3-5% in MDS patients receiving lenalidomide as a single agent, and is more frequent when lenalidomide is used in combination with dexamethasone (especially high dose for myeloma – up to 18%) with concomitant erythropoietin or other thrombogenic agents (hormone replacement therapy, contraceptives). Arterial thromboembolism has been reported in those with known risk factors and within the first 6 months of use. Patients at risk of arterial thromboembolism should have their hypertension and hyperlipidemia appropriately managed and refrain from tobacco use. Prophylaxis is recommended for at risk patients (e.g. low dose aspirin 81-100 mg/day, low molecular weight heparin or warfarin).

Skin rash is common with lenalidomide therapy and usually resolves within 2-3 weeks; no interruption of treatment is required unless severe (6%). Unselective antihistamine, topical steroids or short course of oral prednisone 10mg/day for 2 weeks may relieve symptoms (Palumbo 2009). Rare, fatal cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported. **DRESS** (Drug Rash with Eosinophilia and Systemic Symptoms) syndrome has also been observed, with rash, eosinophilia, and systemic involvement (e.g. fever, lymphadenopathy, elevated transaminases, renal insufficiency, pneumonitis, myocarditis and/or pericarditis).

Rarely, hypersensitivity **pneumonitis**-like syndrome has been reported with lenalidomide use. In the case of unexpected respiratory symptoms such as dyspnea on exertion, crackles on physical examination, radiological bilateral ground-glass opacities and non-resolving pneumonia, lenalidomide should be discontinued until further investigation excludes hypersensitivity pneumonitis-like syndrome.

Cases of **viral reactivation** have been reported and may be fatal, including herpes zoster and hepatitis B virus (HBV) infections. Use with caution in patients with a history of these infections.

Rare, severe cases of **hepatotoxicity**, including fatalities have been reported in multiple myeloma patients. The mechanism of this toxicity is unknown. Risk factors may include pre-existing or concurrent liver infection, history of hepatic and renal disorders, elevated baseline liver enzymes, and concomitant hepatotoxic medications.

Tumour flare has been reported in investigational studies for CLL and MCL.

Tumour lysis syndrome (TLS) has been observed and may be fatal. Patients at risk such as those with high tumour burden, should receive appropriate prophylaxis and be monitored closely.

An increase in **secondary primary malignancies** (SPM, including leukemia, lymphoma and solid tumour, as well as basal and squamous skin cancer) has been reported The risk of SPM should be considered before initiating treatment and standard cancer screening should be used during treatment.

Graft vs. host disease has been reported in post stem cell transplant patients treated with lenalidomide and may be fatal, especially when given within 6 months of allogenic stem cell transplant.

Solid organ transplant (SOT) rejection, including fatal cases, have been reported within 1 to 3 cycles of lenalidomide treatment. Contributing factors may include underlying disease (e.g., amyloidosis), concurrent infections and recent discontinuation or reduction of immunosuppressants. Consider benefit vs risk in patients with a history of SOT before starting lenalidomide.

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E - Dosing

Lenalidomide may only be prescribed and dispensed by physicians and pharmacists registered with a controlled distribution program. Patients must also be registered and meet all conditions of the program.

Women of child bearing potential must have two negative pregnancy tests before initiating treatment; clinical trials in MDS excluded patients with grade 4 neutropenia. MDS patients with platelets < 50 x 10^9/L should not receive lenalidomide.

Consider allopurinol and hydration for patients at risk of tumour lysis as well as thromboembolism prophylaxis for at risk patients (e.g. myeloma with high dose dexamethasone). Optimal control of thyroid function is recommended prior to starting treatment.

Refer to protocol by which patient is being treated.

Adults:

A. Myelodysplastic Syndrome:
Q 28 days: 10 mg PO daily on days 1 to 21

Dosage with Toxicity:

Dose levels (days 1-21): 10mg daily, 5mg daily, 5mg every other day

Dosage with Hematologic Toxicity

Discontinue treatment if no erythroid response within 4 months of therapy initiation (less than 50% reduction in transfusion requirements or, if not transfused, less than 10 g/L rise in hemoglobin).

If myelosuppression develops **within 4** weeks of starting treatment at 10 mg daily							
Baseline Counts ($X10^9$/L)			Counts during therapy ($X10^9$/L)			Action	
Platelets	AND/ OR	ANC*	Platelets	AND/ OR	ANC		
≥ 100		≥ 1	< 50		<0.75	Hold	Restart at 5mg/day when platelets ≥ 50 and ANC ≥ 1
≥60 to <100		<1	↓ 50% of baseline		<0.50	Hold	Restart at 5mg/day when platelets ≥ 50 and ANC ≥ 0.5
< 60**						Hold	Restart at 5mg/day when platelets ≥ 30 and ANC ≥ 0.5

*ANC= Absolute Neutrophil Counts

** Clinical trial excluded patients with platelets < 50 x 10^9/L or grade 4 ANC.

If myelosuppression develops **after 4** weeks of starting treatment at 10 mg daily				
Counts during therapy ($X10^9$/L)			Action	
Platelets	AND/ OR	ANC		
<30, or <50 requiring transfusion		<0.5 ≥ 7 days or with fever (≥38.5°C)	Hold	Restart at 5mg/day when platelets ≥ 30 (without bleeding) and ANC ≥ 0.5

If myelosuppression develops during treatment at **5mg** daily				
Counts during therapy ($X10^9$/L)			Action	
Platelets	AND/ OR	ANC		
<30, or <50 requiring transfusion		<0.5 ≥ 7 days or with fever (≥38.5°C)	Hold	Restart at 5mg **EVERY OTHER DAY** when platelets ≥ 30 (without bleeding) and ANC ≥ 0.5

Non-Hematologic Toxicities

Toxicity	Action
≥Grade 3 non-hematological	Hold; restart with ↓ 1 dose level when ≤Grade 2.
Grade 2 to 3 rash	Hold or consider discontinuing. Discontinue if Stevens-Johnson syndrome suspected.
↑ LFTs	Hold. Consider restarting at a lower dose when ≤ baseline levels.

Pneumonitis	Hold and investigate if suspected; discontinue if confirmed.
Angioedema, OR Grade 4 skin rash, OR Exfoliative or bullous rash, OR Suspected Stevens-Johnson Syndrome, Toxic epidermal necrolysis or DRESS	Discontinue.
Solid organ transplant rejection	Discontinue

B. Multiple Myeloma:

Q 28 days: 25 mg PO daily on Days 1 to 21 in combination with dexamethasone*: 40 mg PO weekly

*The 40mg weekly dexamethasone option is recommended based on a phase 3 study in newly diagnosed myeloma, where the lower dose was associated with lower mortality and morbidity (Rajkumar 2010). In patients over 75 years of age, the dose should be reduced to 20 mg once weekly.

High-dose dexamethasone may still be appropriate for some patients with acute myeloma complications (e.g. acute renal impairment, hypercalcemia or hyperviscosity syndrome).

Dosage with Toxicity

Newly diagnosed (days 1-21): 25mg, 20mg, 15mg, 10mg, 5mg, 2.5mg

Previously treated (days 1-21): 25mg, 20mg, 15mg, 10mg, 5mg

Toxicity (counts x 10^9/L)	**1st Occurrence**	**Second and Subsequent Occurrence**
Hematologic Toxicity (newly diagnosed myeloma)		
Platelets < 25	Hold, restart by ↓ 5mg when platelets ≥ 50.	Hold, restart by ↓ 5mg when platelets ≥ 50.
ANC < 0.5 or febrile neutropenia	Hold, start G-CSF. When ANC ≥ 1, restart: • Without dose reduction if isolated neutropenia. • With 5mg ↓ if other toxicity.	Hold, start G-CSF, restart by ↓ 5mg when ANC ≥ 1.

Hematologic Toxicity (previously treated myeloma)		
Platelets < 30	Hold, restart at 15 mg (if 25 mg starting dose) or 5mg less than the adjusted starting dose, when platelets ≥ 30.	Hold, restart by ↓ 5mg when platelets ≥ 30.
ANC < 1	Hold, start G-CSF, restart when ANC ≥ 1: • Without dose reduction if isolated neutropenia. • At 15mg (if 25 mg starting dose) or 5mg less than the adjusted starting dose, if other toxicity.	Hold, start G-CSF, restart by ↓ 5mg when ANC ≥ 1.
Non-Hematologic Toxicity		
≥ Grade 3 non-hematologic	Hold, restart with ↓ 1 dose level when ≤ Grade 2.	
↑ LFTs	Hold. Consider restarting at a lower dose when ≤ baseline levels.	
Grade 2 to 3 rash	Hold or consider discontinuing. Discontinue if Stevens-Johnson syndrome suspected.	
Angioedema, OR Grade 4 skin rash, OR Exfoliative or bullous rash, OR Suspected Stevens-Johnson syndrome, Toxic epidermal necrolysis or DRESS	Discontinue	
Pneumonitis	Hold and investigate if suspected; discontinue if confirmed.	
Solid organ transplant rejection	Discontinue	

Dosage with Hepatic Impairment:

Population pharmacokinetics suggest no dosage adjustment is necessary in mild hepatic impairment (total bilirubin > 1 to < 1.5 x ULN or AST > ULN). No data available for moderate to severe hepatic impairment.

Dosage with Renal Impairment:

Lenalidomide clearance is decreased while exposure is increased in renal impairment. No dosage adjustment is required for CrCl ≥ 60 ml/min.

Creatinine Clearance (mL/min)	Starting dose in MDS patients†	Starting dose in Multiple Myeloma patients†
30 to < 60	5mg daily	10mg daily*
< 30 (not requiring dialysis)	5mg every other day	15mg every other day
< 30 (requiring dialysis)	5mg 3 times a week following each dialysis	No phase III clinical trial experience in this setting. 5 mg once daily. On dialysis days, the dose should be administered following dialysis

* may be escalated to 15 mg q24h after 2 cycles if patient is not responding to treatment and is tolerating the drug.
† maintain a 3 weeks on, 1 week off schedule (q28 days)

Dosage in the elderly:

For transplant ineligible, newly diagnosed myeloma patients over 75 years of age, the concomitant dexamethasone dose should be reduced by half.

The incidences of serious and non-serious adverse events are significantly higher in patients > 65 years (constipation, confusion, dyspnea, atrial fibrillation, diarrhea, fatigue, pulmonary embolism, syncope). May be related to renal impairment. Monitor geriatric patients closely, especially cardiac and renal function. Dose modification based on degree of renal impairment is required.

Children:

Safety and efficacy not established.

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F - Administration Guidelines

- Drug available by outpatient prescription in pharmacy registered with a controlled distribution program.
- Oral self-administration; swallow capsules whole; they should not be broken, chewed, or opened. Do not extensively handle the capsules.
- Give capsules preferably with water, either with or without food. Do not remove from blister packs until ready to take the dose.
  Note: Females who could become pregnant, or who plan to become pregnant can handle lenalidomide capsules if they are using latex gloves.
- If a dose is missed, it may be taken up to 12 hours after the time it is normally taken. Otherwise, skip this and take the next dose on the following day at its usual scheduled time.
- Store capsules at room temperature (15 to 30°C).

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G - Special Precautions

Contraindications:

- Patients with hypersensitivity (including severe rash) to lenalidomide, pomalidomide, thalidomide or any ingredient in the formulation.
- MDS patients with platelet counts < 50 x 10^9/L. MDS patients with grade 3 or 4 thrombocytopenia or grade 4 neutropenia were excluded from clinical trials.
- Pregnant women.

- Women at risk of being pregnant and male patients who do not comply with contraception requirements (see Pregnancy section).
- Breastfeeding women.
- Not indicated for use in CLL patients outside of clinical trials.

Other Warnings/Precautions:

- Lenalidomide contains lactose; carefully consider use in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.
- Use with caution and consider venous thromboembolism prophylaxis when used in combination with corticosteroids or thrombogenic agents, such as hormones and erythropoietin (see adverse effects section).
- Exercise caution in patients with risk factors for arterial thromboembolism (e.g. hypertension and hyperlipidemia), or risk factors for atrial fibrillation (e.g. electrolyte abnormalities, pre-existing heart disease, hypertension, infection).
- Use with caution in patients with high tumour burden; monitor closely and use appropriate precautions for tumour lysis syndrome.
- Use with caution and monitor closely in patients with previous viral infections such as HBV and herpes zoster.

Other Drug Properties:

- Carcinogenicity: Unknown

Pregnancy and Lactation:

- Teratogenicity: Yes
- Embryotoxicity: Yes
  Lenalidomide is **contraindicated in pregnancy** and in **females and males of childbearing potential who do not comply with the contraception conditions of the controlled distribution program**. Females of childbearing potential (all women who are not ≥ 2 years menopausal OR have not had hysterectomy or bilateral oophorectomy) must be capable of understanding and complying with the patient registration, education, and safety requirements of the program, regular pregnancy testing and the use of two simultaneous contraception methods (must be started at least **one month** prior to starting treatment, continued during dose interruptions, during treatment and for at least **1 month** following the cessation of lenalidomide). Hormonal contraceptives are not recommended due to the increased risk of **thromboembolism**. If pregnancy occurs during treatment, lenalidomide must be discontinued and patient referred to a gynecologist/obstetrician for evaluation and counselling.
  Lenalidomide is present in semen, and there is a potential risk of birth defects, stillbirths and spontaneous abortions in the exposed fetus, Male patients must be capable of understanding and complying with the patient registration, education, and safety requirements of the

controlled distribution program, including mandatory contraceptive measures for men (condoms should be used even with vasectomized males) and must inform their female sexual partners of the risk. Male patients should not donate semen while taking lenalidomide and for **4 weeks** after cessation.
Patients should not donate blood while taking lenalidomide and for **4 weeks** after stopping therapy to prevent fetal exposure via transfusion of pregnant women.

- Excretion into breast milk: Unknown
  Breastfeeding is contraindicated.
- Fertility effects: Unlikely

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H - Interactions

Lenalidomide is not a substrate, inhibitor or inducer of CYP450; co-administration with substrates or inhibitors of this enzyme is unlikely to result in significant drug interactions.

AGENT	EFFECT	MECHANISM	MANAGEMENT
digoxin	↑ digoxin Cmax - 14%	Unknown	Caution; monitor digoxin levels
Hormonal therapy (contraception/HRT), erythropoietic agents, corticosteroids	↑ risk of thromboembolic events	Additive	Caution; monitor carefully; consider prophylaxis with anticoagulants

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Recommended Clinical Monitoring

Monitor Type	Monitor Frequency
Pregnancy testing requirements for women of child-bearing potential	Before starting and as indicated as per controlled distribution program
Renal function tests	Baseline and at each visit; increased frequency in patients 65 years or older

Liver function tests	Baseline and at each visit
CBC	Baseline and as follows: MDS: weekly for first 8 weeks, then monthly; Myeloma: weekly for the first 8 weeks, on days 1 & 15 of cycle 3, then monthly
Thyroid function tests	Baseline and ongoing
Clinical assessments and grading of cardiac and respiratory symptoms, rash, diarrhea, fatigue, constipation, infection (including viral reactivation), bleeding, tumour lysis syndrome, arterial and venous thromboembolism, GVHD, solid organ transplant rejection (if applicable)	At each visit
Cancer screening for occurrence of second primary malignancy	Assess risk prior to starting treatment; then at each visit or as clinically indicated

Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

Monitor Type	Monitor Frequency
ECG	Baseline; repeat if arrhythmia suspected
INR in patients receiving warfarin	Baseline and as clinically indicated

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J - Supplementary Public Funding

ODB Limited Use (ODB Formulary)

- lenalidomide - For the treatment of patients with anemia due to myelodysplastic syndrome (MDS), according to clinical criteria
- lenalidomide - For the maintenance treatment of patients with newly diagnosed multiple myeloma, following ASCT, who have stable disease or better, with no evidence of disease progression, according to clinical criteria
- lenalidomide - For the treatment of patients with multiple myeloma, who are deemed to be lenalidomide sensitive, and/or have not experienced progression while on a lenalidomide-based regimen in the treatment or maintenance setting, according to clinical criteria
- lenalidomide - Induction therapy for transplant eligible, newly diagnosed multiple myeloma, according to clinical criteria

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K - References

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Rajkumar SV, Jacobus S, Callander NS, et al; Eastern Cooperative Oncology Group. Lenalidomide plus high-dose dexamethasone versus lenalidomide plus low-dose dexamethasone as initial therapy for newly diagnosed multiple myeloma: an open-label randomised controlled trial. Lancet Oncol. 2010 Jan;11(1):29-37.

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March 2024 Updated Supplementary public funding section

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L - Disclaimer

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

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