

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrREVLIMID®

lenalidomide capsules

MYELODYSPLASTIC SYNDROMES

Read this carefully before you start taking **REVLIMID** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **REVLIMID**.

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.

Serious Warnings and Precautions

REVLIMID should only be prescribed by a healthcare professional experienced in the use of anti-cancer drugs and registered with the RevAid controlled distribution program. REVLIMID is only available under the RevAid controlled distribution program.

Pregnancy: Birth defects, stillbirths (death of an unborn baby) and spontaneous abortion (miscarriage) can happen in women who take REVLIMID during pregnancy and in pregnant female partners of male patients taking REVLIMID. See the **Other warnings you should know about** section, below, for more information on the conditions female and male patients must meet if they are taking REVLIMID.

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

- **Blood problems:** decrease in the production of blood cells resulting in very low levels of white blood cells (**neutropenia**) and of platelets (**thrombocytopenia**);
- **Blood clots:** blood clots in the veins of the legs or arms (**deep vein thrombosis**), in the lung (**pulmonary embolism**), and in the arteries (**heart attacks** and **stroke**). Your healthcare professional may prescribe a blood thinner medication while you are taking REVLIMID to reduce the risk;
- **Liver problems:** treatment with REVLIMID may lead to a higher risk of liver problems which may cause death;
- **Severe allergic reactions**

See the **Serious side effects and what to do about them** table, below, for more information about these and other serious side effects.

What is REVLIMID used for?

REVLIMID is used in adults 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.

How does REVLIMID work?

It is not known exactly how REVLIMID works. 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 stimulate the bone marrow to produce red blood cells. These effects can improve anemia, and reduce or eliminate the need for transfusions in patients with deletion 5q MDS.

What are the ingredients in REVLIMID?

Medicinal ingredients: lenalidomide

Non-medicinal ingredients: croscarmellose sodium, FD&C blue #2 (10 mg capsule), gelatin, lactose anhydrous, magnesium stearate, microcrystalline cellulose, titanium dioxide, yellow iron oxide (10 mg

capsule).

REVLIMID comes in the following dosage forms:

Capsules: 5 mg, 10 mg

Do not use REVLIMID if:

- you are allergic to lenalidomide, pomalidomide or thalidomide or any of the other ingredients in REVLIMID (see **What are the ingredients in REVLIMID?**)
- you are pregnant or could become pregnant.
- you are breastfeeding
- you are a male patient and are unable to follow or comply with the birth control measures of the RevAid Program
- you have low levels of platelets in your blood

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take REVLIMID. Talk about any health conditions or problems you may have, including if you:

- have chronic lymphocytic leukemia (CLL) and are not part of a clinical trial. **REVLIMID can cause an increased risk of death in people who have CLL.**
- have kidney problems
- have liver problems
- have blood problems
- have or have had heart problems, such as an irregular heartbeat or heart attack
- smoke
- have high blood pressure
- have high cholesterol
- have had a previous viral infection including herpes zoster infection (shingles) and/or hepatitis B virus infection (a viral infection of the liver)
- have had an organ transplant
- are lactose intolerant or have one of the following rare hereditary diseases:
 - galactose intolerance
 - Lapp lactase deficiency
 - glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in REVLIMID.

Other warnings you should know about:

REVLIMID may cause birth defects, stillbirths and spontaneous abortions. In order to take this medicine you must meet the following conditions:

1. Females who can get pregnant:

- Talk to your healthcare professional about the birth control options that are right for you while you are taking REVLIMID.
- You must use at least two effective methods of birth control at the same time.
- Use these two effective methods of birth control:
 - 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 your 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. You must 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

3. All Patients:

- **REVLIMID may cause birth defects, stillbirths and spontaneous abortions and any method of birth control can fail.**
- **Talk to your healthcare professional immediately if you think you or your female partner may be pregnant.**
- **Talk to your healthcare professional if you or your female partner misses a period or experiences 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.
- 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 professional may adjust your dose of REVLIMID or interrupt your treatment based on the results of your blood tests and on your general condition.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with REVLIMID:

- digoxin, used to treat heart problems
- medicines containing hormones (estrogens and progestins), such as Hormonal Replacement Therapy and hormonal birth control

How to take 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.**
- REVLIMID can be taken with or without food.
- Your healthcare professional will decide on the dose that is right for you and how long you will take REVLIMID. Depending on how you respond to treatment they may change your dose. If you don't respond within 4 months of starting REVLIMID, your healthcare professional may decide to stop the treatment.
- Females who could become pregnant, or who plan to become pregnant can only handle REVLIMID capsules if they are using latex gloves. If someone is helping you with your medication make sure they are aware of this.
- Wash your hands with soap and water after handling REVLIMID capsules.

Usual dose:

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

Overdose:

If you think you, or a person you are caring for, have taken too much REVLIMID, contact a healthcare professional, 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, 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 to make up for a missed dose.

What are possible side effects from using REVLIMID?

These are not all the possible side effects you may have when taking REVLIMID. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- nausea, vomiting, diarrhea
- constipation, gas
- loss of appetite, weight loss
- abdominal pain
- change in taste
- toothache
- itchy skin, red skin
- rash, dry skin
- sensation of pricking, tingling, or creeping on the skin
- increased sweating
- tiredness
- trouble sleeping
- dizziness, fainting
- headache
- joint pain, back pain
- pain in the arms or legs
- muscle cramps, muscle pain
- falls
- hair loss
- ear pain
- dry eye, eye redness, eye pain

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Neutropenia (low levels of white blood cells): fever, chills, signs of infection		√	
Thrombocytopenia (low levels of platelets): bruising, red or purple spots on the skin, cuts bleeding longer than normal, blood in stool or urine, nose bleeds, bleeding gums		√	
Infections: cough, sore throat, runny nose, sinus pain, headache, fever, chills, difficulty breathing, shortness of breath, difficulty or pain when urinating, urgent need to urinate, redness and swelling around cuts, flu-like symptoms		√	
Anemia (low levels of red blood cells): fatigue, shortness of breath, pale skin, fast heartbeat, lack of energy, weakness		√	
Acute leukemia: pale skin, fatigue, shortness of breath, infections, unusual bleeding, bruising, fever, night sweats, bone and joint pain		√	
Pancytopenia (low levels of platelets, red and white blood cells): bruising, red or purple spots on the skin, cuts bleeding longer than normal, blood in stool or urine, nose bleeds, bleeding gums, shortness of breath, pale skin, fast heartbeat, lack of energy, weakness, fever, chills, signs of infection		√	
Pulmonary embolism (blood clot in or around the lungs): coughing up blood, sharp pain in chest, or sudden shortness of breath			√
Lung problems (pleural effusion, pulmonary hypertension, pulmonary edema): cough, chest pain, shortness of breath, difficult or painful breathing, wheezing			√
Heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
irregular heartbeat, reduced ability to exercise			
COMMON			
Hyponatremia (low levels of sodium in the blood): nausea, vomiting, headache, confusion, restlessness, muscle cramps, seizures		√	
Hypokalemia (low levels of potassium in the blood): muscle weakness, lack of strength, irregular heartbeat		√	
Edema: swelling of the hands or feet			√
Kidney problems (including kidney failure): decreased urination or lack of urination, blood in the urine, nausea, vomiting, swelling of the arms or legs, fatigue			√
Deep vein thrombosis (blood clot in the arm or leg): swelling, pain, arm or leg may be warm to the touch and may appear red			√
High blood pressure: headache, chest pain, vision problems, ringing in the ears	√		
Heart problems: heart palpitations, abnormal or irregular heartbeats, chest pain			√
Stroke: sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg			√
Heart attack: sudden pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the shoulder, chest, arm, or below the breastbone; discomfort radiating to the back, jaw, throat, arm, stomach, feeling of being full, having indigestion or choking; sweating, nausea, vomiting or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeat			√
Mental health problems: having physical symptoms but originating from mental or emotional causes, confusion, depression		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Dehydration: dry mouth, excessive thirst, dark yellow urine		√	
Angioedema: rapid swelling of the skin, face, eyes, mouth and lips, stomach cramps, trouble breathing			√
Difficulty swallowing		√	
RARE			
Severe skin reactions (Stevens-Johnson Syndrome [SJS], Toxic Epidermal Necrolysis [TEN], Drug reaction with eosinophilia and systemic symptoms [DRESS]): severe skin peeling, scaling or blistering which may affect the mouth, eyes, nose or genitals, itching, severe rash, swelling and redness of the eyes or face, flu-like feeling, fever, chills, body aches, swollen lymph nodes, cough, yellow skin or eyes, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine			√
Tumor lysis syndrome: lack of urination, severe muscle weakness, heart rhythm disturbances, seizures			√
Tumor flare reaction: tender swollen lymph nodes, low-grade fever, pain, rash			√
Graft-versus-host disease following transplant (days/months): itchy and/or painful rash, diarrhea, abdominal pain, yellowing of the skin or whites of the eyes		√	
Thyroid problems: Low thyroid hormone: 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: anxiety or nervousness, weight loss, frequent and loose bowel movements, breathlessness, feeling hot, feelings of having rapid, fluttering or pounding heart			√
Allergic reaction: rapid swelling of the skin, face and lips, tongue,			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
trouble breathing or swallowing, severe rash, itching, hives, fainting, very rapid heartbeat			
VERY RARE			
Reactivation of viral infections: herpes zoster (shingles): painful skin rash with blisters hepatitis B (inflammation of the liver): itchy skin, 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			√
Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark urine		√	
UNKNOWN			
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			√
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			√
Liver problems: 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		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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

If you want more information about REVLIMID:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.bms.com/ca/en, or by calling 1-866-463-6267.

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PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrREVLIMID®

lenalidomide capsules

MULTIPLE MYELOMA

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Serious Warnings and Precautions

REVLIMID should only be prescribed by a healthcare professional experienced in the use of anti-cancer drugs and registered with the RevAid controlled distribution program. REVLIMID is only available under the RevAid controlled distribution program.

Pregnancy: Birth defects, stillbirths (death of an unborn baby) and spontaneous abortion (miscarriage) can happen in women who take REVLIMID during pregnancy and in pregnant female partners of male patients taking REVLIMID. See the **Other warnings you should know about** section, below, for more information on the conditions female and male patients must meet if they are taking REVLIMID.

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

- **Blood problems:** decrease in the production of blood cells resulting in very low levels of white blood cells (**neutropenia**) and of platelets (**thrombocytopenia**);
- **Blood clots:** blood clots in the veins of the legs or arms (**deep vein thrombosis**), in the lung (**pulmonary embolism**), and in the arteries (**heart attacks** and **stroke**). Your healthcare professional may prescribe a blood thinner medication while you are taking REVLIMID to reduce the risk;
- **Liver problems:** treatment with REVLIMID may lead to a higher risk of liver problems which may cause death;
- **Severe allergic reactions**

See the **Serious side effects and what to do about them** table, below, for more information about these and other serious side effects.

What is REVLIMID used for?

REVLIMID is used with dexamethasone to treat adult 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).

How does REVLIMID work?

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

What are the ingredients in REVLIMID?

Medicinal ingredients: lenalidomide

Non-medicinal ingredients: croscarmellose sodium, FD&C blue #2 (2.5 mg, 10 mg, 15 mg, 20 mg capsules), gelatin, lactose anhydrous, magnesium stearate, microcrystalline cellulose, titanium dioxide, yellow iron oxide (2.5 mg, 10 mg, 20 mg capsules).

REVLIMID comes in the following dosage forms:

Capsules: 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg.

Do not use REVLIMID if:

- you are allergic to lenalidomide, pomalidomide or thalidomide or any of the other ingredients in REVLIMID (see **What are the ingredients in REVLIMID?**)
- you are pregnant or could become pregnant.
- you are breastfeeding
- you are a male patient and are unable to follow or comply with the birth control measures of the RevAid Program
- you have low levels of platelets in your blood

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take REVLIMID. Talk about any health conditions or problems you may have, including if you:

- have chronic lymphocytic leukemia (CLL) and are not part of a clinical trial. **REVLIMID can cause an increased risk of death in people who have CLL.**
- have kidney problems
- have liver problems
- have blood problems
- have or have had heart problems, such as an irregular heartbeat or heart attack
- smoke
- have high blood pressure
- have high cholesterol
- have had a previous viral infection including herpes zoster infection (shingles) and/or hepatitis B virus infection (a viral infection of the liver)
- have had an organ transplant
- are lactose intolerant or have one of the following rare hereditary diseases:
 - galactose intolerance
 - Lapp lactase deficiency
 - glucose-galactose malabsorptionBecause lactose is a non-medicinal ingredient in REVLIMID.

Other warnings you should know about:

REVLIMID may cause birth defects, stillbirths and spontaneous abortions. In order to take this medicine you must meet the following conditions:

1. Females who can get pregnant:

- Talk to your healthcare professional about the birth control options that are right for you while you are taking REVLIMID.
- You must use at least two effective methods of birth control at the same time.
- Use these two effective methods of birth control:
 - 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

3. All Patients:

- **REVLIMID may cause birth defects, stillbirths and spontaneous abortions and any method of birth control can fail.**
- **Talk to your healthcare professional immediately if you think you or your female partner may be pregnant.**
- **Talk to your healthcare professional if you or your female partner misses a period or experiences 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.
- 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 professional may adjust your dose of REVLIMID or interrupt your treatment based on the results of your blood tests and on your general condition.
- 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. Talk to your healthcare professional if you have any concerns about your increased risk of having other cancers.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with REVLIMID:

- digoxin, used to treat heart problems
- medicines containing hormones (estrogens and progestins), such as Hormonal Replacement Therapy and hormonal birth control

How to take 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.**
- REVLIMID can be taken with or without food.
- Your healthcare professional will decide on the dose that is right for you and how long you will take REVLIMID. Depending on how you respond to treatment they may change your dose.
- Females who could become pregnant, or who plan to become pregnant can only handle REVLIMID capsules if they are using latex gloves. If someone is helping you with your medication make sure they are aware of this.
- Wash your hands with soap and water after handling REVLIMID capsules.

Usual dose:

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

Overdose:

If you think you, or a person you are caring for, have taken too much REVLIMID, contact a healthcare professional, 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, 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 to make up for a missed dose.

What are possible side effects from using REVLIMID?

These are not all the possible side effects you may have when taking REVLIMID. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- nausea, vomiting, diarrhea
- constipation, hard stool, gas
- change in appetite, change in weight
- abdominal pain
- mouth sores, mouth pain or swelling
- heartburn
- hiccups
- change in taste
- toothache
- hoarse voice
- itchy skin, red skin
- rash, skin discolouration
- increased sweating
- hot flashes
- tiredness/lethargy
- trouble sleeping
- dizziness, fainting
- headache
- nervousness, irritability

- general feeling of discomfort or uneasiness
- joint pain, back pain
- bone pain
- pain in the arms or legs
- muscle cramps, muscle pain
- falls
- hair loss
- hearing loss
- dry eye, eye redness, eye pain or itching
- eye tearing
- cloudy or blurred vision
- decreased sex drive

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Neutropenia (low levels of white blood cells): fever, chills, signs of infection		√	
Hypokalemia (low levels of potassium in the blood) Hypophosphatemia (low levels of phosphate in the blood): muscle weakness, lack or loss of strength		√	
Anemia (low levels of red blood cells): fatigue, shortness of breath, pale skin, fast heartbeat, lack of energy, weakness		√	
Thrombocytopenia (low levels of platelets): bruising, red or purple spots on the skin, cuts bleeding longer than normal, blood in stool or urine, nose bleeds, bleeding gums		√	
Infections: cough, sore throat, runny or stuffy nose, headache, fever, chills, difficulty breathing, shortness of breath, difficulty or pain when urinating, urgent need to urinate, redness and swelling around cuts, flu-like symptoms		√	
Deep vein thrombosis (blood clot in the arm or leg): swelling, pain, arm or leg may be warm to the touch and may appear red			√
Hypocalcaemia (low levels of calcium in the blood): “pins and needles” in hands and feet, muscle spasms		√	
COMMON			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hyperglycemia (high blood sugar): frequent hunger, excessive thirst or urination			√
Pulmonary embolism (blood clot in or around the lungs): coughing up blood, sharp pain in chest, or sudden shortness of breath			√
Lung problems (pulmonary edema): cough, chest pain, shortness of breath, difficult or painful breathing, wheezing			√
Heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			√
Hypotension (low blood pressure): lightheadedness, dizziness or fainting	√		
Heart problems: heart palpitations, abnormal or irregular heartbeats, chest pain			√
Nervous system problems: depression, mood changes, confusion, memory impairment, trouble with balance, walking abnormally, mental status changes, non-coordinated muscle movement		√	
Neuropathy (a disease of the nerves): numbness, abnormal sensations, reduced sense of touch		√	
High blood pressure: headache, chest pain, vision problems, ringing in the ears	√		
Dehydration: dry mouth, excessive thirst, dark yellow urine		√	
Angioedema: rapid swelling of the skin, face, eyes, mouth and lips, stomach cramps, trouble breathing			√
Heart attack: sudden pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the shoulder, chest, arm, or below the breastbone; discomfort radiating to the back, jaw, throat, arm, stomach, feeling of being full, having indigestion or choking; sweating, nausea,			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
vomiting or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeat			
Stroke: sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg			√
Kidney problems (including kidney failure): decreased urination or lack of urination, blood in the urine, nausea, vomiting, swelling of the arms or legs, fatigue			√
RARE			
Severe skin reactions (Stevens-Johnson Syndrome [SJS], Toxic Epidermal Necrolysis [TEN], Drug reaction with eosinophilia and systemic symptoms [DRESS]): severe skin peeling, scaling or blistering which may affect the mouth, eyes, nose or genitals, itching, severe rash, swelling and redness of the eyes or face, flu-like feeling, fever, chills, body aches, swollen lymph nodes, cough, yellow skin or eyes, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine			√
Tumor lysis syndrome: lack of urination, severe muscle weakness, heart rhythm disturbances, seizures			√
Tumor flare reaction: tender swollen lymph nodes, low-grade fever, pain, rash			√
Graft-versus-host disease following transplant (days/months): itchy and/or painful rash, diarrhea, abdominal pain, yellowing of the skin or whites of the eyes		√	
Thyroid problems: Low thyroid hormone: fatigue, increased sensitivity to cold, constipation, dry skin, unexplained weight gain, puffy face, muscle weakness, slow heart rate, thinning hair, impaired memory			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
High thyroid hormone: anxiety or nervousness, weight loss, frequent and loose bowel movements, breathlessness, feeling hot, feelings of having rapid, fluttering or pounding heart			
Allergic reaction: rapid swelling of the skin, face and lips, tongue, trouble breathing or swallowing, severe rash, itching, hives, fainting, very rapid heartbeat VERY RARE			√
Reactivation of viral infections: herpes zoster (shingles): painful skin rash with blisters hepatitis B (inflammation of the liver): itchy skin, 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			√
Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark urine UNKNOWN		√	
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			√
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			√
Difficulty swallowing		√	
Liver problems: 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		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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

If you want more information about REVLIMID:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.bms.com/ca/en, or by calling 1-866-463-6267.

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