

DRUG NAME: Lenalidomide**SYNONYM(S):****COMMON TRADE NAME(S):** REVLIMID®**CLASSIFICATION:** miscellaneous*Special pediatric considerations are noted when applicable, otherwise adult provisions apply.***MECHANISM OF ACTION:**

Lenalidomide is an immunomodulator, a structural and functional analogue of thalidomide. While they remain to be fully characterized, multiple mechanisms of action have been identified, including increasing hemoglobin expression by erythroid cells, inhibiting proliferation of certain hematopoietic tumour cells, enhancing T cell, NK cell and NK T cell number and activity, and inhibiting angiogenesis by blocking the migration and adhesion of endothelial cells and the formation of microvessels.¹ It inhibits production of proinflammatory cytokines e.g., TNF and TNF alpha, and increases production of IL-2 and IFN gamma.² One possible molecular target of lenalidomide is the Akt core signaling pathway, with which some of these effects are associated.¹ Lenalidomide is an immunosuppressive agent.¹

PHARMACOKINETICS:

Oral Absorption	rapid; unaffected by food; time to peak: 0.6-1.5 h (myeloma patients ³ : 0.5-4 h)	
Distribution	cross blood brain barrier?	no information found
	volume of distribution	76-85 L
	plasma protein binding	23-29%
Metabolism	not fully characterized; <i>in vitro</i> tests in human liver preparations suggest it does not undergo oxidative (P450) or conjugative metabolism. Non-enzymatic hydrolysis occurs in aqueous media and plasma	
	active metabolite(s)	no information found
	inactive metabolite(s)	no information found
Excretion	primarily renal ¹ ; AUC increased by 56% in patients with mild renal impairment ³	
	urine	~67%; primarily as unchanged drug
	feces	yes
	terminal half life	3 h
	clearance	240-302 mL/min

Adapted from standard reference¹ unless specified otherwise.**USES:****Primary uses:**

*Myelodysplastic syndromes

*Health Canada approved indication

Other uses:Multiple myeloma²**SPECIAL PRECAUTIONS:****Contraindications:**

- women of childbearing potential or sexually mature males unless they can comply with the criteria of the RevAid® program¹ (see below under **Pregnancy** and **Contraception** and also **Supply and Storage** section).
- history of hypersensitivity reaction to lenalidomide or thalidomide¹
- platelet levels¹ <50 x 10⁹/L
- capsules contain lactose and should not be administered to patients with problems of glucose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption¹

Caution: Do not give blood nor donate semen while taking lenalidomide and for 4 weeks after stopping.¹

Special populations: The incidence of serious side effects was significantly higher (60 vs. 35%) and discontinuation of treatment was higher (30 vs. 10%), in patients **>65 years** old.¹

Carcinogenicity: studies have not been conducted to date¹

Mutagenicity: Not mutagenic in Ames test and mammalian *in vitro* mutation test.¹ Lenalidomide is not clastogenic in mammalian *in vitro* and *in vivo* chromosome tests.¹

Fertility: no information found

Pregnancy: FDA Pregnancy Category X.³ Studies in animals or humans have shown fetal abnormalities, or there is evidence of fetal risk based on human experience, or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. Contraindicated in women who are or may become pregnant.

Contraception: Females of childbearing potential may be treated provided that adequate contraception i.e., two simultaneous effective methods of birth control, are used.¹ Contraceptive measures are indicated even in females with a history of infertility.² Only those who have undergone hysterectomy, bilateral oophorectomy, or who are naturally postmenopausal i.e., have had no menses for >24 consecutive months, do not need to observe contraceptive measures.² Avoid drugs that may interact with oral contraceptives; if these drugs must be used concurrently, use two other reliable forms of contraception (other than oral contraceptives). Contraceptive measures should be used throughout treatment and continued for 4 weeks following the last dose of lenalidomide.

Pregnancy must be excluded in females of childbearing potential i.e., negative **pregnancy test** within 10-14 days prior and again within the 24 h immediately prior to the first dose, using a reliable pregnancy test with the sensitivity to detect human chorionic gonadotropin concentrations of at least 50 mIU/mL.^{1,2} Testing should be repeated during treatment as required by the RevAid® Program.

During treatment, and for 4 weeks following, **males** must use latex condoms during any sexual contact with females of childbearing potential.^{1,2}

Breastfeeding is not recommended due to the potential secretion into breast milk.¹

SIDE EFFECTS:

The table includes adverse events that presented during drug treatment but may not necessarily have a causal relationship with the drug. Because clinical trials are conducted under very specific conditions, the adverse event rates observed may not reflect the rates observed in clinical practice. Adverse events are generally included if they were reported in more than 1% of patients in the product monograph or pivotal trials, and/or determined to be clinically important.⁴

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in bold, italics	
allergy/immunology	allergic dermatitis (1-5%, severe <1%)
	hypersensitivity (1-5%, severe <1%)
	transfusion reaction (1-5%, severe <15%)
auditory/hearing	tinnitus (1-5%, severe <1%)
blood/bone marrow/ febrile neutropenia	<i>anemia</i> (20%, severe 14%)
	febrile neutropenia (6%, severe 6%)
	granulocytopenia (1-5%, severe 1%)

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in bold, italics	
	leukopenia (10%, severe 8%)
	neutropenia (64%, severe 62%); see paragraph following Side Effects table
	pancytopenia (1-5%, severe 3%)
	polycythemia (1-5%, severe <1%)
	thrombocytopenia (62%, severe 53%); see paragraph following Side Effects table
cardiovascular (arrhythmia)	atrial fibrillation (1-5%, severe 3%)
	bradycardia (1-5%, severe <1%)
	palpitations (5%, severe <1%)
	tachycardia (1-5%, severe <1%)
cardiovascular (general)	angina pectoris (1-5%, severe <1%)
	congestive heart failure (1-5%, severe 3%); heart failure, not otherwise specified (1-5%, severe 1%)
	hypertension (7%, severe 4%)
	hypotension (1-5%, severe <1%)
constitutional symptoms	fatigue (36%, severe 6%)
	feeling cold, peripheral coldness (each: 1-5%, severe <1%)
	fever (24%, severe 3%)
	inflammation, not otherwise specified (1-5%, severe <1%)
	insomnia (12%, severe <1%); dyssomnia, sleep disorder (each: 1-5%, severe <1%)
	lethargy, malaise (each: 1-5%, severe <1%)
	night sweats (10%, severe <1%)
	somnolence (1-5%, severe <1%)
	weight gain (1-5%, severe <1%)
	weight loss (6%, severe <1%)
dermatology/skin	abrasion (1-5%, severe <1%)
	alopecia (1-5%, severe <1%)
	contusion (8%, severe <1%)
	decubitus ulcer (1-5%, severe <1%)
	discolouration (1-5%, severe <1%)
	dry skin (14%, severe <1%)
	ecchymosis (6%, severe <1%)
	erythema (6%, severe <1%)
	exanthem (1-5%, severe <1%)
	flushing (1-5%, severe <1%)
	impaired healing (1-5%, severe <1%)
	irritation (1-5%, severe <1%)

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in bold, italics	
	laceration (1-5%, severe <1%)
	lesion, not otherwise specified (5%, severe <1%)
	mucosal inflammation (1-5%, severe <1%)
	neutrophilic dermatosis (Sweet Syndrome); case report ⁵
	pruritis (44%, severe 3%)
	rash (36%, severe 6%)
	sweating (9%, severe 1%)
	urticaria (1-5%, severe <1%)
	wound, not otherwise specified (1-5%, severe <1%)
endocrine	diabetes mellitus (1-5%, severe <1%)
	hypothyroidism (8%, severe <1%)
gastrointestinal	<i>emetogenic potential: low</i> ⁶
	abdominal distension (1-5%, severe <1%)
	abdominal tenderness (1-5%, severe <1%)
	ageusia (1-5%, severe <1%)
	anorexia (12%, severe 1%)
	colonic polyp (1-5%, severe <1%)
	constipation (25%, severe <1%)
	diarrhea (54%, severe 5%); loose stools (8%, severe <1%)
	diverticulitis (1-5%, severe <1%)
	diverticulum (1-5%, severe <1%)
	dry mouth (7%, severe <1%)
	dysgeusia (6%, severe <1%)
	dyspepsia (1-5%, severe <1%)
	dysphagia (1-5%, severe 1%)
	flatulence (5%, severe <1%)
	frequent bowel movements (1-5%, severe <1%)
	gastritis, gastroenteritis, gastrointestinal upset (each: 1-5%, severe <1%)
	gastroesophageal reflux disease (1-5%, severe <1%)
	hemorrhoids (1-5%, severe <1%)
	intestinal spasm (1-5%, severe <1%)
	mouth ulceration (1-5%, severe <1%)
	nausea (26%, severe 5%)
	stomatitis, aphthous stomatitis (each: 1-5%, severe <1%)
	vomiting (11%, severe 2%)
hemorrhage	conjunctival, eye, not otherwise specified (each: 1-5%, severe <1%)

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in bold, italics	
	epistaxis (16%, severe 1%)
	gingival bleeding (1-5%, severe <1%)
	hematoma (1-5%, severe <1%)
	hemorrhoidal, rectal (each: 1-5%, severe <1%)
	metrorrhagia, vaginal (each: 1-5%, severe <1%)
	petechiae (1-5%, severe <1%)
hepatobiliary/pancreas	splenomegaly (1-5%, severe <1%)
infection	abscess, including skin, subcutaneous, tooth, and not otherwise specified (each: 1-5%, severe <1%)
	bacteremia (1-5%, severe 1%)
	cellulitis (6%, severe 1%)
	ear (1-5%, severe <1%)
	fungal, including skin, vaginosis, oral candidiasis, and <i>Candida</i> not otherwise specified (each: 1-5%, severe 1%)
	infection, not otherwise specified (1-5%, severe 1%)
	influenza (7%, severe 2%)
	influenza-like illness (1-5%, severe <1%)
	pneumonia (12%, severe 10%)
	respiratory tract (1-5%, severe 1%)
	sepsis, <i>Klebsiella</i> sepsis (each: 1-5%, severe 4%)
	sinusitis (11%, severe 1%)
	skin, furuncle, hordeolum, pustular rash (each: 1-5%, severe <1%)
	upper respiratory tract (18%, severe 1%)
	urinary tract (13%, severe 1%)
viral, <i>Herpes simplex</i> , viral not otherwise specified (each: 1-5%, severe <1%)	
lymphatics	lymphadenopathy (1-5%, severe <1%)
	edema (12%, severe <1%)
	peripheral edema (24%, severe 2%)
	pitting edema (1-5%, severe <1%)
metabolic/laboratory	abnormal LFTs (1-5%, severe <1%)
	alkaline phosphatase increase (1-5%, severe <1%)
	ALT increase (8%, severe 3%)
	AST increase (1-5%, severe 1%)
	blood glucose increase (1-5%, severe <1%)
	dehydration (1-5%, severe 1%)
	gout (1-5%, severe <1%)
	hemochromatosis (1-5%, severe <1%)

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in bold, italics	
	hypercholesterolemia (1-5%, severe <1%)
	hypo- or hyper-bilirubinemia (1-5%, severe <1%)
	hypocalcemia (1-5%, severe <1%)
	hypokalemia (12%, severe 4%)
	hypomagnesemia (6%, severe <1%)
	hyponatremia (1-5%, severe 2%)
	serum creatinine increase (1-5%, severe 1%)
	uric acid increase (1-5%, severe <1%)
musculoskeletal	asthenia (15%, severe 2%)
	arthritis, aggravated arthritis, periartthritis (each: 1-5%, severe <1%)
	joint swelling (1-5%, severe <1%)
	limb injury (1-5%, severe <1%)
	muscle cramp (19%, severe 2%)
	muscle spasm (1-5%, severe <1%)
	osteopenia, osteoporosis, each: (1-5%, severe <1%)
	rib fracture (1-5%, severe <1%)
	rigors (6%, severe <1%)
	spinal compression fracture (1-5%, severe <1%)
	stiffness (1-5%, severe <1%)
neurology	anxiety, agitation, burning sensation, mental status changes, mood alteration (each: 1-5%, severe <1%)
	depression (6%, severe <1%)
	dizziness (22%, severe 3%)
	fall (10%, severe 1%)
	hypoesthesia (7%, severe <1%)
	neuropathy, polyneuropathy (each: 1-5%, severe <1%); peripheral neuropathy (6%, severe <1%)
	paraesthesia (5%, severe <1%)
	psychosomatic disease (1-5%, severe 1%)
	sciatica (1-5%, severe <1%)
	sensory disturbance (1-5%, severe <1%)
	syncope (1-5%, severe 1%)
	transient ischemic attack (1-5%, severe 2%)
	tremor (1-5%, severe <1%)
	vasovagal attack (1-5%, severe <1%)
	vertigo (1-5%, severe <1%)

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in bold, italics	
ocular/visual	blurred vision, conjunctivitis, diplopia, dry eye, eyelid edema, eye pruritis, macular degeneration, visual disturbance (each: 1-5%, severe <1%)
pain	abdominal, not otherwise specified (14%, severe <1%); lower abdominal (1-5%, severe <1%); upper abdominal (8%, severe 1%)
	arthralgia (25%, severe 2%)
	back (24%, severe 5%)
	bone (1-5%, severe <1%)
	chest (6%, severe 2%)
	chest wall (1-5%, severe <1%)
	dental discomfort (1-5%, severe <1%)
	discomfort (1-5%, severe <1%)
	ear discomfort, ear pain (each: 1-5%, severe <1%)
	flank (1-5%, severe <1%)
	foot (6%, severe <1%)
	headache (20%, severe 1%)
	jaw (1-5%, severe <1%)
	limb (13%, severe 1%)
	musculoskeletal (1-5%, severe <1%)
	myalgia (10%, severe <1%)
	neck (1-5%, severe <1%)
	oral (1-5%, severe <1%)
	pain, not otherwise specified (9%, severe <1%)
	post-procedural (1-5%, severe <1%)
sinus (1-5%, severe <1%)	
pulmonary	asthma (1-5%, severe <1%)
	bronchitis (12%, severe <1%)
	COPD exacerbated (1-5%, severe <1%)
	cough (23%, severe <1%); productive cough (1-5%, severe <1%)
	crackles (1-5%, severe <1%)
	dyspnea, exacerbated (1-5%, severe <1%); dyspnea, not otherwise specified (22%, severe 5%); dyspnea on exertion (7%, severe <1%)
	hoarseness (1-5%, severe <1%)
	hypoxia (1-5%, severe 1%)
	infiltration (1-5%, severe <1%)
	nasal congestion (1-5%, severe <1%)
	nasopharyngitis (27%, severe 1%)
	pharyngitis (18%, severe <1%)

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in bold, italics	
	pleural effusion (1-5%, severe 2%)
	pneumonitis (1-5%, severe 1%)
	pulmonary edema (1-5%, severe 1%)
	pulmonary hypertension (1-5%, severe 1%)
	respiratory distress (1-5%, severe 2%)
	rhinitis (7%, severe <1%); allergic rhinitis (1-5%, severe <1%)
	rhinorrhea (1-5%, severe <1%)
	sinus congestion (1-5%, severe <1%)
renal/genitourinary	cystitis, frequency, incontinence, urgency (each: 1-5%, severe <1%)
	dysuria (7%, severe <1%)
	failure (1-5%, severe 2%)
secondary malignancy	acute leukemia (5%, severe 5%)
	carcinoma, basal cell, squamous (each 1-5%, severe <1%)
syndromes	hypersensitivity pneumonitis-like syndrome ^{1,7}
	irritable bowel syndrome (1-5%, severe <1%)
	multi-organ failure (1-5%, severe 1%)
vascular	arterial aneurysm (1-5%, severe <1%)
	deep vein thrombosis (5%, severe 5%); see paragraph following Side Effects table
	pulmonary embolism (severe 3%); see paragraph following Side Effects table
	thrombophlebitis (1-5%, severe <1%)

Adapted from standard reference¹ unless specified otherwise.

The incidence of serious side effects was significantly higher (60 vs. 35%) and discontinuation of treatment was higher (30 vs. 10%) in patients **>65 years** old.¹

Neutropenia and **thrombocytopenia** were reversible and not cumulative.¹ In patients with myelodysplastic syndromes, monitor CBC weekly for the first 8 weeks of therapy and at least monthly thereafter^{1,2}; in patients with multiple myeloma, less frequent monitoring, every 2 weeks for the first 12 weeks of therapy and at least monthly thereafter, has been recommended.² Refer to **Dosage Guidelines, Dosage in myelosuppression**.

Thromboembolic events: various risk factors have been identified including newly diagnosed disease, use in a combination regimen including doxorubicin or high dose dexamethasone, immobilization, infection, history of thromboembolism, prior thalidomide treatment, and concurrent erythropoietin use.⁸ Prophylactic anticoagulation may be appropriate, and has been recommended for patients being treated with lenalidomide plus dexamethasone.^{8,9}

INTERACTIONS:

AGENT	EFFECT	MECHANISM	MANAGEMENT
digoxin ¹	maximum digoxin concentration increased by 14%; AUC not significantly changed	unknown	monitor digoxin levels periodically

AGENT	EFFECT	MECHANISM	MANAGEMENT
warfarin ¹	no effect		

In vitro, lenalidomide is not a substrate, inhibitor, or inducer of cytochrome P450 enzymes.¹

Simultaneous hormone replacement therapy and/or hormonal contraceptives may increase the risk of deep vein thrombosis and pulmonary embolism.¹

See **Contraception** under **Special Precautions** in regard to drugs that can affect contraception.

SUPPLY AND STORAGE:

Oral:¹ Celgene supplies 5, 10, 15, and 25 mg capsules which contain lactose. Store at room temperature.

Additional information: Available only through a controlled distribution program called RevAid®. Only prescribers and pharmacists registered with the program are able to prescribe and dispense to patients who are registered and meet all the conditions of the RevAid® program.¹ Further information available at www.RevAid.ca or by calling 1-888-RevAid1.

DOSAGE GUIDELINES:

Refer to protocol by which patient is being treated. Numerous dosing schedules exist and depend on disease, response, and concomitant therapy. Guidelines for dosing also include consideration of absolute neutrophil count (ANC). Dosage may be reduced, delayed or discontinued in patients with bone marrow depression due to cytotoxic/radiation therapy or with other toxicities.

Adults:

BCCA usual dose noted in **bold, italics**

Oral:	Cycle length:	
	4 weeks ^{2,3} :	25 mg PO once daily for 21 consecutive days starting on day 1. Administer with food or on an empty stomach.
	4 weeks ^{10,11} :	10 mg PO once daily for 21 consecutive days starting on day 1. Administer with food or on an empty stomach.
	n/a ¹⁻³ :	10 mg (range 5-25 mg) PO once daily. Administer with food or on an empty stomach.

Concurrent radiation: has been used¹²

Dosage in myelosuppression¹⁻³:

<i>Dose adjustment for myelosuppression developed WITHIN 4 weeks of starting at 10 mg daily:</i>						
Counts at baseline (x 10 ⁹ /L)			Counts during treatment			Recommended course
platelets	And /Or	ANC	platelets	And /Or	ANC	
≥100		≥1	<50		<0.75	Interrupt treatment. Resume at 5 mg daily when platelets recover to ≥50 and/or ANC ≥1
60-99		<1	≤50% of baseline		<0.5	Interrupt treatment. Resume at 5 mg daily when platelets recover to ≥50 and/or ANC ≥1
50-59						Interrupt treatment. Resume at 5 mg daily when platelets recover to ≥30 and/or ANC ≥0.5

<u>Dose adjustment for myelosuppression developed AFTER 4 weeks of starting at 10 mg daily:</u>			
Counts during treatment (x 10 ⁹ /L)			Recommended course
platelets	And/Or	ANC	
<30 or <50 with platelet transfusion			<0.5 x 7 days or associated with fever >38.5°C

<u>Dose adjustment for myelosuppression developed during treatment at reduced dose of 5 mg daily:</u>			
Counts during treatment (x 10 ⁹ /L)			Recommended course
platelets	And/Or	ANC	
<30 or <50 with platelet transfusion			<0.5 x 7 days or associated with fever >38.5°C

<u>Dose adjustment for thrombocytopenia developed after starting at 25 mg daily:</u>	
Counts during treatment (x 10 ⁹ /L)	Recommended course
if count falls <30	Interrupt treatment; check CBC weekly
if count returns to ≥30 following an interruption	Resume at 15 mg daily
for each subsequent fall <30	Interrupt treatment
if count returns to ≥30 following interruption for subsequent falls <30	Resume at a dose 5 mg less than previous dose (minimum dose 5 mg daily)

<u>Dose adjustment for neutropenia developed after starting at 25 mg daily:</u>	
Counts during treatment (x 10 ⁹ /L)	Recommended course
if count falls <1	Interrupt treatment, add filgrastim, check CBC weekly
if count returns to ≥1 following an interruption and no other toxicity is present	Resume at 25 mg daily
if count returns to ≥1 following an interruption and if other toxicity is present	Resume at 15 mg daily
for each subsequent fall to <1	Interrupt treatment
if count returns to ≥1 following interruption in treatment for subsequent falls to <1	Resume at a dose 5 mg less than the previous dose (minimum dose 5 mg daily)

Dosage in renal failure:

<u>Patients with myelodysplastic syndrome^{1-3,13}:</u>	
Creatinine clearance (mL/min)	Dose
≥60	10 mg daily
30-59	5 mg daily
<30, not requiring dialysis	5 mg every other day
<30, requiring dialysis	5 mg three times a week following each dialysis

<u>Patients with multiple myeloma^{2,3,13}:</u>	
Creatinine clearance (mL/min)	Dose
≥60	25 mg daily
30-59	10 mg daily*
<30, not requiring dialysis	15 mg every other day
<30, requiring dialysis	5 mg daily; take following dialysis on dialysis days

*dose may be increased to 15 mg daily after 2 cycles in patients who have not responded to treatment.

$$\text{Calculated creatinine clearance} = \frac{N^* \times (140 - \text{Age}) \times \text{weight in kg}}{\text{Serum Creatinine in } \mu\text{mol/L}}$$

* For males N=1.23; for females N=1.04

Dosage in hepatic failure: no information found

Dosage in dialysis: starting dose adjustment should be considered¹; See **Dosage in renal failure** section

Children:

Oral: safety and effectiveness in patients <18 years old have not been established¹

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