PrREVLIMID®

lenalidomide capsules

PART III: CONSUMER INFORMATION

MYELODYSPLASTIC SYNDROMES

This leaflet is part III of a three-part "Product Monograph" published when REVLIMID® (lenalidomide) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about REVLIMID®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

REVLIMID® can only be given to patients who are registered in and meet all conditions of the RevAid® program. RevAid® is a controlled distribution program of REVLIMID®.

What the medication is used for:

REVLIMID® is used in the treatment of patients who require blood transfusions due to myelodysplastic syndromes (MDS) with a chromosome problem in which part of chromosome 5 is missing. This type of MDS is known as deletion 5q MDS.

What it does:

The details of how REVLIMID® works in deletion 5q MDS are still being studied. When patients with deletion 5q MDS are treated with REVLIMID®, abnormal cells in their bone marrow are often eliminated and replaced by normal-appearing cells. REVLIMID® can also directly stimulate the production of red blood cells by the bone marrow. These effects can improve anemia, and reduce or eliminate the need for transfusions in patients with MDS.

When it should not be used:

Do not take REVLIMID® if:

- You are pregnant
- You are at risk of becoming pregnant
- You become pregnant during REVLIMID® treatment
- You are breastfeeding
- You are a male patient and are unable to follow or comply with the contraceptive measures of the RevAid Program
- **REVLIMID® can cause an increased risk of death in people who have chronic lymphocytic leukemia (CLL).** Do not take REVLIMID® if you have CLL unless you are participating in a controlled clinical trial.
- REVLIMID® treatment should not be started in patients whose platelet levels are less than 50×10^9/L.
- You are allergic to lenalidomide, pomalidomide or thalidomide or any of the other ingredients in REVLIMID®. REVLIMID® contains lactose.

What the medicinal ingredient is:

lenalidomide

What the important nonmedicinal ingredients are:

Each capsule contains croscarmellose sodium, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. The additional composition of the different capsule strengths is provided in the table below.

Strength	Imprint	Composition	Colour	Package size
5 mg	REV, 5 mg	Gelatin, titanium dioxide	White opaque	28 count blisters
10 mg	REV, 10 mg	FD&C blue #2, gelatin, titanium dioxide, yellow iron oxide	Blue/green opaque and pale yellow opaque	28 count blisters

What dosage forms it comes in:

Capsules. Each capsule contains 5 mg or 10 mg lenalidomide.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

REVLIMID® should only be prescribed by a doctor experienced in the use of anti-cancer drugs and registered with the RevAid® controlled distribution program.

Serious side effects may occur with the use of REVLIMID® and could include:

- birth defects (deformed babies) or death of an unborn baby and spontaneous abortion;
- decrease in the production of blood cells resulting in very low levels of white blood cells (neutropenia) and of platelets (thrombocytopenia);
- blood clots in the veins (Deep Vein Thrombosis), in the lung (Pulmonary Embolism), and in the arteries (heart attacks and stroke). Use of a blood thinner medication is recommended to reduce the risk;
- Liver problems. Treatment with REVLIMID® may lead to a higher risk of liver problems which may cause death.

REVLIMID® is only available under a controlled distribution program called RevAid®.

BEFORE you use REVLIMID® talk to your doctor or pharmacist if you:

- are pregnant or are planning to get pregnant
- are breastfeeding
- have kidney problems
- have liver problems

- have blood problems
- have or have had heart problems (irregular heart beat, heart attack)
- smoke, have high blood pressure or high cholesterol levels
- have had previous viral infection including herpes zoster infection (shingles) and/or hepatitis B virus infection (a viral infection of the liver)
- have had organ transplantation

REVLIMID® may cause birth defects. In order to take this drug you must meet the following conditions:

1. Females who can get pregnant:

- Discuss contraception (birth control) with your healthcare provider.
- Use at least two effective methods of contraception at the same time.
- Use these two effective methods of contraception:
  - For at least 4 weeks before starting REVLIMID® treatment
  - During interruptions of REVLIMID® treatment
  - During REVLIMID® treatment
  - For at least 4 weeks after stopping REVLIMID® treatment
- You must have two negative pregnancy tests before starting treatment:
  - The first 7-14 days prior to starting treatment
  - The second within 24 hours of starting treatment.
- You must have negative pregnancy tests during treatment:
  - Once weekly for the first 4 weeks
  - Once every 4 weeks (or once every 2 weeks if your period is irregular) for the duration of treatment and during treatment interruption
- You must have a final pregnancy test 4 weeks after stopping REVLIMID®.

2. Males:

- REVLIMID® is present in the sperm of males who take this drug. Use a condom every time you have sexual intercourse with a woman who is pregnant or can get pregnant. This must be done even if you have undergone a successful vasectomy. The condom must be used while:
  - You are taking REVLIMID®
  - During interruptions of treatment
  - For 4 weeks after stopping REVLIMID®.
- Do not donate sperm while taking REVLIMID® and for 4 weeks after stopping REVLIMID®.
- Inform your sexual partner who can get pregnant that:
  - You are taking REVLIMID®
  - There is a risk of birth defects, stillbirths, and spontaneous abortions if a fetus is exposed to your sperm.
  - You must use a condom.

You should contact your doctor immediately if you think your female partner becomes pregnant while you are taking REVLIMID®.

3. All Patients:

REVLIMID® may cause birth defects and any method of birth control can fail. You should contact your doctor immediately if you think you or your female partner may be pregnant. You should also contact your doctor if you miss your period or experience unusual menstrual bleeding.

- Do not give blood while you take REVLIMID® and for 4 weeks after stopping REVLIMID®.
- Do not share REVLIMID® with other people.
- Do not take REVLIMID® if you are not enrolled in or do not meet the requirements of the RevAid® controlled distribution program.

REVLIMID® is not recommended for use in children under 18 years of age.

INTERACTIONS WITH THIS MEDICATION

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. It is possible that REVLIMID® and other medicines may affect each other causing serious side effects.

Drugs that may interact with REVLIMID® include: digoxin, Hormonal Replacement Therapy, and Hormonal Contraception (estrogens and progestins).

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist.

PROPER USE OF THIS MEDICATION

Dosage: Myelodysplastic Syndrome: Starting dose: 10 mg daily on days 1-21 of 28-day cycles.

Your doctor may change the dosage during treatment, and will decide the total duration of therapy that you need. If you don't respond within 4 months of starting REVLIMID®, your doctor may decide to stop the treatment. It all depends on your response to the treatment.

Take REVLIMID® exactly as prescribed.

Swallow REVLIMID® capsules whole with water once a day. You should try to take it at about the same time each day.

Do not break, chew, or open your capsules.

It is important to remember that if you are being assisted with your medications, females who could become pregnant, or who plan to become pregnant can handle REVLIMID® capsules if they are using latex gloves.

You will have regular blood tests during your treatment with REVLIMID®. You should have your blood tested every week during your first 8 weeks of treatment, and at least monthly after that. Your healthcare provider may adjust your dose of REVLIMID® or interrupt your treatment based on the results of your blood tests and on your general condition.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If less than 12 hours have passed since missing a dose, take the dose. If more than 12 hours have passed since missing a dose at the normal time, do not take the dose. Take the next dose at the normal time on the following day. Do **not** take 2 doses at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, REVLIMID® can have side effects. The following are the most commonly reported side effects (≥ 10%):

Very Common: decrease in white blood cells, decrease in platelets, diarrhea, itchy skin, rash, tiredness, nausea, infection of the nasal passages, constipation, joint pain, back pain, swelling of arms and/or legs, fever, cough, dizziness, difficulty breathing, headache, decrease in red blood cells, muscle cramp, infection of the pharynx, upper respiratory tract infection, nose bleed, lack or loss of strength, dry skin, abdominal pain, pain in arm or leg, urinary tract infection, pneumonia, loss of appetite, decrease in blood potassium level, swelling, bronchitis, difficulty sleeping, sinus infection, vomiting, night sweats, muscle pain.

The following are commonly reported side effects (≥1% and <10%):

Common: fall, pain, increased sweating, bruise, upper abdominal pain, loose stools, arm and/or leg swelling, acquired decreased thyroid activity, high blood pressure, difficult or painful urination, dry mouth, toothache, allergy (rhinitis), flu, decreased sensitivity to stimulation, ruptured blood vessels, skin redness, chest pain, rigors, foot pain, distortion of sense of taste, loss of sensation in limbs, decrease in blood magnesium level, weight loss, infection under the skin, depression, skin lesion, flatulence, sensation of pricking, tingling, or creeping on the skin, heart palpitations, acute leukemia, hair loss, ear pain, dry eye, eye redness, eye pain.

Tell your doctor or pharmacist if you experience a side effect which is not listed above or any of the listed side effects that bother you or does not go away.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / Effect		**Only if severe**	**In all cases**	**your doctor or pharma-cist**
Very common	Fever / Neutropenia (decrease in white blood cells)		√	
Very common	Bleeding from the gums or other sites or abnormal bleeding / Thrombocytopenia (decrease in platelets that help with blood clotting)		√	
Very common	Chest or other infections / Pneumonia, Sepsis, Flu, Various Infections		√	
Very common	Tiredness / Anemia (decrease in red blood cells), Fatigue, Acute Leukemia, Pancytopenia (decrease in platelet, red blood cell and white blood cell counts)		√	
Very common	Difficulty breathing, breathlessness / Pulmonary Embolism (blood clot in or around the lungs), Heart failure, Pleural Effusion (excess fluid around the lungs), Hypoxia (decrease in oxygen to the body), Pneumonitis (inflammation of the lungs), Pulmonary Hypertension (increased blood pressure in vessels around or in the lungs), Pulmonary edema (build up of fluid in spaces outside blood vessels of the lungs)			√
Common	Nausea / Hyponatremia (decrease in sodium levels in the blood)		√	
Common	Skin rash		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / Effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharma-cist**
		Only if severe	**In all cases**	
Common	Muscle weakness / Asthenia (lack or loss of strength), Hypokalemia (decrease in potassium levels in blood)		√	
Common	Swelling of arms or legs / Edema peripheral, Kidney failure, Blood creatinine increase (decreased kidney function)			√
Common	Back pain	√		
Common	Loose or frequent bowel movements / Diarrhea	√		
Common	Arm or leg pain with swelling / Deep Vein Thrombosis (blood clots that form in your blood vessels)			√
Common	Dizziness or fainting	√		
Common	Headache / High blood pressure	√		
Common	Joint pain and muscle cramps	√		
Common	Heart palpitations, awareness of abnormal heart rhythm / Atrial fibrillation (abnormal or irregular heartbeats)			√
Common	Itchy skin	√		
Common	Pain	√		
Common	Chest pain / Angina		√	
Common	Vomiting	√		
Common	Difficulty moving limbs, walking or speaking / stroke and mini-stroke			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / Effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharma-cist**
		Only if severe	**In all cases**	
Common	Confusion / Psychosomatic Disease (disorder having physical symptoms but originating from mental or emotional causes)		√	
Common	Dry mouth, excessive thirst, dark yellow urine / Dehydration		√	
Common	Difficulty swallowing / Dysphagia		√	
Common	Fall		√	
Common	Increased sweating		√	
Common	Loss of appetite / Anorexia		√	
Rare	Red rash across face and body / Peeling skin or blistered skin, flat red rash, fever, body aches (Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis)			√
Rare	Symptoms of tumor lysis syndrome: lack of urination, severe muscle weakness, heart rhythm disturbances, and seizures			√
Rare	Symptoms of tumor flare reaction: tender swollen lymph nodes, low-grade fever, pain, or rash			√
Rare	Symptoms of graft-versus-host disease following transplant (days/months): itchy and/or painful rash, diarrhea, abdominal pain, skin/eye yellowing			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / Effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharma-cist**
		Only if severe	**In all cases**	
Rare	Changes to blood thyroid hormone. Low thyroid hormone may cause fatigue, increased sensitivity to cold, constipation, dry skin, unexplained weight gain, puffy face, muscle weakness, slow heart rate, thinning hair, impaired memory. High thyroid hormone may cause anxiety or nervousness, weight loss, frequent and loose bowel movements, breathlessness, feeling hot and possibly feelings of having rapid, fluttering or pounding heart.			√
Very Rare	Reactivation of viral infections including: herpes zoster (also known as 'shingles', a viral disease that causes a painful skin rash with blisters); hepatitis B that may cause symptoms of inflammation of the liver (hepatitis), itchy skin, jaundice (yellowing of the skin or whites of eyes), fever, tiredness, joint/muscle pain, loss of appetite, nausea and vomiting, pain in the upper right abdomen, pale stools and dark urine			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / Effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharma-cist**
		Only if severe	**In all cases**	
Very Rare	Symptoms of muscle breakdown (rhabdomyolysis), muscle pain, weakness or swelling, dark urine		√	
Very Rare	Flu-like symptoms and a rash on the face then an extended rash with a high temperature and swollen glands (Drug reaction with eosinophilia and systemic symptoms [DRESS])			√
Unknown	Symptoms of organ transplant rejection: flu-like symptoms (fever, chill, body ache, nausea, cough, shortness of breath, feeling unwell or tired), pain at the area of the transplant, less urine, sudden weight gain. There may be other possible symptoms specific to the type of transplant; your physician may discuss those with you.			√
Unknown	Symptoms of progressive multifocal leukoencephalopathy: vision changes, difficulty speaking, weakness in limbs, change in the way you walk or balance, persistent numbness, decreased or loss sensation, memory loss or confusion			√

These are not all the possible side effects possible with the use of REVLIMID®. Ask your healthcare provider or pharmacist for more information.

HOW TO STORE IT

Store REVLIMID® at 15-30° C. Keep out of the reach of children. Contact RevAid® to return any unused REVLIMID® capsules.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 0701D
  Ottawa, Ontario
  K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The information in this document is current as of the last revision date shown below. The most current information can be found at: www.RevAid.ca or by contacting the sponsor, Celgene, at:

1-888-RevAid1 (1-888-738-2431) or by visiting www.celgenecanada.net.

This leaflet was prepared by Celgene Inc.

Last revised: November 16, 2018

PrREVLIMID®

lenalidomide capsules

PART III: CONSUMER INFORMATION

MULTIPLE MYELOMA

This leaflet is part III of a three-part "Product Monograph" published when REVLIMID® (lenalidomide) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about REVLIMID®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

REVLIMID® can only be given to patients who are registered in and meet all conditions of the RevAid® program. RevAid® is a controlled distribution program of REVLIMID®.

What the medication is used for:

REVLIMID® is used with dexamethasone to treat patients with multiple myeloma who are not eligible for stem cell transplant. Multiple myeloma is a cancer of plasma cells. Plasma cells are found in the bone marrow. Plasma cells produce a protein called antibodies. Some antibodies can attack and kill disease causing germs. Patients with this type of cancer may have low blood cell counts and immune problems giving them a higher chance for getting infections such as pneumonia. The bones can be affected leading to bone pain and breaks (fractures).

What it does:

REVLIMID® works in multiple ways within the bone marrow to stop or slow the growth of cancerous myeloma cells.

When it should not be used:

Do not take REVLIMID® if:

- You are pregnant
- You are at risk of becoming pregnant
- You become pregnant during REVLIMID® treatment
- You are breastfeeding
- You are a male patient and are unable to follow or comply with the contraceptive measures of the RevAid Program
- **REVLIMID can cause an increased risk of death in people who have chronic lymphocytic leukemia (CLL).** Do not take REVLIMID® if you have CLL unless you are participating in a controlled clinical trial.
- You are allergic to lenalidomide, pomalidomide or thalidomide or any of the other ingredients in REVLIMID®. REVLIMID® contains lactose.

What the medicinal ingredient is:

lenalidomide

What the important nonmedicinal ingredients are:

Each capsule contains croscarmellose sodium, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. The additional composition of the different capsule strengths is provided in the table below.

Strength	Imprint	Composition	Colour	Package size
2.5 mg	REV, 2.5 mg	FD&C blue #2, gelatin, titanium dioxide, yellow iron oxide	White opaque and blue/green opaque	21 count blisters
5 mg	REV, 5 mg	Gelatin, titanium dioxide	White opaque	28 count blisters
10 mg	REV, 10 mg	FD&C blue #2, gelatin, titanium dioxide, yellow iron oxide	Blue/green opaque and pale yellow opaque	28 count blisters
15 mg	REV, 15 mg	FD&C blue #2, gelatin, titanium dioxide	Powder blue opaque and white opaque	21 count blisters
20 mg	REV, 20 mg	FD&C blue #2, gelatin, titanium dioxide, yellow iron oxide	Blue-green opaque and powder blue opaque	21 count blisters
25 mg	REV, 25 mg	Gelatin, titanium dioxide	White opaque	21 count blisters

What dosage forms it comes in:

Capsules. Each capsule contains 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg or 25 mg of lenalidomide.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

REVLIMID® should only be prescribed by a doctor experienced in the use of anti-cancer drugs and registered with the RevAid® controlled distribution program.

Serious side effects may occur with the use of REVLIMID® and could include:

- birth defects (deformed babies) or death of an unborn baby and spontaneous abortion;
- decrease in the production of blood cells resulting in very low levels of white blood cells (neutropenia) and of platelets (thrombocytopenia);
- blood clots in the veins (Deep Vein Thrombosis), in the lung (Pulmonary Embolism), and in the arteries (heart attacks and stroke). Use of a blood thinner medication is recommended to reduce the risk;
- Liver problems. Treatment with REVLIMID® may lead to a higher risk of liver problems which may cause death.

REVLIMID® is only available under a controlled distribution program called RevAid®.

BEFORE you use REVLIMID® talk to your doctor or pharmacist if you:

- are pregnant or are planning to get pregnant
- are breastfeeding
- have kidney problems
- have liver problems
- have blood problems
- have or have had heart problems (irregular heart beat, heart attack)
- smoke, have high blood pressure or high cholesterol levels
- have had previous viral infection including herpes zoster infection (shingles) and/or hepatitis B virus infection (a viral infection of the liver)
- have had organ transplantation

REVLIMID® may cause birth defects. In order to take this drug you must meet the following conditions:

1. Females who can get pregnant:

- Discuss contraception (birth control) with your healthcare provider.
- Use at least two effective methods of contraception at the same time.
- Use these two effective methods of contraception:
  - For at least 4 weeks before starting REVLIMID® treatment
  - During interruptions of REVLIMID® treatment
  - During REVLIMID® treatment
  - For at least 4 weeks after stopping REVLIMID® treatment
- You must have two negative pregnancy tests before starting treatment:
  - The first 7-14 days prior to starting treatment
  - The second within 24 hours of starting treatment.
- You must have negative pregnancy tests during treatment:
  - Once weekly for the first 4 weeks
  - Once every 4 weeks (or once every 2 weeks if your period is irregular) for the duration of treatment and during treatment interruption

You must have a final pregnancy test 4 weeks after stopping REVLIMID®.

2. Males:

- REVLIMID® is present in the sperm of males who take this drug. Use a condom every time you have sexual intercourse with a woman who is pregnant or can get pregnant. This must be done even if you have undergone a successful vasectomy. The condom must be used while:
  - You are taking REVLIMID®
  - During interruptions of treatment
  - For 4 weeks after stopping REVLIMID®.
- Do not donate sperm while taking REVLIMID® and for 4 weeks after stopping REVLIMID®.
- Inform your sexual partner who can get pregnant that:
  - You are taking REVLIMID®
  - There is a risk of birth defects, stillbirths, and spontaneous abortions if a fetus is exposed to your sperm.
  - You must use a condom.

You should contact your doctor immediately if you think your female partner becomes pregnant while you are taking REVLIMID®.

3. All Patients:

REVLIMID® may cause birth defects and any method of birth control can fail. You should contact your doctor immediately if you think you or your female partner may be pregnant. You should also contact your doctor if you miss your period or experience unusual menstrual bleeding.

- Do not give blood while you take REVLIMID® and for 4 weeks after stopping REVLIMID®.
- Do not share REVLIMID® with other people.
- Do not take REVLIMID® if you are not enrolled in or do not meet the requirements of the RevAid® controlled distribution program.

REVLIMID® is not recommended for use in children under 18 years of age.

Second cancers such as skin cancers, blood cancers, and solid tumor cancers have been reported in a small number of patients while taking REVLIMID® or after treatment with REVLIMID® is completed. Patients should talk to their doctors if they have any concerns about their own increased risk of having other cancers.

INTERACTIONS WITH THIS MEDICATION

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. It is possible that REVLIMID® and other medicines may affect each other causing serious side effects.

Drugs that may interact with REVLIMID® include: digoxin, Hormonal Replacement Therapy, and Hormonal Contraception (estrogens and progestins).

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist.

PROPER USE OF THIS MEDICATION

Dosage: Multiple Myeloma: Starting dose: 25 mg daily on days 1-21 of 28 day cycles in combination with dexamethasone.

Your doctor may change the dosage during treatment, and will continue therapy as long as you are responding to and tolerating REVLIMID®.

Take REVLIMID® exactly as prescribed.

Swallow REVLIMID® capsules whole with water once a day. You should try to take it at about the same time each day.

Do not break, chew, or open your capsules.

It is important to remember that if you are being assisted with your medication, females who could become pregnant, or who plan to become pregnant can handle REVLIMID® capsules if they are using latex gloves.

You will have regular blood tests during your treatment with REVLIMID®. You should have your blood tested once every week during the first 2 cycles (8 weeks) of treatment, every 2 weeks during the third cycle, and at least monthly after that. Your healthcare provider may adjust your dose of REVLIMID® or interrupt your treatment based on the results of your blood tests and on your general condition.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If less than 12 hours have passed since missing a dose, take the dose. If more than 12 hours have passed since missing a dose at the normal time, do not take the dose. Take the next dose at the normal time on the following day. Do **not** take 2 doses at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, REVLIMID® can have side effects. The following are the most commonly reported side effects (≥ 10%):

Very Common: chest and other infections, tiredness/lethargy, fever, muscle weakness, joint pain and muscle cramps, pain, abdominal pain, difficulty breathing/breathlessness, hard stools / difficult to pass, difficulty sleeping, diarrhea, bleeding from gums or other sites, numbness / abnormal sensations, dizziness, swelling of arms or legs, cough, cloudy (cataracts) or blurred vision, headache, nausea, skin rash, back pain, loss of appetite, weight loss, frequent hunger with excessive thirst and urination, taste altered, heart palpitations/awareness of abnormal heart rhythm, chest pain, swelling, mouth pain, general feeling of discomfort or uneasiness, sore throat, shaking, confusion, weight gain, depression, arm pain with arm or leg swelling, vomiting, reduced sense of touch, irritability, "pins and needles" in hands and feet, heartburn.

The following are commonly reported side effects (≥1% and <10%):

Common: bruise, increased sweating, dry skin, inflammation mouth, frequent urination, high blood pressure (headache), hoarse voice, dry mouth, stuffy nose, itchy skin, lightheadedness or dizziness, dehydration (dry mouth, excessive thirst, dark yellow urine), mood changes, hiccups, flatulence, runny nose, swelling face, sweating increased, skin redness, dizziness or fainting, muscle spasm, fever with shaking, face redness, balance impaired, canker sores, loose stools, bone pain, skin cancer, skin discoloration, decreased urination, hot flashes, painful urination, toothache, hair loss, increased tears, skin lesions, skin wound, decreased sex drive, nervousness, difficulty moving limbs, walking or speaking (stroke), dry eye, eye redness, fall, hives, memory impairment, difficulty swallowing, eye itch, rash, ringing in ears, allergic reaction, bedsores, blood in urine, deafness, increased hair growth, walking abnormally, increased appetite, mental status changes, non-coordinated muscle movement, painful or frequent urination, pale skin, urgent need to urinate, wheezing, wound.

Tell your doctor or pharmacist if you experience a side effect which is not listed above or any of the listed side effects that bother you or does not go away.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / Effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharma-cist
	Only if severe	In all cases	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / Effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharma-cist**
		Only if severe	**In all cases**	
Very common	Fever / Neutropenia (decrease in white blood cells)		√	
Very common	Muscle weakness / Asthenia (lack or loss of strength), Hypokalemia (decrease in potassium levels in blood), Hypophosphatemia (decrease in phosphate levels in blood)		√	
Very common	Tiredness / Anemia (decrease in red blood cells), Fatigue		√	
Very common	Bleeding from the gums or other sites or abnormal bleeding / Thrombocytopenia (decrease in platelets that help with blood clotting)		√	
Very common	Chest or other infections / Pneumonia, Various Infections		√	
Very common	Arm or leg pain with swelling / Deep Vein Thrombosis (blood clots that form in your blood vessels)			√
Very common	"Pins and needles" in hands and feet / Hypocalcaemia (low blood calcium)		√	
Common	Frequent hunger, excessive thirst or urination / Hyperglycemia (high blood sugar)			√
Common	Difficulty breathing, breathlessness / Pulmonary Embolism (blood clot in or around the lungs) / Heart Failure / Pulmonary edema			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / Effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharma-cist**
		Only if severe	**In all cases**	
Common	Lightheadedness, dizziness or fainting / Hypotension (low blood pressure)	√		
Common	Heart palpitations, awareness of abnormal heart rhythm / Atrial fibrillation (abnormal or irregular heartbeats)			√
Common	Loose or frequent bowel movements / Diarrhea	√		
Common	Depression		√	
Common	Bone Pain	√		
Common	Confusion		√	
Common	Constipation	√		
Common	Numbness, abnormal sensations / Neuropathy (a disease of the nerves)		√	
Common	Nausea		√	
Common	Headache / High blood pressure	√		
Common	Dry mouth, excessive thirst, dark yellow urine / Dehydration		√	
Common	Rapid swelling of the skin, face and lips / Angioedema			√
Common	Chest pain spreading to arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick or vomiting which may be symptoms of a heart attack			√
Common	Production of much more or much less urine than usual which may be symptoms of kidney failure			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / Effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharma-cist**
		Only if severe	**In all cases**	
Common	Shortness of breath especially when lying down which may be a symptom of heart failure			√
Rare	Red rash across face and body / Peeling skin or blistered skin, flat red rash, fever, body aches (Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis)			√
Rare	Symptoms of tumor lysis syndrome: lack of urination, severe muscle weakness, heart rhythm disturbances, and seizures			√
Rare	Symptoms of tumor flare reaction: tender swollen lymph nodes, low-grade fever, pain, or rash			√
Rare	Symptoms of graft-versus-host disease following transplant (days/months): itchy and/or painful rash, diarrhea, abdominal pain, skin/eye yellowing		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / Effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharma-cist**
		Only if severe	**In all cases**	
Rare	Changes to blood thyroid hormone. Low thyroid hormone may cause fatigue, increased sensitivity to cold, constipation, dry skin, unexplained weight gain, puffy face, muscle weakness, slow heart rate, thinning hair, impaired memory. High thyroid hormone may cause anxiety or nervousness, weight loss, frequent and loose bowel movements, breathlessness, feeling hot and possibly feelings of having rapid, fluttering or pounding heart.			√
Very Rare	Reactivation of viral infections: including herpes zoster (also known as 'shingles', a viral disease that causes a painful skin rash with blisters); hepatitis B which may cause symptoms of inflammation of the liver (hepatitis), itchy skin, jaundice (yellowing of the skin or whites of eyes), fever, tiredness, joint/muscle pain, loss of appetite, nausea and vomiting, pain in the upper right abdomen, pale stools and dark urine			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / Effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharma-cist
		Only if severe	In all cases	
Very Rare	Symptoms of muscle breakdown (rhabdomyolysis), muscle pain, weakness or swelling, dark urine		√	
Very Rare	Flu-like symptoms and a rash on the face then an extended rash with a high temperature and swollen glands (Drug reaction with eosinophilia and systemic symptoms [DRESS])			√
Unknown	Symptoms of organ transplant rejection: flu-like symptoms (fever, chill, body ache, nausea, cough, shortness of breath, feeling unwell or tired), pain at the area of the transplant, less urine, sudden weight gain. There may be other possible symptoms specific to the type of transplant; your physician may discuss those with you.			√
Unknown	Symptoms of progressive multifocal leukoencephalopathy: vision changes, difficulty speaking, weakness in limbs, change in the way you walk or balance, persistent numbness, decreased or loss sensation, memory loss or confusion			√

These are not all the possible side effects possible with the use of REVLIMID®. Ask your healthcare provider or pharmacist for more information.

HOW TO STORE IT

Store REVLIMID® at 15-30° C. Keep out of the reach of children. Contact RevAid® to return any unused REVLIMID® capsules.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect

- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The information in this document is current as of the last revision date shown below. The most current information can be found at: www.RevAid.ca or by contacting the sponsor, Celgene, at:

1-888-RevAid1 (1-888-738-2431) or visiting www.celgenecanada.net.

This leaflet was prepared by Celgene Inc.

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